

PRESCRIPTION DRUG PRODUCTS FOR WHICH THE  
FOOD AND DRUG ADMINISTRATION HAS MADE A FINDING OF SUITABILITY  
FOR ABBREVIATED NEW DRUG APPLICATIONS

U.S. Department of Health and Human Services  
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I. PREFACE

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DRUG PRODUCTS FOR WHICH THE FOOD AND DRUG ADMINISTRATION HAS MADE  
A FINDING THAT ABBREVIATED NEW DRUG APPLICATIONS ARE ACCEPTABLE

I. PREFACE

Background

The List of Drug Products Suitable for Abbreviated New Drug Applications (the List) identifies prescription drug products for which the Food and Drug Administration (FDA) has made a finding that abbreviated new drug applications (ANDAs) are sufficient. As a result of that finding, ANDAs are acceptable in place of full new drug applications (NDAs) for the listed drug products. (21 CFR 314.1(a)). FDA has determined that when properly manufactured, tested and labeled, the drug products identified in the List are safe and effective for their indicated uses: either FDA has evaluated them under the Drug Efficacy Study Implementation (DESI) project or has determined that they are sufficiently similar or related to an effective DESI drug product that the same conclusions of safety and efficacy apply. Drug products identical to products on the List will be approved as safe and effective if they are suitably formulated, manufactured, labeled and if bioavailability requirements are met. The products listed are not all marketed at the present time for various reasons, the most common one being that newer drugs are being utilized by the medical profession and have replaced previous drugs of choice. Hence, these older drugs have fallen into disuse and firms are no longer marketing them.

Through the DESI project, FDA is reviewing the effectiveness of all drug products approved for marketing between 1938 and 1962.\* The first DESI notices announcing effectiveness determinations were published in the FEDERAL REGISTER in 1968. DESI is an ongoing project, with over 93 percent of the review having been completed and the effectiveness conclusions announced in the FEDERAL REGISTER. For drug products determined to be effective, these notices state the conditions under which the approved products may continue to be marketed.

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\* The Federal Food, Drug, and Cosmetic Act requires that new drugs be shown to be both safe and effective before they are approved, through the new drug application procedures, for marketing (21 U.S.C. 355). Before October 10, 1962, the act required proof of safety, but not of efficacy. The Drug Amendments of 1962 required that an efficacy review of those drugs approved for safety only be undertaken.

These notices also state whether a full NDA (21 CFR 314.1(c)) or an ANDA (21 CFR 314.1(f), recently reviewed and recodified as § 314.2 (48 FR 2751, January 21, 1983)) is required for the marketing by other firms of drug products that are identical to the products described in the notices. Because these notices are not codified and are not readily retrievable, FDA has prepared this list as a convenient reference to identify drug products suitable for ANDAs.

The drug products on this List have been screened to confirm their eligibility and to assure that the information on active ingredient(s), potency or strength, dosage form, and route(s) of administration is accurate. The drug products are arranged alphabetically by the nonproprietary name of the active ingredient(s). For products with more than one ingredient, the ingredients appear alphabetically. For example, a product containing meprobamate with aspirin would be listed as "ASPIRIN; MEPROBAMATE."

Under the nonproprietary ingredient name(s) of each drug, all acceptable dosage forms and routes of administration are given, followed by the various strengths for each dosage form.

#### Definitions and Explanations

Identical Drug Products. A drug product is considered to be identical to a product on the List, and thus suitable for submission of an ANDA, if it is the same in active ingredient(s) (including the same salt or ester), dosage form, strength, and route(s) of administration. Product labeling must be consistent with DESI FEDERAL REGISTER notices and agency guidelines.

Generally, dosage forms, strengths and routes of administration for products on the List are limited to those of the innovator's product reviewed in the DESI program. Labeling guidelines for ANDA suitable drug products are available from the Division of Generic Drug Monographs (HFN-530). In those cases where additional indications (post-1962) are included in the current labeling of the innovator's product, clinical data or literature reports must be submitted by each ANDA applicant to demonstrate effectiveness of the drug products for that indication unless FDA has published a notice in the FEDERAL REGISTER permitting the indication in the labeling.

Parenteral Drug Products. Parenteral dosage forms, represented by the term "injectable," include aqueous or oily solutions, aqueous or oily suspensions, emulsions, and dry solids for reconstitution. Routes of administration for parenteral dosage forms are represented by the broad term "injection". It is the

manufacturer's responsibility to give more specific information in the product's label and package labeling. The formulation of a drug product is a critical factor and must be appropriate for the routes stated in the product's labeling.

Strengths. In preparing this List, FDA noted variations in the way applicants have expressed similar strengths of a drug. The most commonly accepted strength was used in drug products with less than 1 percent variation in strength. Drug products with more than a 1 percent variation in strength were reviewed individually and where possible the innovator's strength was chosen to represent the drug product's strength on the List. For example, Butabarbital Sodium Elixir has approved applications for the following strengths: 33.3 mg/5 mL, 33 mg/5 mL, and 30 mg/5 mL, all representing similar drug strengths. The strength chosen for the List was 30 mg/5 mL. In some cases the labeling expressed strengths in the apothecary system (grains, etc.). Those strengths were converted to the metric system (milligrams, etc.).

In the List, the strength of a drug that is a salt may be expressed in terms of the active moiety, as, "EQ(X) mg base" where the term base refers to the active moiety of the drug; for example, Methotrexate Sodium Injection EQ 20 mg base/vial means that the ingredient is the sodium salt in an amount equivalent to 20 mg Methotrexate.

The Division of Generic Drug Monographs will accept and approve ANDAs only for drug products at strengths stated on the List.

Status of Prescription Drug Products Being Marketed as Over-the-Counter Drug Products. Some ingredients of prescription drug products, such as antihistamines and hydrocortisone in topical preparations, are under review in the ongoing study of over-the-counter (OTC) drugs (21 CFR Part 330) and the subject of a proposal that would change them from prescription to OTC status. These changes are proposed and will not officially go into effect unless a final OTC monograph is published for the specific ingredient. Nevertheless, many firms, anticipating that a regulation will be finalized as proposed, are now marketing these as OTC products. The regulation (21 CFR 330.13) covering interim OTC marketing of such products specifically states that marketing after publication of a proposed monograph but before finalization of the OTC monograph is subject to the risk that the Commissioner of Food and Drugs may not accept the review panel's recommendation and may instead adopt a different position that may require relabeling, recall, or other regulatory action.

Since these products technically are still prescription products, they are included on the List. The Division of Generic Drug Monographs will accept an ANDA if the product is labeled for prescription use but will not accept an ANDA if the product is labeled for OTC use. When an OTC final monograph is published, approval of NDAs or ANDAs for products that come under the monograph will be withdrawn.

#### Drug Products Excluded from the List

DESI "Paragraph XIV" Drug Products. This term is used to describe certain drug products that were exempted from a regulatory schedule established by court order in American Public Health Ass'n v. Veneman, 349 F. Supp. 1311 (D.D.C. 1972). Paragraph XIV of the order permitted a limited number of drug products, for which there is compelling justification of medical need, to remain on the market pending completion of scientific studies to determine whether the drugs are effective. These drug products were initially classified as less-than-effective and further action on them was deferred until a determination could be made on the results of the effectiveness studies. Until FDA determines that, for the drug products remaining in Paragraph XIV, the studies provide substantial evidence of effectiveness, these drugs are excluded from the List.

Conditionally Approved Drug Products. These are drug products that are identical, similar, or related to DESI paragraph XIV drug products. Conditional approval of an ANDA has been granted to certain drug products in the following classes: coronary vasodilators, anticholinergics-antispasmodics, monoamine oxidase inhibitors, and anabolic steroids. While efficacy studies are ongoing or under review, these products may be marketed if they are the subject of conditionally approved ANDAs. If a DESI paragraph XIV drug product is reclassified to effective status, a FEDERAL REGISTER notice will be issued which sets forth the conditions (including bioavailability/bioequivalence requirements) for obtaining full approval. If the DESI paragraph XIV drug product is not found effective, FDA will publish in the FEDERAL REGISTER a notice proposing to withdraw approval of the NDA for the DESI drug and the conditional approval of the ANDAs for identical, similar, or related products. Because efficacy is an unresolved issue at this time, the agency is excluding conditionally approved products from the List.

Antibiotics. Antibiotic drug products are not included on the List because they are governed by published monographs, which fully describe the drug products that are suitable for approval through the antibiotic procedures.

Medical Devices. Although some medical devices, approved in earlier years through the new drug application procedures, were reviewed under DESI and determined to be suitable for ANDAs, these articles are now subject to the device provisions of the statute. Therefore, none of these products is included on the List.

Oral Vitamin Preparations. Oral vitamin A and vitamin D preparations offered for treatment or prevention of vitamin A or vitamin D deficiencies are no longer regulated as new drugs. (21 U.S.C. 350). Therefore, they are not required to have approved new drug applications and are not included on the List.

Drugs with Subsequent Safety Issues. If a drug product that has been determined to be effective under DESI and suitable for ANDAs is subsequently shown, on the basis of new evidence, to present risks that outweigh its benefits, FDA will take action to remove it from the market. Products that have been removed or that are in the process of removal from the market for such reason are excluded from the List.

#### Similar or Related Drug Products

The agency has made a number of findings of ANDA suitability for drug products that are similar or closely related to certain products found to be effective in the DESI project. These drug products are included on the List to notify interested persons that the agency will accept ANDA submissions for them.

#### Bioavailability/Bioequivalence Requirements

For many DESI drug products, in vivo bioavailability/bioequivalence testing is required before FDA will approve an application. Applicants can determine from the List whether in vivo bioavailability/bioequivalence studies must be included in the ANDA. The in vivo test will be waived for some drug products if adequate product dissolution is demonstrated.

If "BIO" is printed next to the dosage form or strength on the List under the ingredient heading, there is a bioavailability requirement and an in vivo study is necessary. However, if

"B10\*" is printed then in vivo bioavailability must be demonstrated only if the product fails to achieve adequate dissolution when compared to the test drug product. The code "DEF" identifies a drug product for which there is a bioavailability requirement, but which does not currently require in vivo bioavailability/bioequivalence studies for approval; i.e., the requirement is deferred. If none of the above terms appear, then no in vivo bioavailability study is necessary.

The "B10," "B10\*," and "DEF" codes are used to identify those pre-1962 drugs determined by FDA to have a known or potential bioequivalence problem. For more information about these determinations, see 21 CFR 320.21 and 320.22, as well as the FDA Approved Prescription Drug Products with Therapeutic Equivalence Evaluations list.

#### Updating Procedure

The List will be updated and published annually to include (1) corrections or omissions from the previous List; (2) DESI products that have been published in the FEDERAL REGISTER during the interim as effective if FDA made a finding that ANDAs are sufficient; and (3) similar or related products determined to be suitable for ANDAs since the previous List. In the interim period between printings of the List, there will be published in the FEDERAL REGISTER, about every three months, a list of all DESI drug products and any similar or related drug products determined to be suitable for ANDAs since the previous List was published. It will also include any corrections or omissions from the previous List.

#### Availability

Additional copies of the List may be purchased from National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, Sales Desk No. 703-487-4650.

#### Questions

More information about a specific product, procedure, or requirements for submission and approval of ANDAs may be obtained by writing or calling: David Rosen, Consumer Safety Officer, Division of Generic Drug Monographs (HFN-530), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (301-443-4080).

## II. FORMAT GUIDE: LIST OF DRUG PRODUCTS SUITABLE FOR ANDAs

The list of drug products suitable for an ANDA submission is composed of the following four (4) data elements: active ingredient(s), dosage form(s), route(s) of administration, and strength(s) of each suitable product. For those drug products determined by FDA to have a known or potential bioequivalence problem an indicator "BIO" or "DEF" is displayed. A "BIO\*" is displayed in cases where in vivo bioavailability must be demonstrated only if a product fails to achieve adequate dissolution when compared to the test product. (See BIOAVAILABILITY/ BIOEQUIVALENCE REQUIREMENTS, above.) The absence of a "BIO," a "BIO\*," or a "DEF," i.e., a blank, indicates the bioavailability/bioequivalence requirement is waived for that particular product(s). (See FORMAT EXAMPLE below for explanation of the format used in the List.)

Active ingredients are listed alphabetically by their nonproprietary names and are underlined. If a product has multiple active ingredients, the ingredients are listed alphabetically within the ingredient field (e.g., Meprobamate with Aspirin is listed under ASPIRIN; MEPROBAMATE).

Terminology to represent dosage form(s), route(s) of administration, and strength(s) are standardized and, in some cases, may differ from terminology used in labels and labeling for drug products already marketed. For the purpose of the List, all parenteral dosage forms are represented by the term "INJECTABLE". The term "INJECTION" has been selected as an all-inclusive term for the various routes of administration of parenteral products. Each acceptable strength, or combination of strengths for multiple ingredient products, is listed on a separate line. Strengths of multiple ingredient products are separated by a semi-colon and appear in the same sequence as the ingredients.

FORMAT EXAMPLE: LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

ASPIRIN; MEPROBAMATE ← MULTIPLE ACTIVE INGREDIENTS IN DRUG PRODUCT  
TABLET; ORAL ← DOSAGE FORM; ROUTE OF ADMINISTRATION  
325MG; 200MG ← INDICATES SUITABLE STRENGTHS, READ AS: 325MG ASPIRIN AND 200MG MEPROBAMATE  
↑ INDICATES IN VIVO BIOAVAILABILITY/BIOEQUIVALENCE STUDY WAIVED (BLANK)

DEXAMETHASONE ACETATE ← SINGLE ACTIVE INGREDIENT IN DRUG PRODUCT

DEF INJECTABLE; INJECTION  
EQ 8MG BASE/ML

BIO INJECTABLE; INJECTION  
EQ 16MG BASE/ML

↑ INDICATES IN VIVO BIOAVAILABILITY/BIOEQUIVALENCE STUDY REQUIRED (BIO)

HYDROXYZINE HYDROCHLORIDE

BIO\* TABLET; ORAL  
10MG  
25MG  
50MG  
100MG

↑ IN VIVO BIOAVAILABILITY MUST BE DEMONSTRATED ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION WHEN COMPARED TO THE TEST PRODUCT (BIO\*)

PREDNISOLONE

DEF TABLET; ORAL  
1MG  
2.5MG  
5MG

↑ IDENTIFIES THREE SUITABLE STRENGTHS FOR THIS PRODUCT

↑ INDICATES IN VIVO BIOAVAILABILITY/BIOEQUIVALENCE STUDY DEFERRED (DEF)

III. LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

1

ACENOCOUMAROL

BIO TABLET; ORAL  
4MG

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL  
300MG;30MG  
300MG;60MG  
325MG;15MG  
325MG;30MG  
325MG;60MG

ELIXIR; ORAL  
120MG/5ML;12MG/5ML

SUSPENSION; ORAL  
120MG/5ML;12MG/5ML

TABLET; ORAL  
300MG;7.5MG  
300MG;15MG  
300MG;30MG  
300MG;60MG  
325MG;7.5MG  
325MG;15MG  
325MG;30MG  
325MG;45MG  
325MG;60MG  
650MG;30MG

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL  
500MG;5MG

TABLET; ORAL  
500MG;5MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL  
325MG;5MG  
500MG;2.5MG  
500MG;5MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL  
500MG;4.5MG;0.38MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL  
325MG;4.5MG;0.38MG

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL  
325MG;32MG  
650MG;65MG

ACETAZOLAMIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
500MG

BIO TABLET; ORAL  
125MG  
250MG

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION  
500MG/VIAL

ACETIC ACID, GLACIAL

SOLUTION; OTIC  
2%

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION; OTIC  
2%;0.79%

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION; OTIC  
2%;1%

ACETOPHENAZINE MALEATE

BIO TABLET; ORAL  
20MG

ACETOSULFONE SODIUM

BIO TABLET; ORAL  
500MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

2

ACETRIZOATE SODIUMSOLUTION; INTRAUTERINE  
53%SOLUTION; URETERAL  
30%SOLUTION; URETHRAL  
50%ACETYLDIGITOXINBIO TABLET; ORAL  
0.1MG  
0.2MGALCOHOL; DEXTROSEINJECTABLE; INJECTION  
5ML/100ML;5GM/100MLALCOHOL; DEXTROSE; SODIUM CHLORIDEINJECTABLE; INJECTION  
5ML/100ML;5GM/100ML;900MG/100MLALKAVERVIRBIO TABLET; ORAL  
1MG  
2MG  
3MGALSEROXYLONBIO TABLET; ORAL  
2MGALUMINUM NICOTINATETABLET; ORAL  
625MGAMBENONIUM CHLORIDEBIO TABLET; ORAL  
10MG  
25MGAMINOHIPPURATE SODIUMINJECTABLE; INJECTION  
20%AMINOPENTAMIDEELIXIR; ORAL  
0.1MG/MLTABLET; ORAL  
0.5MGAMINOPHYLLINEINJECTABLE; INJECTION  
25MG/MLLIQUID; ORAL  
105MG/5MLBIO SUPPOSITORY; RECTAL  
100MG  
250MG  
500MGDEF TABLET; ORAL  
100MG  
200MGBIO TABLET, CONTROLLED RELEASE; ORAL  
225MGDEF TABLET, ENTERIC COATED; ORAL  
100MG  
200MGAMINOPHYLLINE; SODIUM CHLORIDEINJECTABLE; INJECTION  
0.5MG/ML;0.45%  
1MG/ML;0.45%  
2MG/ML;0.45%AMINOSALICYLIC ACIDPOWDER; ORAL  
100%BIO TABLET; ORAL  
500MG  
1GM

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

3

AMINOSALICYLIC ACID

BIO TABLET, ENTERIC COATED; ORAL  
500MG

AMINOSALICYLIC ACID; ISONIAZID

BIO TABLET; ORAL  
500MG;12.5MG  
500MG;20MG

AMINOSALICYLIC ACID; SODIUM AMINOSALICYLATE

BIO TABLET; ORAL  
112MG;846MG

AMINOSALICYLIC ACID RESIN COMPLEX

BIO POWDER; ORAL  
EQ 500MG BASE/GM

AMITRIPTYLINE HYDROCHLORIDE

CONCENTRATE; ORAL  
40MG/ML

INJECTABLE; INJECTION  
10MG/ML

SOLUTION; ORAL  
50MG/5ML

DEF TABLET; ORAL  
10MG  
25MG  
50MG  
75MG  
100MG  
150MG

AMMONIUM CHLORIDE

INJECTABLE; INJECTION  
0.4MEQ/ML  
3MEQ/ML  
5MEQ/ML

AMMONIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION  
900MG/100ML;900MG/100ML

AMOBARBITAL SODIUM

INJECTABLE; INJECTION  
250MG/AMP  
500MG/AMP

AMODIAQUINE HYDROCHLORIDE

TABLET; ORAL  
EQ 200MG BASE

AMODIAQUINE HYDROCHLORIDE; PRIMAQUINE PHOSPHATE

TABLET, CHEWABLE; ORAL  
EQ 150MG BASE;EQ 15MG BASE

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

CAPSULE; ORAL  
1.25MG;1.25MG;1.25MG;1.25MG  
2.5MG;2.5MG;2.5MG;2.5MG  
3.75MG;3.75MG;3.75MG;3.75MG  
5MG;5MG;5MG;5MG

TABLET; ORAL  
1.25MG;125MG;125MG;1.25MG  
2.5MG;2.5MG;2.5MG;2.5MG  
3.75MG;3.75MG;3.75MG;3.75MG  
5MG;5MG;5MG;5MG

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
EQ 3.75MG BASE;EQ 3.75 BASE  
EQ 6.25MG BASE;EQ 6.25MG BASE  
EQ 10MG BASE;EQ 10MG BASE

AMPHETAMINE SULFATE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
15MG

TABLET; ORAL  
5MG  
10MG

ANILERIDINE HYDROCHLORIDE

TABLET; ORAL  
EQ 25MG BASE

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

4

ANILERIDINE PHOSPHATEINJECTABLE; INJECTION  
EQ 25MG BASE/MLANISINDIONEBIO TABLET; ORAL  
50MGANISOTROPINE METHYLBROMIDEELIXIR; ORAL  
10MG/5MLTABLET; ORAL  
10MG  
50MGASPIRIN; BUTALBITALBIO\* CAPSULE; ORAL  
325MG;50MG  
650MG;50MGBIO\* TABLET; ORAL  
325MG;50MG  
650MG;50MGASPIRIN; BUTALBITAL; CAFFEINEBIO\* CAPSULE; ORAL  
325MG;50MG;40MG  
650MG;50MG;40MGBIO\* TABLET; ORAL  
325MG;50MG;40MG  
650MG;50MG;40MGASPIRIN; CAFFEINE; CARISOPRODOLBIO\* TABLET; ORAL  
160MG;32MG;200MGASPIRIN; CAFFEINE; CARISOPRODOL; CODEINE PHOSPHATEBIO\* TABLET; ORAL  
160MG;32MG;200MG;16MGASPIRIN; MEPROBAMATETABLET; ORAL  
325MG;200MGASPIRIN; METHOCARBAMOLBIO\* TABLET; ORAL  
325MG;400MGASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATETABLET; ORAL  
325MG;2.25MG;0.19MG  
325MG;4.5MG;0.38MGASPIRIN; PROPOXYPHENE HYDROCHLORIDETABLET; ORAL  
325MG;32MG  
325MG;65MGATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDECAPSULE; ORAL  
0.025MG;2.5MGLIQUID; ORAL  
0.025MG/5ML;2.5MG/MLTABLET; ORAL  
0.025MG;2.5MGATROPINE SULFATE; HYOSCYAMINE HYDROBROMIDE; SCOPOLAMINE HYDROBROMIDETABLET; ORAL  
0.0372MG;0.4507MG;0.0119MGATROPINE SULFATE; MEPERIDINE HYDROCHLORIDEINJECTABLE; INJECTION  
0.4MG/ML;50MG/ML  
0.4MG/ML;75MG/ML  
0.4MG/ML;100MG/MLAZURESINGRANULE; ORAL  
2GM/PACKET

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

5

BELLADONNA ALKALOIDSTABLET; ORAL  
0.4MGBENDROFLUMETHIAZIDEBIO TABLET; ORAL  
2.5MG  
5MGBENOXINATE HYDROCHLORIDESOLUTION; OPHTHALMIC  
0.4%BENZOCAINE; BENZYL BENZOATE; CHLOROPHENOTHANELOTION; TOPICAL  
20MG/ML;125MG/ML;10MG/MLBENZONATATECAPSULE; ORAL  
50MG  
100MGBENZOYLPAS CALCIUMPOWDER; ORAL  
100%BIO TABLET; ORAL  
500MGBENZPHETAMINE HYDROCHLORIDETABLET; ORAL  
25MG  
50MGBENZTHIAZIDEDEF TABLET; ORAL  
25MG  
50MGBENZTROPINE MESYLATEINJECTABLE; INJECTION  
1MG/MLTABLET; ORAL  
0.5MG  
2MGBENZYL BENZOATEEMULSION; TOPICAL  
50%LOTION; TOPICAL  
25%  
50%BETAINE; MERSALYL SODIUM; THEOPHYLLINEINJECTABLE; INJECTION  
59.1MG/ML;100MG/ML;50MG/MLBETAMETHASONESYRUP; ORAL  
0.6MG/5MLBIO TABLET; ORAL  
0.6MGBETAMETHASONE SODIUM PHOSPHATEINJECTABLE; INJECTION  
EQ 3MG BASE/MLBETAZOLE HYDROCHLORIDEINJECTABLE; INJECTION  
50MG/MLBETHANECHOL CHLORIDEINJECTABLE; INJECTION  
5MG/MLTABLET; ORAL  
5MG  
10MG  
25MG  
50MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

6

BIALAMICOL HYDROCHLORIDE

TABLET; ORAL  
250MG

BIPERIDEN HYDROCHLORIDE

TABLET; ORAL  
2MG

BIPERIDEN LACTATE

INJECTABLE; INJECTION  
5MG/ML

BROMODIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL  
25MG

ELIXIR; ORAL  
12.5MG/5ML

INJECTABLE; INJECTION  
5MG/ML

SYRUP; ORAL  
12.5MG/5ML

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL  
2MG/5ML

INJECTABLE; INJECTION  
10MG/ML  
100MG/ML

TABLET; ORAL  
4MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
8MG  
12MG

BUCLIZINE HYDROCHLORIDE

TABLET; ORAL  
25MG  
50MG

BUSULFAN

BIO TABLET; ORAL  
2MG

BUTABARBITAL SODIUM

CAPSULE; ORAL  
15MG  
30MG  
50MG  
100MG

ELIXIR; ORAL  
30MG/5ML

INJECTABLE; INJECTION  
125MG/ML

TABLET; ORAL  
15MG  
30MG  
50MG  
100MG

BUTETHAMINE HYDROCHLORIDE; EPINEPHRINE; PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
1.25%; 0.0154MG/ML; 2%

CAFFEINE; ERGOTAMINE TARTRATE

BIO SUPPOSITORY; RECTAL  
100MG; 2MG

TABLET; ORAL  
100MG; 1MG

CALCIUM AMINOSALICYLATE

BIO CAPSULE; ORAL  
500MG

BIO GRANULE; ORAL  
4.25GM/PACKET  
85%

POWDER; ORAL  
85%

BIO TABLET; ORAL  
500MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

7

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION  
EQ 90MG CALCIUM/AMP

CARBINOXAMINE MALEATE

ELIXIR; ORAL  
4MG/5ML

TABLET; ORAL  
4MG

CARISOPRODOL

CAPSULE; ORAL  
250MG

TABLET; ORAL  
350MG

CHLOPHEDIANOL HYDROCHLORIDE

SYRUP; ORAL  
25MG/5ML

CHLORAMBUCIL

BIO TABLET; ORAL  
2MG

CHLORAMINE-T; SULFANILAMIDE

SOLUTION; OPHTHALMIC  
0.13%;0.4%

CHLORCYCLIZINE HYDROCHLORIDE

TABLET; ORAL  
50MG

CHLORDIAZEPOXIDE

BIO TABLET; ORAL  
5MG  
10MG  
25MG

CHLORDIAZEPOXIDE HYDROCHLORIDE

BIO CAPSULE; ORAL  
5MG  
10MG  
25MG

INJECTABLE; INJECTION  
100MG/AMP

CHLORMEZANONE

TABLET; ORAL  
100MG  
200MG

CHLOROPROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
1%  
2%  
3%

CHLOROQUINE HYDROCHLORIDE

INJECTABLE; INJECTION  
EQ 40MG BASE/ML

CHLOROQUINE PHOSPHATE

TABLET; ORAL  
EQ 75MG BASE  
EQ 150MG BASE  
EQ 300MG BASE

CHLOROTHIAZIDE

BIO SUSPENSION; ORAL  
250MG/5ML

BIO\* TABLET; ORAL  
250MG

BIO TABLET; ORAL  
500MG

CHLOROTHIAZIDE; RESERPINE

DEF TABLET; ORAL  
250MG;0.125MG  
500MG;0.125MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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CHLOROTHIAZIDE SODIUM

INJECTABLE; INJECTION  
EQ 500MG BASE/VIAL

CHLOROTRIANISENE

CAPSULE; ORAL  
12MG  
25MG  
72MG

CHLOROTRIANISENE; METHYLTESTOSTERONE

BIO CAPSULE; ORAL  
6MG;2.5MG

CHLORPHENIRAMINE MALEATE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
8MG  
12MG

INJECTABLE; INJECTION  
10MG/ML  
100MG/ML

SYRUP; ORAL  
2MG/5ML  
2.5MG/5ML

TABLET; ORAL  
4MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
8MG  
12MG

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
12MG;75MG

CHLORPHENOXAMINE HYDROCHLORIDE

TABLET; ORAL  
50MG

CHLORPROMAZINE

BIO SUPPOSITORY; RECTAL  
25MG  
100MG

CHLORPROMAZINE HYDROCHLORIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
30MG  
75MG  
150MG  
200MG  
300MG

CONCENTRATE; ORAL  
30MG/ML  
100MG/ML

INJECTABLE; INJECTION  
25MG/ML

SYRUP; ORAL  
10MG/5ML

DEF TABLET; ORAL  
10MG  
25MG  
50MG  
100MG  
200MG

CHLORPROPAMIDE

BIO TABLET; ORAL  
100MG  
250MG

CHLORPROTHIXENE

CONCENTRATE; ORAL  
100MG/5ML

INJECTABLE; INJECTION  
12.5MG/ML

BIO TABLET; ORAL  
10MG  
25MG  
50MG  
100MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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CHLORTHALIDONE

BIO TABLET; ORAL  
25MG  
50MG

CHLORZOAZONE

TABLET; ORAL  
250MG

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC  
750 UNITS/VIAL

CLEMIZOLE HYDROCHLORIDE

TABLET; ORAL  
20MG  
40MG

COLCHICINE; PROBENECID

DEF TABLET; ORAL  
0.5MG;500MG

CORTICOTROPIN

INJECTABLE; INJECTION  
20 UNITS/ML  
25 UNITS/VIAL  
40 UNITS/VIAL

BIO INJECTABLE; INJECTION  
20 UNITS/ML  
40 UNITS/ML  
80 UNITS/ML

CORTICOTROPIN-ZINC HYDROXIDE

BIO INJECTABLE; INJECTION  
20 UNITS/ML  
40 UNITS/ML

CORTISONE ACETATE

DEF INJECTABLE; INJECTION  
25MG/ML  
50MG/ML

CORTISONE ACETATE

OINTMENT; OPHTHALMIC  
1.5%  
2.5%

SUSPENSION; OPHTHALMIC  
0.5%  
2.5%

DEF TABLET; ORAL  
5MG  
10MG  
25MG

CROTAMITON

CREAM; TOPICAL  
10%

LOTION; TOPICAL  
10%

CRYPTENAMINE ACETATES

INJECTABLE; INJECTION  
260 CSR UNITS/ML

CRYPTENAMINE TANNATES

BIO TABLET; ORAL  
260 CSR UNITS

CYANOCOBALAMIN

INJECTABLE; INJECTION  
0.02MG/ML  
0.03MG/ML  
0.05MG/ML  
0.1MG/ML  
1MG/ML  
2MG/ML

TABLET; ORAL  
1MG

CYANOCOBALAMIN; TANNIC ACID; ZINC ACETATE

INJECTABLE; INJECTION  
0.5MG/ML;2.3MG/ML;1MG/ML

CYCLIZINE LACTATE

INJECTABLE; INJECTION  
50MG/ML

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION; OPHTHALMIC  
0.1%  
0.5%  
1%  
2%

CYCLOPENTOLATE HYDROCHLORIDE; PHENYLEPHRINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC  
0.2%;1%

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION  
100MG/VIAL  
200MG/VIAL  
500MG/VIAL

BIO TABLET; ORAL  
50MG

CYCRIMINE HYDROCHLORIDE

BIO TABLET; ORAL  
1.25MG  
2.5MG

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL  
2MG/5ML

TABLET; ORAL  
4MG

DAPSONE

DEF TABLET; ORAL  
25MG  
100MG

DECAMETHONIUM BROMIDE

INJECTABLE; INJECTION  
1MG/ML

DEMECARIUM BROMIDE

SOLUTION; OPHTHALMIC  
0.125%  
0.25%

DESERPIDINE

BIO TABLET; ORAL  
0.1MG  
0.25MG

DESERPIDINE; HYDROCHLOROTHIAZIDE

BIO TABLET; ORAL  
0.125MG;25MG  
0.125MG;50MG  
0.25MG;25MG

DESERPIDINE; METHYCLOTHIAZIDE

BIO TABLET; ORAL  
0.25MG;5MG  
0.5MG;5MG

DESLANOSIDE

INJECTABLE; INJECTION  
0.2MG/ML

DESOXYCORTICOSTERONE ACETATE

INJECTABLE; INJECTION  
5MG/ML

BIO PELLETT; IMPLANTATION  
75MG  
125MG

DESOXYCORTICOSTERONE PIVALATE

BIO INJECTABLE; INJECTION  
25MG/ML

DEXAMETHASONE

AEROSOL; TOPICAL  
0.01%  
10MG/25GM

ELIXIR; ORAL  
0.5MG/5ML  
0.5MG/0.5ML

SUSPENSION; OPHTHALMIC  
0.1%

DEF TABLET; ORAL  
0.25MG  
0.5MG  
0.75MG  
1.5MG  
2MG  
4MG

DEXAMETHASONE ACETATE

DEF INJECTABLE; INJECTION  
EQ 8MG BASE/ML

BIO INJECTABLE; INJECTION  
EQ 16MG BASE/ML

DEXAMETHASONE SODIUM PHOSPHATE

BIO AEROSOL; INHALATION  
0.1MG/INH

CREAM; TOPICAL  
0.1%

INJECTABLE; INJECTION  
EQ 4MG PHOSPHATE/ML  
EQ 10MG PHOSPHATE/ML  
EQ 24MG PHOSPHATE/ML

OINTMENT; OPHTHALMIC, OTIC  
EQ 0.05% PHOSPHATE

SOLUTION; OPHTHALMIC, OTIC  
EQ 0.1% PHOSPHATE

DEXAMETHASONE SODIUM PHOSPHATE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
EQ 4MG PHOSPHATE/ML;10MG/ML

DEXBROMPHENIRAMINE MALEATE

SYRUP; ORAL  
2MG/5ML

TABLET; ORAL  
2MG

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET; ORAL  
2MG;60MG

DEXCHLORPHENIRAMINE MALEATE

TABLET; ORAL  
2MG

DEXTRIFERRON

INJECTABLE; INJECTION  
EQ 20MG FE+++/ML

DEXTROAMPHETAMINE SULFATE

CAPSULE; ORAL  
15MG

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
5MG  
10MG  
15MG

ELIXIR; ORAL  
5MG/5ML

TABLET; ORAL  
5MG  
10MG  
15MG

DEXTROSE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
7.5%;5%

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

30%  
60%  
76%  
85%

SOLUTION; ORAL

76%

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

34.3%;35%  
50%;25%  
52%;8%  
60%;30%  
66%;10%DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE

SOLUTION; INTRAUTERINE

52.7%;26.8%

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

50%

POWDER FOR RECONSTITUTION; ORAL, RECTAL

100%

SOLUTION; ORAL, RECTAL

40%

SOLUTION; URETERAL

20%

DIATRIZOATE SODIUM; DIPROTRIZOATE SODIUM

INJECTABLE; INJECTION

37%;31%

DIBUCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

2.5MG/ML

DIBUTOLINE SULFATE

INJECTABLE; INJECTION

25MG/ML

DICHLORPHENAMIDE

BIO TABLET; ORAL

50MG

DICUMAROL

BIO CAPSULE; ORAL

25MG  
50MG  
100MG

BIO TABLET; ORAL

25MG  
50MG  
100MGDIENESTROL

CREAM; VAGINAL

0.01%

SUPPOSITORY; VAGINAL

0.7MG

BIO TABLET; ORAL

0.1MG  
0.5MG  
10MGDIETHYLCARBAMAZINE CITRATE

SYRUP; ORAL

120MG/5ML

TABLET; ORAL

50MG

DIETHYLPROPION HYDROCHLORIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL

75MG

TABLET; ORAL

25MG

BIO TABLET, CONTROLLED RELEASE; ORAL

75MG

DIETHYLSTILBESTROL

DEF CAPSULE; ORAL  
1MG  
5MG

INJECTABLE; INJECTION  
5MG/ML

SUPPOSITORY; VAGINAL  
0.1MG  
0.5MG

DEF TABLET; ORAL  
0.1MG  
0.25MG  
0.5MG  
1MG  
5MG

DEF TABLET, ENTERIC COATED; ORAL  
0.1MG  
0.25MG  
0.5MG  
1MG  
5MG

DIETHYLSTILBESTROL; METHYLTESTOSTERONE

INJECTABLE; INJECTION  
0.25MG/ML;5MG/ML

BIO TABLET; ORAL  
0.25MG;5MG

DIETHYLSTILBESTROL DIPHOSPHATE

INJECTABLE; INJECTION  
250MG/5ML

BIO TABLET; ORAL  
50MG

DIETHYLSTILBESTROL DIPROPIONATE

BIO TABLET; ORAL  
1MG  
5MG

BIO TABLET, ENTERIC COATED; ORAL  
1MG

DIGITOXIN

INJECTABLE; INJECTION  
0.2MG/ML

DIGOXIN

INJECTABLE; INJECTION  
0.25MG/ML

DIHYDROERGOTAMINE MESYLATE

INJECTABLE; INJECTION  
1MG/ML

DIMENHYDRINATE

INJECTABLE; INJECTION  
50MG/ML

BIO SUPPOSITORY; RECTAL  
100MG

DIMERCAPROL

INJECTABLE; INJECTION  
10%

DIMETHINDENE MALEATE

SOLUTION; ORAL  
0.5MG/0.6ML

SYRUP; ORAL  
1MG/5ML

TABLET; ORAL  
1MG

DIMETHYL TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION  
1MG/ML

DIPHEMANIL METHYLSULFATE

INJECTABLE; INJECTION  
25MG/ML

BIO TABLET; ORAL  
100MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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DIPHENADIONE

BIO TABLET; ORAL  
5MG

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL  
25MG  
50MG

ELIXIR; ORAL  
12.5MG/5ML

INJECTABLE; INJECTION  
10MG/ML  
50MG/ML

LIQUID; ORAL  
12.5MG/5ML

TABLET; ORAL  
25MG

BIO TABLET, ENTERIC COATED; ORAL  
50MG

DIPHENHYDRAMINE HYDROCHLORIDE; EPHEDRINE SULFATE

CAPSULE; ORAL  
50MG; 25MG

DIPHENYLPYRALINE HYDROCHLORIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
5MG

TABLET; ORAL  
2MG  
4MG

DIPROTRIZOATE SODIUM

INJECTABLE; INJECTION  
50%

DISULFIRAM

DEF TABLET; ORAL  
250MG  
500MG

DOXYLAMINE SUCCINATE

TABLET; ORAL  
12.5MG  
25MG

DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE

BIO TABLET, CONTROLLED RELEASE; ORAL  
10MG; 10MG

DROMOSTANOLONE PROPIONATE

INJECTABLE; INJECTION  
50MG/ML

DYDROGESTERONE

BIO TABLET; ORAL  
5MG  
10MG

DYPHYLLINE

INJECTABLE; INJECTION  
250MG/ML

DEF TABLET; ORAL  
200MG  
400MG

ECHOTHIOPHATE IODIDE

POWDER FOR RECONSTITUTION; OPHTHALMIC  
0.03%  
0.06%  
0.125%  
0.25%

EDETATE CALCIUM DISODIUM

INJECTABLE; INJECTION  
200MG/ML

TABLET; ORAL  
500MG

EDETATE DISODIUM

INJECTABLE; INJECTION  
150MG/ML  
200MG/ML

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION  
10MG/ML

EPINEPHRINE

BIO INJECTABLE; INJECTION  
5MG/ML

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.005MG/ML;0.5%  
0.005MG/ML;1%  
0.005MG/ML;1.5%  
0.005MG/ML;2%  
0.01MG/ML;1%  
0.01MG/ML;2%  
0.02MG/ML;2%

EPINEPHRINE; METABUTETHAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.017MG/ML;38MG/ML

EPINEPHRINE; PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.02MG/ML;1%  
0.02MG/ML;2%

EPINEPHRINE; PYRROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.004MG/ML;2%  
0.0066MG/ML;2%  
0.01MG/ML;2%

ERGOLOID MESYLATES

BIO TABLET; ORAL  
1MG

ERGOLOID MESYLATES

TABLET; SUBLINGUAL  
0.5MG  
1MG

ERGOTAMINE TARTRATE

BIO AEROSOL; INHALATION  
0.36MG/INH

TABLET; SUBLINGUAL  
2MG

ESTRADIOL

CREAM; VAGINAL  
0.01%

DEF TABLET; ORAL  
1MG  
2MG

ESTRADIOL CYPIONATE

INJECTABLE; INJECTION  
1MG/ML  
3MG/ML  
5MG/ML

ESTRADIOL DIPROPIONATE

INJECTABLE; INJECTION  
1MG/ML  
2.5MG/ML  
5MG/ML

ESTRADIOL VALERATE

INJECTABLE; INJECTION  
10MG/ML  
20MG/ML  
40MG/ML

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION  
4MG/ML;90MG/ML  
8MG/ML;180MG/ML

ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL  
0.625MG/GM

INJECTABLE; INJECTION  
20MG/VIAL

BIO INJECTABLE; INJECTION  
2MG/ML

TABLET; ORAL  
0.3MG  
0.625MG  
1.25MG  
2.5MG

ESTROGENS, CONJUGATED; Meprobamate

BIO\* TABLET; ORAL  
0.4MG; 200MG  
0.4MG; 400MG

ESTROGENS, CONJUGATED; METHYLTESTOSTERONE

BIO TABLET; ORAL  
0.625MG; 5MG  
1.25MG; 10MG

ESTROGENS, ESTERIFIED

TABLET; ORAL  
0.3MG  
0.625MG  
1.25MG  
2.5MG

ESTRONE

DEF INJECTABLE; INJECTION  
1MG/ML  
2MG/ML  
5MG/ML

ETHCHLORVYNOL

CAPSULE; ORAL  
100MG  
200MG  
250MG  
500MG  
750MG

ETHINAMATE

TABLET; ORAL  
500MG

ETHINYL ESTRADIOL

BIO TABLET; ORAL  
0.01MG  
0.02MG  
0.05MG

ETHINYL ESTRADIOL; FLUOXYMESTERONE

BIO TABLET; ORAL  
0.02MG; 1MG

ETHIODIZED OIL

INJECTABLE; INJECTION  
99%

ETHIONAMIDE

BIO TABLET; ORAL  
250MG

ETHOPROPAZINE HYDROCHLORIDE

BIO TABLET; ORAL  
10MG  
50MG  
100MG

ETHOSUXIMIDE

BIO CAPSULE; ORAL  
250MG  
  
SYRUP; ORAL  
250MG/5ML

ETHOTOIN

BIO TABLET; ORAL  
250MG  
500MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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ETHOXZOLAMIDE

BIO TABLET; ORAL  
62.5MG  
125MG

ETHYL BISCOUMACETATE

BIO TABLET; ORAL  
150MG  
300MG

EVANS BLUE

INJECTABLE; INJECTION  
0.5%

FERROUS GLUCONATE; FOLIC ACID

ELIXIR; ORAL  
281MG/5ML; 0.89MG/5ML

FERROUS SULFATE; FOLIC ACID

CAPSULE; ORAL  
182MG; 0.33MG

FLUDROCORTISONE ACETATE

OINTMENT; TOPICAL  
0.1%

BIO TABLET; ORAL  
0.1MG

FLUDROCORTISONE HEMISUCCINATE

SOLUTION; OPHTHALMIC  
EQ 0.1% ACETATE

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL  
0.01%  
0.025%

GEL; TOPICAL  
0.025%

FLUOCINOLONE ACETONIDE

OINTMENT; TOPICAL  
0.025%

SOLUTION; TOPICAL  
0.01%

FLUOROMETHOLONE

CREAM; TOPICAL  
0.025%

FLUOROURACIL

INJECTABLE; INJECTION  
50MG/ML

FLUOXYMESTERONE

BIO TABLET; ORAL  
2MG  
5MG  
10MG

FLUPHENAZINE HYDROCHLORIDE

ELIXIR; ORAL  
0.5MG/ML

INJECTABLE; INJECTION  
2.5MG/ML

BIO TABLET; ORAL  
0.25MG  
1MG  
2.5MG  
5MG  
10MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
1MG

FLUPREDNISOLONE

BIO TABLET; ORAL  
0.75MG  
1.5MG

FLURANDRENOLIDE

CREAM; TOPICAL  
0.05%

LOTION; TOPICAL  
0.05%

OINTMENT; TOPICAL  
0.05%

FLUROXENE

LIQUID; INHALATION  
99.9%

FOLATE SODIUM

INJECTABLE; INJECTION  
EQ 5MG ACID/ML

FOLIC ACID

INJECTABLE; INJECTION  
1MG/ML

TABLET; ORAL  
1MG

FURAZOLIDONE

BIO SUSPENSION; ORAL  
50MG/15ML

BIO TABLET; ORAL  
100MG

GALLAMINE TRIETHIODIDE

INJECTABLE; INJECTION  
20MG/ML  
100MG/ML

GENTIAN VIOLET

CREAM; TOPICAL  
1.35%

JELLY; VAGINAL  
0.1%

GENTIAN VIOLET

SUPPOSITORY; VAGINAL  
0.4%

TAMPON; VAGINAL  
5MG

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION  
EQ 1MG BASE/AMP  
EQ 10MG BASE/AMP

GLUCOSULFONE SODIUM

INJECTABLE; INJECTION  
400MG/ML

GLUTETHIMIDE

CAPSULE; ORAL  
500MG

TABLET; ORAL  
125MG  
250MG  
500MG

GLYCOBIARSOL

TABLET; ORAL  
500MG

GLYCOPYRROLATE

INJECTABLE; INJECTION  
0.2MG/ML

TABLET; ORAL  
1MG  
2MG

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION  
10,000 IU/VIAL

GUANETHIDINE SULFATE

BIO TABLET; ORAL  
10MG  
25MG

GUANIDINE HYDROCHLORIDE

TABLET; ORAL  
125MG

HALOTHANE

LIQUID; INHALATION  
99.99%

HEPARIN SODIUM

INJECTABLE; INJECTION  
10 UNITS/ML  
100 UNITS/ML  
500 UNITS/ML  
1,000 UNITS/ML  
5,000 UNITS/ML  
10,000 UNITS/ML  
20,000 UNITS/ML  
40,000 UNITS/ML

HEPTABARBITAL

TABLET; ORAL  
200MG

HEXACHLOROPHENE

EMULSION; TOPICAL  
3%

HEXAFLUORENIUM BROMIDE

INJECTABLE; INJECTION  
20MG/ML

HEXETIDINE

GEL; VAGINAL  
0.1%

HEXOCYCLIUM METHYLSULFATE

SOLUTION; ORAL  
25MG/0.6ML

TABLET; ORAL  
25MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
50MG

HEXYLCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
1%  
25MG/ML

SOLUTION; TOPICAL  
5%

HISTAMINE PHOSPHATE

INJECTABLE; INJECTION  
0.275MG/ML  
0.55MG/ML  
1MG/ML  
2.75MG/ML

HOMATROPINE METHYLBROMIDE

TABLET; ORAL  
5MG  
10MG

TABLET, CHEWABLE; ORAL  
3MG

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL  
1.5MG/5ML; 5MG/5ML

TABLET; ORAL  
1.5MG; 5MG

HYALURONIDASE

INJECTABLE; INJECTION  
5 UNITS/VIAL  
150 UNITS/ML  
150 UNITS/VIAL  
1,500 UNITS/VIAL

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
20MG/ML

TABLET; ORAL  
10MG  
25MG  
50MG  
100MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

BIO CAPSULE; ORAL  
25MG;25MG  
50MG;50MG  
100MG;50MG

DEF TABLET; ORAL  
25MG;15MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

DEF TABLET; ORAL  
25MG;15MG;0.1MG

HYDRALAZINE HYDROCHLORIDE; RESERPINE

DEF TABLET; ORAL  
25MG;0.1MG  
50MG;0.2MG

HYDROCHLOROTHIAZIDE

SOLUTION; ORAL  
50MG/5ML  
50MG/0.5ML

BIO TABLET; ORAL  
25MG  
50MG  
100MG

HYDROCHLOROTHIAZIDE; RESERPINE

DEF TABLET; ORAL  
25MG;0.1MG  
25MG;0.125MG  
50MG;0.1MG  
50MG;0.125MG

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

BIO TABLET; ORAL  
25MG;25MG

HYDROCORTAMATE HYDROCHLORIDE

OINTMENT; TOPICAL  
0.5%

HYDROCORTISONE

AEROSOL; TOPICAL  
0.5%  
1%

CREAM; RECTAL  
1%

CREAM; TOPICAL  
0.5%  
1%  
2%  
2.5%

GEL; TOPICAL  
1%  
2.5%

BIO INJECTABLE; INJECTION  
50MG/ML

INJECTABLE; INJECTION  
5MG/ML

LIQUID; TOPICAL  
1%  
2.5%

LOTION; TOPICAL  
0.5%  
1%  
2%  
2.5%

OINTMENT; OPHTHALMIC  
0.5%

OINTMENT; TOPICAL  
0.5%  
1%  
2.5%

HYDROCORTISONE

SOLUTION; OPHTHALMIC  
0.2%

SUSPENSION; OPHTHALMIC  
0.5%  
2.5%

DEF TABLET; ORAL  
5MG  
10MG  
20MG

TABLET; VAGINAL  
10MG

HYDROCORTISONE; UREA

CREAM; TOPICAL  
1%;10%

HYDROCORTISONE ACETATE

AEROSOL; TOPICAL  
1%

CREAM; TOPICAL  
0.5%  
1%

DEF INJECTABLE; INJECTION  
25MG/ML  
50MG/ML

LOTION; TOPICAL  
0.5%

OINTMENT; OPHTHALMIC  
0.5%  
2.5%

OINTMENT; OPHTHALMIC, OTIC  
1.5%

OINTMENT; TOPICAL  
1%  
1.5%  
2.5%

PASTE; TOPICAL  
0.5%

HYDROCORTISONE ACETATE

SOLUTION; OPHTHALMIC, OTIC  
0.5%  
1.5%

SUSPENSION; OPHTHALMIC  
2%

SUSPENSION; OPHTHALMIC, OTIC  
0.5%  
2.5%

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; RECTAL  
1%;1%

CREAM; TOPICAL  
0.5%;1%  
1%;1%

LOTION; TOPICAL  
0.5%;1%  
1%;1%  
2.5%;1%

HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL  
1%;10%

HYDROCORTISONE CYPIONATE

BIO SUSPENSION; ORAL  
EQ 10MG BASE/5ML

HYDROCORTISONE HEMISUCCINATE

INJECTABLE; INJECTION  
EQ 100MG BASE/VIAL  
EQ 250MG BASE/VIAL  
EQ 500MG BASE/VIAL

HYDROCORTISONE SODIUM PHOSPHATE

INJECTABLE; INJECTION  
EQ 50MG BASE/ML

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION  
EQ 100MG BASE/VIAL  
EQ 250MG BASE/VIAL  
EQ 500MG BASE/VIAL  
EQ 1GM BASE/VIAL

HYDROCORTISONE TEBUTATE

BIO INJECTABLE; INJECTION  
25MG/ML

HYDROFLUMETHIAZIDE

SYRUP; ORAL  
50MG/5ML

BIO TABLET; ORAL  
50MG

HYDROFLUMETHIAZIDE; RESERPINE

BIO TABLET; ORAL  
50MG;0.125MG

HYDROXOCOBALAMIN

INJECTABLE; INJECTION  
1MG/ML

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION; OPHTHALMIC  
1%

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL  
EQ 155MG BASE  
EQ 300MG BASE

HYDROXYDIONE SODIUM SUCCINATE

INJECTABLE; INJECTION  
500MG/VIAL

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION  
125MG/ML  
250MG/ML

HYDROXYSTILBAMIDINE ISETHIONATE

INJECTABLE; INJECTION  
225MG/VIAL

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
25MG/ML  
50MG/ML

SYRUP; ORAL  
10MG/5ML

BIO\* TABLET; ORAL  
10MG  
25MG  
50MG  
100MG

HYDROXYZINE PAMOATE

BIO CAPSULE; ORAL  
EQ 25MG HCL  
EQ 50MG HCL  
EQ 100MG HCL

BIO SUSPENSION; ORAL  
EQ 25MG HCL/5ML

HYOSCYAMINE SULFATE; PHENOBARBITAL

TABLET; ORAL  
0.125MG;15MG

IMIPRAMINE HYDROCHLORIDE

CONCENTRATE; ORAL  
25MG/ML

INJECTABLE; INJECTION  
12.5MG/ML

BIO TABLET; ORAL  
10MG  
25MG  
50MG

INDOCYANINE GREEN

INJECTABLE; INJECTION  
10MG/VIAL  
25MG/VIAL  
40MG/VIAL  
50MG/VIAL

INULIN

INJECTABLE; INJECTION  
100MG/ML

INVERT SUGAR; UREA

INJECTABLE; INJECTION  
10GM/100ML; 4GM/100ML  
10GM/100ML; 30GM/100ML

IODIPAMIDE MEGLUMINE

INJECTABLE; INJECTION  
52%

IODIPAMIDE SODIUM

INJECTABLE; INJECTION  
20%

IOPANOIC ACID

TABLET; ORAL  
500MG

IOPHENDYLATE

INJECTABLE; INJECTION  
100%

IOPYDOL; IOPYDONE

SUSPENSION; INTRATRACHEAL  
46%; 30.5%

IOTHALAMATE MEGLUMINE

INJECTABLE; INJECTION  
60%

IOTHALAMATE SODIUM

INJECTABLE; INJECTION  
80%

IPODATE CALCIUM

GRANULE; ORAL  
3GM/PACKET

IPODATE SODIUM

CAPSULE; ORAL  
500MG

IRON DEXTRAN COMPLEX

INJECTABLE; INJECTION  
EQ 50MG IRON/ML

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION  
0.062%  
0.077%  
0.0833%  
0.1%  
0.125%  
0.143%  
0.167%  
0.17%  
0.2%  
0.25%  
0.5%  
1%

ISOETHARINE MESYLATE

BIO AEROSOL; INHALATION  
0.61%

ISOFLUROPHATE

OINTMENT; OPHTHALMIC  
0.025%

SOLUTION; OPHTHALMIC  
0.1%

ISONIAZID

INJECTABLE; INJECTION  
25MG/ML  
100MG/ML

SYRUP; ORAL  
50MG/5ML

TABLET; ORAL  
50MG  
100MG  
300MG

ISONIAZID; SODIUM AMINOSALICYLATE

BIO TABLET; ORAL  
12.5MG;500MG  
20MG;500MG

ISOPROPAMIDE IODIDE

TABLET; ORAL  
EQ 5MG BASE

ISOPROTERENOL HYDROCHLORIDE

DEF AEROSOL; INHALATION  
0.25%

INJECTABLE; INJECTION  
0.02MG/ML  
0.2MG/ML

SOLUTION; INHALATION  
0.031%  
0.062%  
0.25%  
0.5%  
1%

BIO TABLET; RECTAL, SUBLINGUAL  
10MG  
15MG

ISOPROTERENOL HYDROCHLORIDE; PHENYLEPHRINE BITARTRATE

BIO AEROSOL; INHALATION  
4MG/ML;6MG/ML

ISOPROTERENOL SULFATE

BIO AEROSOL; INHALATION  
2MG/ML

BIO POWDER; INHALATION  
10%  
25%

ISOTHIPENDYL HYDROCHLORIDE

SYRUP; ORAL  
4MG/5ML

TABLET; ORAL  
4MG

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION  
3MG/ML

LEVALLORPHAN TARTRATE

INJECTABLE; INJECTION  
1MG/ML

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.05MG/ML;2%

LEVONORDEFRIN; PROCAINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.05MG/ML;2%;0.4%

LEVONORDEFRIN; PROCAINE HYDROCHLORIDE; TETRACAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.05MG/ML;2%;0.15%

LIDOCAINE

OINTMENT; TOPICAL  
5%

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

0.5%  
1%  
1.5%  
2%  
4%  
10%

JELLY; TOPICAL

2%

SOLUTION; ORAL

2%

SOLUTION; TOPICAL

2%  
4%LINDANE

CREAM; TOPICAL

1%

LOTION; TOPICAL

1%

SHAMPOO; TOPICAL

1%

LIOTHYRONINE SODIUM

BIO TABLET; ORAL

EQ 0.005MG BASE  
EQ 0.025MG BASE  
EQ 0.05MG BASEMANNITOLINJECTABLE; INJECTION  
12.5GM/50MLMANNITOL; SORBITOLSOLUTION; IRRIGATION  
540MG/100ML; 2.7GM/100MLSOLUTION; URETHRAL  
5.4GM/100ML; 27GM/100MLMECAMYLAMINE HYDROCHLORIDE

BIO TABLET; ORAL

2.5MG  
10MGMECHLORETHAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

10MG/VIAL

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

12.5MG  
25MGMEDROXYPROGESTERONE ACETATE

DEF TABLET; ORAL

2.5MG  
10MGMENADIOL SODIUM DIPHOSPHATE

INJECTABLE; INJECTION

5MG/ML  
10MG/ML  
37.5MG/ML

BIO TABLET; ORAL

5MG

MENADIONE

BIO TABLET; ORAL

5MG

MENADIONE SODIUM BISULFITE

INJECTABLE; INJECTION

2.5MG/ML  
5MG/ML  
7.2MG/ML  
10MG/ML

BIO TABLET; ORAL

5MG

MEPENZOLATE BROMIDELIQUID; ORAL  
25MG/5MLTABLET; ORAL  
25MGMEPERIDINE HYDROCHLORIDEELIXIR; ORAL  
50MG/5MLINJECTABLE; INJECTION  
10MG/ML  
25MG/ML  
50MG/ML  
75MG/ML  
100MG/MLTABLET; ORAL  
50MG  
100MGMEPERIDINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDEINJECTABLE; INJECTION  
25MG/ML; 25MG/MLMEPHENTERMINE SULFATEINJECTABLE; INJECTION  
15MG/ML  
30MG/MLMEPHENYTOINBIO TABLET; ORAL  
100MGMEPIVACAINE HYDROCHLORIDEINJECTABLE; INJECTION  
1%  
2%  
3%MEPROBAMATECAPSULE; ORAL  
200MGMEPROBAMATEBIO CAPSULE, CONTROLLED RELEASE; ORAL  
200MG  
400MGINJECTABLE; INJECTION  
80MG/MLSUSPENSION; ORAL  
200MG/5MLTABLET; ORAL  
200MG  
400MG  
600MGMERCAPTOMERIN SODIUMINJECTABLE; INJECTION  
125MG/ML  
1.4GM/VIALMERCAPTOPURINEBIO TABLET; ORAL  
50MGMERCUMATILIN SODIUMINJECTABLE; INJECTION  
132MG/MLMERSALYL SODIUM; THEOPHYLLINEINJECTABLE; INJECTION  
100MG/ML; 50MG/MLMETARAMINOL BITARTRATEINJECTABLE; INJECTION  
EQ 10MG BASE/ML  
EQ 20MG BASE/MLMETAXALONETABLET; ORAL  
400MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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METHADONE HYDROCHLORIDEINJECTABLE; INJECTION  
10MG/MLSOLUTION; ORAL  
5MG/5ML  
10MG/5MLSYRUP; ORAL  
10MG/30MLTABLET; ORAL  
5MG  
10MGMETHALLENESTRILBIO TABLET; ORAL  
3MG  
20MGMETHAMPHETAMINE HYDROCHLORIDEELIXIR; ORAL  
3.3MG/5MLTABLET; ORAL  
2.5MG  
5MG  
10MGBIO TABLET, CONTROLLED RELEASE; ORAL  
5MG  
10MG  
15MGMETHANTHELINE BROMIDEINJECTABLE; INJECTION  
50MG/VIALTABLET; ORAL  
50MGMETHARBITALTABLET; ORAL  
100MGMETHAZOLAMIDEBIO TABLET; ORAL  
50MGMETHDILAZINEBIO TABLET, CHEWABLE; ORAL  
3.6MGMETHDILAZINE HYDROCHLORIDESYRUP; ORAL  
4MG/5MLBIO TABLET; ORAL  
8MGMETHIMAZOLEBIO TABLET; ORAL  
5MG  
10MGMETHOCARBAMOLINJECTABLE; INJECTION  
100MG/MLTABLET; ORAL  
500MG  
750MGMETHOHEXITAL SODIUMINJECTABLE; INJECTION  
500MG/AMP  
2.5GM/AMP  
5GM/AMPMETHOTREXATEBIO TABLET; ORAL  
2.5MG

METHOTREXATE SODIUM

INJECTABLE; INJECTION  
 EQ 2.5MG BASE/ML  
 EQ 5MG BASE/VIAL  
 EQ 20MG BASE/VIAL  
 EQ 25MG BASE/ML  
 EQ 50MG BASE/VIAL  
 EQ 100MG BASE/VIAL

METHOXAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 10MG/ML  
 20MG/ML

METHOXAMINE HYDROCHLORIDE; PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 15MG/ML;10MG/ML

METHOXSALEN

DEF CAPSULE; ORAL  
 10MG  
  
 LOTION; TOPICAL  
 1%

METHOXYFLURANE

SOLUTION; INHALATION  
 99.9%

METHSCOPOLAMINE BROMIDE

INJECTABLE; INJECTION  
 1MG/ML  
  
 SYRUP; ORAL  
 1.25MG/5ML  
  
 TABLET; ORAL  
 2.5MG

METHSUXIMIDE

BIO CAPSULE; ORAL  
 150MG  
 300MG

METHYLCLOTHIAZIDE

BIO TABLET; ORAL  
 2.5MG  
 5MG

METHYLCLOTHIAZIDE; RESERPINE

BIO TABLET; ORAL  
 2.5MG;0.1MG

METHYLATROPINE NITRATE

INJECTABLE; INJECTION  
 5MG/ML  
  
 SOLUTION; ORAL  
 1MG/ML  
  
 TABLET; ORAL  
 1MG

METHYLERGONOVIINE MALEATE

INJECTABLE; INJECTION  
 0.2MG/ML  
  
 BIO TABLET; ORAL  
 0.2MG

METHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL  
 5MG  
 10MG  
 20MG

METHYLPREDNISOLONE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
 2MG  
 4MG  
  
 DEF TABLET; ORAL  
 2MG  
 4MG  
  
 BIO TABLET; ORAL  
 16MG

METHYLPREDNISOLONE ACETATE

DEF INJECTABLE; INJECTION  
20MG/ML  
40MG/ML  
80MG/ML

OINTMENT; TOPICAL  
0.25%  
1%

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION  
EQ 40MG BASE/VIAL  
EQ 125MG BASE/VIAL  
EQ 500MG BASE/VIAL  
EQ 1GM BASE/VIAL

METHYLTESTOSTERONE

DEF CAPSULE; ORAL  
10MG

DEF TABLET; BUCCAL, SUBLINGUAL  
5MG  
10MG

DEF TABLET; ORAL  
5MG  
10MG  
25MG

METHYPRYLON

CAPSULE; ORAL  
300MG

TABLET; ORAL  
50MG  
200MG

METHYSERGIDE MALEATE

TABLET; ORAL  
2MG

METOCURINE IODIDE

INJECTABLE; INJECTION  
1MG/ML  
2MG/ML

METYRAPONE

TABLET; ORAL  
250MG

METYRAPONE TARTRATE

INJECTABLE; INJECTION  
100MG/ML

MONOBENZONE

OINTMENT; TOPICAL  
20%

NALORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.2MG/ML  
5MG/ML

NAPHAZOLINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC  
0.1%

NEGATOL

SOLUTION; TOPICAL, VAGINAL  
45%

NEGOSTIGMINE BROMIDE

SOLUTION; OPHTHALMIC  
5%

NIACIN

CAPSULE; ORAL  
500MG

TABLET; ORAL  
500MG

NITROFURANTOIN

BIO CAPSULE; ORAL  
50MG  
100MG

NITROFURANTOIN

BIO SUSPENSION; ORAL  
25MG/5ML

BIO TABLET; ORAL  
50MG  
100MG

NITROFURANTOIN SODIUM

INJECTABLE; INJECTION  
EQ 180MG BASE/VIAL

NITROFURAZONE

CREAM; TOPICAL  
0.2%

DRESSING; TOPICAL  
0.2%

ointment; TOPICAL  
0.2%

POWDER; TOPICAL  
0.2%

SOLUTION; TOPICAL  
0.2%

NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION  
EQ 0.1MG BASE/ML  
EQ 1MG BASE/ML

NOREPINEPHRINE BITARTRATE; PROCAINE HYDROCHLORIDE;  
PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
EQ 0.033MG BASE/ML;2%;0.4%

NOREPINEPHRINE BITARTRATE; PROCAINE HYDROCHLORIDE; TETRACAINE  
HYDROCHLORIDE

INJECTABLE; INJECTION  
0.033MG/ML;2%;0.15%

NORETHINDRONE

BIO TABLET; ORAL  
5MG

NORETHINDRONE ACETATE

BIO TABLET; ORAL  
5MG

ORPHENADRINE CITRATE

INJECTABLE; INJECTION  
30MG/ML

BIO TABLET, CONTROLLED RELEASE; ORAL  
100MG

ORPHENADRINE HYDROCHLORIDE

BIO TABLET; ORAL  
50MG

OXTRIPHYLLINE

ELIXIR; ORAL  
100MG/5ML

BIO TABLET, CONTROLLED RELEASE; ORAL  
400MG  
600MG

BIO TABLET, ENTERIC COATED; ORAL  
100MG  
200MG

OXYMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION  
1MG/ML  
1.5MG/ML

BIO SUPPOSITORY; RECTAL  
5MG

TABLET; ORAL  
10MG

OXYPHENBUTAZONE

BIO TABLET; ORAL  
100MG

OXYPHENCYCLIMINE HYDROCHLORIDE

TABLET; ORAL  
10MG

OXYPHENONIUM BROMIDE

INJECTABLE; INJECTION  
2MG/ML

SYRUP; ORAL  
5MG/4ML

TABLET; ORAL  
5MG

OXYTOCIN

SOLUTION; NASAL  
40 USP UNITS/ML

PARAMETHADIONE

BIO CAPSULE; ORAL  
150MG  
300MG

CONCENTRATE; ORAL  
300MG/ML

PARAMETHASONE ACETATE

BIO TABLET; ORAL  
1MG  
2MG

PENTHIENATE BROMIDE

ELIXIR; ORAL  
2.5MG/5ML

TABLET; ORAL  
5MG

PENTOBARBITAL

ELIXIR; ORAL  
18.2MG/5ML

PENTOBARBITAL SODIUM

CAPSULE; ORAL  
30MG  
50MG  
100MG

INJECTABLE; INJECTION  
50MG/ML  
130MG/ML  
162MG/ML  
325MG/ML

BIO SUPPOSITORY; RECTAL  
30MG  
60MG  
120MG  
200MG

TABLET; ORAL  
100MG

PENTOLINIUM TARTRATE

INJECTABLE; INJECTION  
10MG/ML

TABLET; ORAL  
20MG  
40MG  
100MG

PERPHENAZINE

CONCENTRATE; ORAL  
16MG/5ML

INJECTABLE; INJECTION  
5MG/ML

BIO SUPPOSITORY; RECTAL  
2MG  
4MG  
8MG

SYRUP; ORAL  
2MG/5ML

BIO TABLET; ORAL  
2MG  
4MG  
8MG  
16MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
8MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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PHENACEMIDEBIO TABLET; ORAL  
500MGPHENAZOCINE HYDROBROMIDEINJECTABLE; INJECTION  
EQ 2MG BASE/MLPHENDIMETRAZINE TARTRATECAPSULE; ORAL  
35MGBIO CAPSULE, CONTROLLED RELEASE; ORAL  
105MGTABLET; ORAL  
17.5MG  
35MGPHENELZINE SULFATEBIO TABLET; ORAL  
EQ 15MG BASEPHENINDAMINE TARTRATESYRUP; ORAL  
10MG/5MLTABLET; ORAL  
25MGPHENINDIONEBIO TABLET; ORAL  
20MG  
50MGPHENIRAMINE MALEATETABLET; ORAL  
25MGPHENMETRAZINE HYDROCHLORIDETABLET; ORAL  
25MGPHENMETRAZINE HYDROCHLORIDEBIO TABLET, CONTROLLED RELEASE; ORAL  
75MGPHENOXYBENZAMINE HYDROCHLORIDEBIO CAPSULE; ORAL  
10MGPHENPROCOUMONBIO TABLET; ORAL  
3MGPHENSUXIMIDEBIO CAPSULE; ORAL  
250MG  
500MGBIO SUSPENSION; ORAL  
300MG/5MLPHENTERMINE HYDROCHLORIDECAPSULE; ORAL  
8MG  
15MG  
30MG  
37.5MGTABLET; ORAL  
8MG  
30MG  
37.5MGPHENTERMINE RESIN COMPLEXBIO CAPSULE, CONTROLLED RELEASE; ORAL  
EQ 15MG BASE  
EQ 30MG BASEPHENTOLAMINE HYDROCHLORIDEBIO TABLET; ORAL  
50MG

POLDINE METHYLSULFATE

TABLET; ORAL  
4MG

POLYESTRADIOL PHOSPHATE

INJECTABLE; INJECTION  
40MG/AMP

POLYTHIAZIDE

BIO TABLET; ORAL  
1MG  
2MG  
4MG

POTASSIUM AMINOSALICYLATE

BIO CAPSULE; ORAL  
500MG

POWDER; ORAL  
3GM/PACKET  
100%

BIO TABLET; ORAL  
500MG

POTASSIUM CHLORIDE

INJECTABLE; INJECTION  
1MEQ/ML  
1.5MEQ/ML  
2MEQ/ML  
2.4MEQ/ML  
3MEQ/ML  
3.2MEQ/ML  
4MEQ/ML  
5MEQ/ML

PREDNISOLONE

DEF TABLET; ORAL  
1MG  
2.5MG  
5MG

PREDNISOLONE ACETATE

DEF INJECTABLE; INJECTION  
20MG/ML  
25MG/ML  
40MG/ML  
50MG/ML

SOLUTION; OPHTHALMIC  
0.2%

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

OINTMENT; OPHTHALMIC  
0.2%;10%  
0.25%;10%

SUSPENSION; OPHTHALMIC  
0.25%;10%  
0.5%;10%

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION  
EQ 20MG PHOSPHATE/ML

OINTMENT; OPHTHALMIC, OTIC  
EQ 0.25% PHOSPHATE

SOLUTION; OPHTHALMIC  
EQ 0.1% BASE  
EQ 0.113% PHOSPHATE  
0.125%  
EQ 0.8% BASE  
1%

SOLUTION; OPHTHALMIC, OTIC  
EQ 0.5% PHOSPHATE  
EQ 0.9% PHOSPHATE

PREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION  
EQ 50MG BASE/VIAL

PREDNISOLONE TEBUTATE

BIO INJECTABLE; INJECTION  
20MG/ML

PREDNISON

DEF CAPSULE; ORAL  
50MG

BIO CAPSULE, (SPRINKLES); ORAL  
5MG  
10MG  
20MG  
30MG

BIO SYRUP; ORAL  
5MG/5ML  
5MG/0.5ML

DEF TABLET; ORAL  
1MG  
2.5MG  
5MG  
10MG  
20MG  
25MG  
50MG

PRIMAQUINE PHOSPHATE

TABLET; ORAL  
EQ 15MG BASE

PRIMIDONE

BIO SUSPENSION; ORAL  
250MG/5ML

BIO TABLET; ORAL  
50MG  
250MG

PROBENECID

BIO TABLET; ORAL  
500MG

PROCAINAMIDE HYDROCHLORIDE

BIO CAPSULE; ORAL  
250MG  
375MG  
500MG

INJECTABLE; INJECTION  
100MG/ML  
500MG/ML

PROCAINAMIDE HYDROCHLORIDE

BIO TABLET; ORAL  
250MG  
375MG  
500MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
250MG  
500MG  
750MG

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
0.5%  
1%  
2%  
10%  
20%

PROCAINE HYDROCHLORIDE; TESTOSTERONE PHENYLACETATE

BIO INJECTABLE; INJECTION  
1%;50MG/ML

PROCAINE MERETHOXYLLINE; THEOPHYLLINE

INJECTABLE; INJECTION  
100MG/ML;50MG/ML

PROCHLORPERAZINE

BIO SUPPOSITORY; RECTAL  
2.5MG  
5MG  
25MG

PROCHLORPERAZINE EDISYLATE

CONCENTRATE; ORAL  
EQ 10MG BASE/ML

INJECTABLE; INJECTION  
EQ 5MG BASE/ML

SYRUP; ORAL  
EQ 5MG BASE/5ML

PHENTOLAMINE MESYLATEINJECTABLE; INJECTION  
5MG/VIALPHENYL AMINOSALICYLATEPOWDER; ORAL  
50%BIO TABLET; ORAL  
500MGPHENYLBUTAZONEBIO CAPSULE; ORAL  
100MGBIO TABLET; ORAL  
100MGPHENYTOINBIO SUSPENSION; ORAL  
30MG/5ML  
50MG/5ML  
125MG/5MLBIO TABLET, CHEWABLE; ORAL  
50MGPHENYTOIN SODIUMINJECTABLE; INJECTION  
50MG/MLPHENYTOIN SODIUM, EXTENDEDBIO CAPSULE; ORAL  
30MG  
100MGPHENYTOIN SODIUM, PROMPTBIO CAPSULE; ORAL  
30MG  
100MGPHYTONADIONEDEF INJECTABLE; INJECTION  
1MG/0.5ML  
10MG/MLBIO TABLET; ORAL  
5MGPIMINODINE ESYLATEINJECTABLE; INJECTION  
20MG/MLTABLET; ORAL  
50MGPIPENZOLATE BROMIDECAPSULE; ORAL  
5MGELIXIR; ORAL  
5MG/15MLTABLET; ORAL  
5MGPIPERAZINE CITRATESYRUP; ORAL  
EQ 500MG BASE/5MLTABLET; ORAL  
EQ 250MG BASE  
EQ 500MG BASEPIPERAZINE ESTRONE SULFATECREAM; VAGINAL  
1.5MG/GMBIO TABLET; ORAL  
0.75MG  
1.5MG  
3MG  
6MGPIPERAZINE PHOSPHATETABLET, CHEWABLE; ORAL  
EQ 500MG BASE

PROCHLORPERAZINE MALEATE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
 EQ 10MG BASE  
 EQ 15MG BASE  
 EQ 30MG BASE  
 EQ 75MG BASE

BIO TABLET; ORAL  
 EQ 5MG BASE  
 EQ 10MG BASE  
 EQ 25MG BASE

PROCYCLIDINE HYDROCHLORIDE

TABLET; ORAL  
 5MG

PROGESTERONE

INJECTABLE; INJECTION  
 25MG/ML  
 50MG/ML

PROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL  
 30MG/ML  
 100MG/ML

INJECTABLE; INJECTION  
 25MG/ML  
 50MG/ML

SYRUP; ORAL  
 10MG/5ML

BIO TABLET; ORAL  
 10MG  
 25MG  
 50MG  
 100MG  
 200MG

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 25MG/ML  
 50MG/ML

BIO SUPPOSITORY; RECTAL  
 25MG  
 50MG

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
 6.25MG/5ML  
 12.5MG/5ML  
 25MG/5ML

DEF TABLET; ORAL  
 12.5MG  
 25MG  
 50MG

PROMETHESTROL DIPROPIONATE

BIO TABLET; ORAL  
 1MG

PROPANTHELINE BROMIDE

INJECTABLE; INJECTION  
 30MG/VIAL

TABLET; ORAL  
 7.5MG  
 15MG

PROPARACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC  
 0.5%

PROPIOMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 20MG/ML

PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 0.5%

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL  
 32MG  
 65MG

TABLET; ORAL  
 65MG

PROPYLIODONE

SUSPENSION; INTRATRACHEAL  
50%  
60%

PROPYLTHIOURACIL

DEF TABLET; ORAL  
50MG

PROTAMINE SULFATE

INJECTABLE; INJECTION  
10MG/ML  
50MG/VIAL

PROTOKYLOL HYDROCHLORIDE

SOLUTION; INHALATION  
10MG/ML

TABLET; ORAL  
2MG

PROTOVERATRINE A

BIO TABLET; ORAL  
0.2MG

PROTOVERATRINES

INJECTABLE; INJECTION  
0.2MG/ML

BIO TABLET; ORAL  
0.2MG  
0.5MG

PROTOVERATRINES, MALEATE

BIO TABLET; ORAL  
0.5MG

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL  
30MG/5ML; 1.25MG/5ML

TABLET; ORAL  
60MG; 2.5MG

PYRAZINAMIDE

BIO TABLET; ORAL  
500MG

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL  
60MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
180MG

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION  
50MG/ML  
100MG/ML

PYRILAMINE MALEATE

TABLET; ORAL  
25MG  
50MG

PYRIMETHAMINE

BIO TABLET; ORAL  
25MG

PYRROBUTAMINE PHOSPHATE

TABLET; ORAL  
15MG

PYRVINIUM PAMOATE

SUSPENSION; ORAL  
EQ 50MG BASE/5ML

TABLET; ORAL  
EQ 50MG BASE

QUINETHAZONE

BIO TABLET; ORAL  
50MG

QUINIDINE GLUCONATE

INJECTABLE; INJECTION  
80MG/ML

BIO TABLET; ORAL  
266MG  
400MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
324MG

QUINIDINE HYDROCHLORIDE

INJECTABLE; INJECTION  
120MG/ML

QUINIDINE POLYGALACTURONATE

BIO TABLET; ORAL  
275MG

QUINIDINE SULFATE

BIO CAPSULE; ORAL  
200MG  
300MG

BIO TABLET; ORAL  
100MG  
200MG  
300MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
300MG

RAUWOLFIA SERPENTINA

DEF TABLET; ORAL  
50MG  
100MG

RESCINNAMINE

DEF CAPSULE; ORAL  
0.5MG

BIO TABLET; ORAL  
0.25MG  
0.5MG  
1MG

RESERPINE

DEF CAPSULE; ORAL  
0.25MG

ELIXIR; ORAL  
0.25MG/5ML  
1MG/4ML

INJECTABLE; INJECTION  
2.5MG/ML  
5MG/ML

DEF TABLET; ORAL  
0.1MG  
0.25MG  
0.5MG  
1MG

RESERPINE; TRICHLORMETHIAZIDE

DEF TABLET; ORAL  
0.1MG;2MG  
0.1MG;4MG

RIBOFLAVIN PHOSPHATE SODIUM

INJECTABLE; INJECTION  
50MG/ML

SECOBARBITAL

ELIXIR; ORAL  
22MG/5ML

SECOBARBITAL SODIUM

CAPSULE; ORAL  
50MG  
100MG

INJECTABLE; INJECTION  
50MG/ML  
100MG/VIAL  
250MG/AMP

BIO SUPPOSITORY; RECTAL  
30MG  
60MG  
120MG  
200MG

TABLET; ORAL  
100MG

SELENIUM SULFIDE

CREAM; TOPICAL  
2.5%

LOTION/SHAMPOO; TOPICAL  
2.5%

SITOSTEROLS

BIO POWDER; ORAL  
1.5GM/PACKET  
3GM/PACKET

BIO SUSPENSION; ORAL  
3GM/15ML

SODIUM AMINOSALICYLATE

GRANULE; ORAL  
5.5GM/PACKET

POWDER; ORAL  
4GM/PACKET  
100%

BIO TABLET; ORAL  
500MG  
690MG  
1GM

SODIUM BICARBONATE; SULFADIAZINE

BIO TABLET; ORAL  
324MG;324MG

SODIUM IOTHIOURACIL

BIO TABLET; ORAL  
50MG

SODIUM LACTATE; SULFADIAZINE

BIO SUSPENSION; ORAL  
1.67GM/5ML;500MG/5ML

SODIUM MERALLURIDE; THEOPHYLLINE

INJECTABLE; INJECTION  
EQ 39MG HG/ML;48MG/ML

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL  
453.6GM/BOT

SUSPENSION; ORAL, RECTAL  
15GM/60ML

SODIUM SUCCINATE

INJECTABLE; INJECTION  
30%

SODIUM SUCCINATE HEXAHYDRATE

INJECTABLE; INJECTION  
30%

SODIUM TETRADECYL SULFATE

INJECTABLE; INJECTION  
1%  
3%

SPIRONOLACTONE

BIO TABLET; ORAL  
25MG  
100MG

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION  
20MG/ML  
25MG/ML  
50MG/ML  
100MG/ML  
500MG/VIAL  
1GM/VIAL

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE; UREA

CREAM; VAGINAL  
3.7%;2.86%;3.42%;0.64%

SULFACETAMIDE SODIUM

OINTMENT; OPHTHALMIC  
10%  
15%  
30%

SULFACETAMIDE SODIUM

SOLUTION; OPHTHALMIC  
10%  
15%  
30%

SULFACHLORPYRIDAZINE

BIO TABLET; ORAL  
500MG

SULFADIAZINE

BIO SUSPENSION; ORAL  
250MG/5ML  
500MG/5ML

BIO TABLET; ORAL  
250MG  
300MG  
500MG

SULFADIAZINE; SULFAMERAZINE

BIO SUSPENSION; ORAL  
150MG/5ML;150MG/5ML  
250MG/5ML;250MG/5ML

SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE

BIO TABLET; ORAL  
187.5MG;125MG;187.5MG  
200MG;100MG;200MG

SULFADIAZINE SODIUM

INJECTABLE; INJECTION  
250MG/ML  
5GM/AMP

SULFAETHIDOLE

BIO SUSPENSION; ORAL  
650MG/5ML

BIO TABLET, CONTROLLED RELEASE; ORAL  
650MG

SULFAMERAZINE

BIO TABLET; ORAL  
500MG

SULFAMETHIZOLE

SOLUTION; NASAL, OPHTHALMIC  
40MG/ML

BIO SUSPENSION; ORAL  
250MG/5ML  
500MG/5ML

BIO TABLET; ORAL  
250MG  
500MG  
1GM

SULFAMETHOXAZOLE

BIO SUSPENSION; ORAL  
500MG/5ML

BIO TABLET; ORAL  
500MG  
1GM

SULFAPYRIDINE

BIO TABLET; ORAL  
500MG

SULFASALAZINE

BIO SUSPENSION; ORAL  
250MG/5ML

DEF TABLET; ORAL  
500MG

SULFATHIAZOLE

JELLY; VAGINAL  
10%

SULFINPYRAZONE

BIO CAPSULE; ORAL  
200MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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SULFINPYRAZONE

BIO TABLET; ORAL  
100MG

SULFISOMIDINE

BIO SUSPENSION; ORAL  
250MG/4ML

BIO TABLET; ORAL  
500MG

SULFISOXAZOLE

CREAM; VAGINAL  
10%

BIO SUSPENSION; ORAL  
500MG/5ML

BIO SYRUP; ORAL  
500MG/5ML

BIO\* TABLET; ORAL  
500MG

SULFISOXAZOLE ACETYL

BIO SUSPENSION; ORAL  
EQ 500MG BASE/5ML

BIO SYRUP; ORAL  
EQ 500MG BASE/5ML

SULFISOXAZOLE DIOLAMINE

INJECTABLE; INJECTION  
EQ 400MG BASE/ML

OINTMENT; OPHTHALMIC  
EQ 4% BASE

SOLUTION; OPHTHALMIC  
EQ 4% BASE

SULFOXONE SODIUM

BIO TABLET, ENTERIC COATED; ORAL  
330MG

TALBUTAL

TABLET; ORAL  
120MG

TESTOSTERONE

BIO PELLET; IMPLANTATION  
75MG

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION  
50MG/ML  
100MG/ML  
200MG/ML

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION  
100MG/ML  
200MG/ML

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION  
25MG/ML  
50MG/ML  
100MG/ML

TETRAHYDROZOLINE HYDROCHLORIDE

SOLUTION; NASAL  
0.05%  
0.1%

SPRAY; NASAL  
0.1%

THEOPHYLLINE

DEF CAPSULE; ORAL  
50MG  
100MG  
200MG  
250MG

THEOPHYLLINE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
 50MG  
 60MG  
 100MG  
 125MG  
 130MG  
 250MG  
 260MG  
 300MG

BIO CAPSULE, CONTROLLED RELEASE (SPRINKLES); ORAL  
 25MG  
 50MG  
 75MG  
 125MG  
 200MG

ELIXIR; ORAL  
 80MG/15ML  
 112.5MG/15ML

SOLUTION; ORAL  
 80MG/15ML

BIO SUSPENSION; ORAL  
 100MG/5ML

SYRUP; ORAL  
 80MG/15ML  
 150MG/15ML

DEF TABLET; ORAL  
 100MG  
 125MG  
 200MG  
 225MG  
 250MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
 100MG  
 200MG  
 250MG  
 300MG  
 400MG

THEOPHYLLINE SODIUM GLYCINATE

ELIXIR; ORAL  
 EQ 165MG BASE/15ML

INJECTABLE; INJECTION  
 EQ 20MG BASE/ML

THEOPHYLLINE SODIUM GLYCINATE

BIO SUPPOSITORY; RECTAL  
 EQ 390MG BASE

SYRUP; ORAL  
 EQ 65MG BASE/5ML

BIO TABLET; ORAL  
 EQ 150MG BASE  
 EQ 162MG BASE  
 EQ 165MG BASE

BIO TABLET, CONTROLLED RELEASE; ORAL  
 EQ 100MG BASE  
 EQ 300MG BASE

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 100MG/ML  
 200MG/ML

THIAMYLAL SODIUM

INJECTABLE; INJECTION  
 500MG/AMP  
 1GM/AMP  
 5GM/AMP

THIETHYLPERAZINE MALATE

INJECTABLE; INJECTION  
 5MG/ML

THIETHYLPERAZINE MALEATE

BIO TABLET; ORAL  
 10MG

THIOPENTAL SODIUM

BIO SUSPENSION; RECTAL  
 400MG/GM

THIOPROPAZATE HYDROCHLORIDE

BIO TABLET; ORAL  
 5MG

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

43

THIORIDAZINE HYDROCHLORIDECONCENTRATE; ORAL  
30MG/MLBIO TABLET; ORAL  
10MG  
15MG  
25MG  
50MG  
100MG  
150MG  
200MGTHIOTEPAINJECTABLE; INJECTION  
15MG/VIALTHONZYLAMINE HYDROCHLORIDETABLET; ORAL  
50MGTHYROGLOBULINDEF TABLET; ORAL  
16MG  
32MG  
65MGBIO TABLET; ORAL  
100MG  
200MG  
325MGTHYROTROPININJECTABLE; INJECTION  
10 IU/VIALTOLBUTAMIDEBIO TABLET; ORAL  
500MGTOLBUTAMIDE SODIUMINJECTABLE; INJECTION  
EQ 1GM BASE/VIALTRIAMCINOLONEDEF TABLET; ORAL  
1MG  
2MG  
4MG  
8MGBIO TABLET; ORAL  
16MGTRIAMCINOLONE ACETONIDEAEROSOL; TOPICAL  
0.1%  
0.147MG/GM  
0.75%CREAM; TOPICAL  
0.025%  
0.1%  
0.25%  
0.5%GEL; TOPICAL  
0.1%DEF INJECTABLE; INJECTION  
10MG/ML  
40MG/MLLOTION; TOPICAL  
0.025%  
0.1%OINTMENT; TOPICAL  
0.025%  
0.1%  
0.5%PASTE; DENTAL  
0.1%TRIAMCINOLONE DIACETATEDEF INJECTABLE; INJECTION  
25MG/ML  
40MG/MLSYRUP; ORAL  
2MG/5ML

## LIST OF DRUG PRODUCTS SUITABLE FOR ANDAS

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TRIAMCINOLONE HEXACETONIDE

DEF INJECTABLE; INJECTION  
5MG/ML  
20MG/ML

TRICHLORMETHIAZIDE

DEF TABLET; ORAL  
2MG  
4MG

TRICYCLAMOL CHLORIDE

CAPSULE; ORAL  
50MG

TABLET; ORAL  
50MG

TRICYCLAMOL SULFATE

CAPSULE; ORAL  
25MG

TRIDIHEXETHYL CHLORIDE

INJECTABLE; INJECTION  
10MG/ML

TABLET; ORAL  
25MG

TRIETHANOLAMINE POLYPEPTIDE OLEATE CONDENSATE

SOLUTION; OTIC  
10%

TRIETHYLENEMELAMINE

BIO TABLET; ORAL  
5MG

TRIFLUOPERAZINE HYDROCHLORIDE

CONCENTRATE; ORAL  
EQ 10MG BASE/ML

INJECTABLE; INJECTION  
EQ 2MG BASE/ML

TRIFLUOPERAZINE HYDROCHLORIDE

BIO TABLET; ORAL  
EQ 1MG BASE  
EQ 2MG BASE  
EQ 5MG BASE  
EQ 10MG BASE

TRIFLUPROMAZINE

BIO SUSPENSION; ORAL  
EQ 50MG HCL/5ML

TRIFLUPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
3MG/ML  
10MG/ML  
20MG/ML

BIO TABLET; ORAL  
10MG  
25MG  
50MG

TRIHEXYPHENIDYL HYDROCHLORIDE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
5MG

ELIXIR; ORAL  
2MG/5ML

TABLET; ORAL  
2MG  
5MG

TRIMEPAZINE TARTRATE

BIO CAPSULE, CONTROLLED RELEASE; ORAL  
EQ 5MG BASE

SYRUP; ORAL  
EQ 2.5MG BASE/5ML

BIO TABLET; ORAL  
EQ 2.5MG BASE

TRIMETHADIONE

BIO CAPSULE; ORAL  
300MG

SOLUTION; ORAL  
200MG/5ML

BIO TABLET, CHEWABLE; ORAL  
150MG

TRIMETHAPHAN CAMSYLATE

INJECTABLE; INJECTION  
50MG/ML

TRIMETHIDINIUM METHOSULFATE

BIO TABLET; ORAL  
20MG

TRIMETHOBENZAMIDE HYDROCHLORIDE

BIO CAPSULE; ORAL  
200MG  
400MG

INJECTABLE; INJECTION  
100MG/ML

TRIPLENNAMINE CITRATE

ELIXIR; ORAL  
EQ 25MG HCL/5ML

TRIPLENNAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
25MG/ML

TABLET; ORAL  
25MG  
50MG

BIO TABLET, CONTROLLED RELEASE; ORAL  
50MG  
100MG

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL  
1.25MG/5ML

TABLET; ORAL  
2.5MG

TRISULFAPYRIMIDINES

BIO SUSPENSION; ORAL  
500MG/5ML

BIO TABLET; ORAL  
250MG  
500MG

TROPICAMIDE

SOLUTION; OPHTHALMIC  
0.5%  
1%

TRYPSIN

POWDER; INHALATION  
125,000 UNITS/VIAL  
250,000 UNITS/VIAL

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION  
3MG/ML  
15MG/ML

URACIL MUSTARD

BIO CAPSULE; ORAL  
1MG

VASOPRESSIN TANNATE

INJECTABLE; INJECTION  
5 PRESSOR UNITS/ML

VERATRUM VIRIDE

BIO TABLET; ORAL  
130 CSR UNITS

VINBARBITAL

CAPSULE; ORAL  
100MG

VINBLASTINE SULFATE

INJECTABLE; INJECTION  
10MG/AMP

VITAMIN A

INJECTABLE; INJECTION  
25,000 IU/ML  
50,000 IU/ML

VITAMIN A PALMITATE

INJECTABLE; INJECTION  
EQ 50,000 UNITS BASE

WARFARIN POTASSIUM

BIO TABLET; ORAL  
5MG  
10MG

WARFARIN SODIUM

INJECTABLE; INJECTION  
50MG/VIAL  
75MG/VIAL

BIO TABLET; ORAL  
2MG  
2.5MG  
5MG  
7.5MG  
10MG  
25MG

APPENDIX A

Dosage Forms

AEROSOL  
CAPSULE  
CAPSULE (sprinkles)  
CAPSULE, CONTROLLED RELEASE  
CAPSULE, CONTROLLED RELEASE (sprinkles)  
CONCENTRATE  
CREAM  
DRESSING  
ELIXIR  
EMULSION  
GEL  
GRANULE  
INJECTABLE  
JELLY  
LIQUID  
LOTION  
LOTION/SHAMPOO

OINTMENT  
PASTE  
PELLET  
POWDER  
\*POWDER FOR RECONSTITUTION  
SHAMPOO  
SOLUTION  
SPRAY  
SUPPOSITORY  
SUSPENSION  
SYRUP  
TABLET  
TABLET, CHEWABLE  
TABLET, CONTROLLED RELEASE  
TABLET, ENTERIC COATED  
TAMPON

\* For Oral or Ophthalmic use only

APPENDIX B

Routes of Administration

BUCCAL  
DENTAL  
IMPLANTATION  
INHALATION  
INJECTION  
INTRATRACHEAL  
INTRAUTERINE  
IRRIGATION  
NASAL

OPHTHALMIC  
ORAL  
OTIC  
RECTAL  
SUBLINGUAL  
TOPICAL  
URETERAL  
URETHRAL  
VAGINAL

## APPENDIX C

### Abbreviations

AMP	ampule
BOT	bottle
CSR	carotid sinus reflex
EQ	equivalent + 0
GM	gram
HG	mercury
INH	inhalation
IU	international units
MEQ	milliequivalent
MG	milligram
ML	milliliter
UGM	microgram
USP	United States Pharmacopeia