



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	60451	CYSTAGON mercaptamine (cysteamine) (as bitartrate) 50mg capsule bottle
ARTG entry for	Medicine Registered	
Sponsor	Alphapharm Pty Ltd	
Postal Address	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
ARTG Start Date	5/08/1997	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . CYSTAGON mercaptamine (cysteamine) (as bitartrate) 50mg capsule bottle

Product Type	Single Medicine Product	Effective Date	11/10/2023
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

For the management of nephropathic cystinosis in children and adults.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	18 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Protect from Moisture



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Pack Size/Poison information

Pack Size
500

Poison Schedule
(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification white opaque capsule printed with CYSTA 50 on the body and MYLAN on the cap

Active Ingredients

mercaptamine (cysteamine) bitartrate **147.24 mg**
Equivalent: mercaptamine (cysteamine) 50 mg

Other Ingredients (Excipients)

butan-1-ol

croscarmellose sodium

ethanol

Gelatin

iron oxide black

isopropyl alcohol

magnesium stearate

microcrystalline cellulose

pregelatinised maize starch

propylene glycol

Shellac

silicon dioxide

sodium lauryl sulfate

strong ammonia solution

sulfuric acid

titanium dioxide

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Public Summary