



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453225 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : AGO-CPM Generic Name : (Chlorphenamine Oral Solution BP)	2021
Module 1 1.5	Administrative Information and Product Information Product Information
	Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Chlorphenamine Oral Solution BP

1.1 (Trade) name of product

AGO-CPM

1.2 Strength

Each 5 ml contains: Chlorphenamine Maleate BP 2 mg

1.3 Pharmaceutical Dosage Form

Oral liquid



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453225 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Chlorphenamine Oral Solution BP

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / 5 ml.
<u>ACTIVE</u>				
Chlorpheniramine maleate	BP	2 mg	2.00 %	1.224 mg
<u>NON ACTIVE</u>				
Sucrose	BP	-	-	1.500 gm
Methyl Paraben Sodium	BP	-	-	3.000 mg
Propyl Paraben Sodium	BP	-	-	1.003 mg
Sodium benzoate	BP	-	-	7.500 mg
Citric acid monohydrate	BP	-	-	4.084 mg
Sorbitol 70%	BP	-	-	0.359 gm
Glycerine	BP	-	-	0.150 gm
Di sodium EDTA	BP	-	-	1.500 mg
Colour tartrazine supra	INH	-	-	0.300 mg
Essence orange sweet no. 1	INH	-	-	0.006 ml
Purified silicious earth (hyflo super cell powder)	USP	-	-	2.079 mg

BP = British Pharmacopoeia.
USP = United states Pharmacopoeia
INH = Inhouse



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453025 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

3. PHARMACEUTICAL DOSAGE FORM

PET Amber Bottle of 60 ml.
Yellow Colour, clear, syrupy liquid on shaking.



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453225 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

4. CLINICAL PARTICULARS

Chlorphenamine Maleate

Chlorpheniramine maleate are first generation antihistamines that are widely used to treat symptoms of allergic rhinitis and the common cold. Clinically apparent liver injury from brompheniramine or chlorpheniramine must be exceeding rare, if it occurs at all.

LiverTox

Chlorpheniramine maleate appears as odorless white crystalline solid or white powder with a bitter taste. pH (2% aqueous solution) 5. pH (1% aqueous solution) 4-5. (NTP, 1992)

CAMEO Chemicals

Chlorphenamine is a tertiary amino compound that is propylamine which is substituted at position 3 by a pyridin-2-yl group and a p-chlorophenyl group and in which the hydrogens attached to the nitrogen are replaced by methyl groups. A histamine H1 antagonist, it is used to relieve the symptoms of hay fever, rhinitis, urticaria, and asthma. It has a role as a H1-receptor antagonist, an antipruritic drug, a histamine antagonist, a serotonin uptake inhibitor, an antidepressant and an anti-allergic agent. It is a tertiary amino compound, a member of monochlorobenzenes and a member of pyridines.

Chlorpheniramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes/nose/throat/skin, cough, runny nose, and sneezing.



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 208, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453225 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

5. PHARMACOLOGICAL PROPERTIES

Chlorphenamine Maleate

5.1 Pharmacodynamic properties

Chlorpheniramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes/nose/throat/skin, cough, runny nose, and sneezing.

5.2 Pharmacokinetic properties

Chlorpheniramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes/nose/throat/skin, cough, runny nose, and sneezing. This medication works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. By blocking another natural substance made by your body (acetylcholine), it helps dry up some body fluids to relieve symptoms such as watery eyes and runny nose. Cough-and-cold products have not been shown to be safe or effective in children younger than 6 years. Therefore, do not use this product to treat cold symptoms in children younger than 6 years unless specifically directed by the doctor. Some products (such as long-acting tablets/capsules) are not recommended for use in children younger than 12 years. Ask your doctor or pharmacist for more details about using your product safely. These products do not cure or shorten the length of the common cold and may cause serious side effects. To decrease the risk for serious side effects, carefully follow all dosage directions. Do not use this product to make a child sleepy. Do not give other cough-and-cold medication that might contain the same or similar ingredients (see also Drug Interactions section). Ask the doctor or pharmacist about other ways to relieve cough and cold symptoms (such as drinking enough fluids, using a humidifier or saline nose drops/spray).



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453225 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@india@india.com

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose	BP	1.500 gm
Methyl Paraben Sodium	BP	3.000 mg
Propyl Paraben Sodium	BP	1.003 mg
Sodium benzoate	BP	7.500 mg
Citric acid monohydrate	BP	4.084 mg
Sorbitol 70%	BP	0.359 gm
Glycerine	BP	0.150 gm
Di sodium EDTA	BP	1.500 mg
Colour tartrazine supra	INH	0.300 mg
Essence orange sweet no. 1	INH	0.006 ml
Purified silicious earth (hyflo super cell powder)	USP	2.079 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store under normal storage condition (15°C -30°C)
Protect from light.



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 308, INDIA.
Tel. : 95250 - 2452801 / 2452714 / 2453025 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

6.5 Nature and Contents of Container

PET Amber Bottle of 60 ml.

Date:
Director of the manufacturer
(Signature, Full name, Stamp)



Date:
Director of applicant company
(Signature, Full name, Stamp)

