National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS

ALKOLD CAPSULE

1. NAME OF THE MEDICINAL PRODUCT

ALKOLD (Chlorpheniramine Maleate & Phenylephrine HCl Capsule)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each hard gelatin capsule contains:
Chlorpheniramine Maleate BP. …… 4 mg
Phenylephrine Hydrochloride BP……2.5mg
Excipients …….. q.s

3. PHARMACEUTICAL FORM

Capsule for Oral Administration.

FOR ORAL USE ONLY

4. Clinical particulars

4.1 Therapeuticindications

It is indicated for:
- Relief of nasal and sinus congestion.
- Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies.
- Relief of sinus pain and headache.
- Adjunct with antibacterials in sinusitis, tonsillitis and otitis media.

4.2 Posology and method ofadministration

Adults: 1 Capsule is s 3 OR 4 daily or as directed by the physician
Not for Children under 12 years

4.3 Contraindications

- Hypersensitivity to any of the ingredients of the formulation.
- Severe hypertension.
- Patients sensitive to Paracetamol or to any of the excipients of the product.
- Patients in whom aspirin or other NSAIDs, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to these drugs.
- Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleedingdisorders.
- Patients with severe heart failure, hypertension, hepatic or renal insufficiency.
- Last trimester of pregnancy.

4.4 Special warnings and precautions foruse

4.5 Interaction with other medicinal products and other forms ofinteraction

Interaction with other medicinal products and other forms of interaction:
Chlorpheniramine/Alcohol/ CNS Depressants/Tricyclic Antidepressants:
Concurrentuse may potentiate the effects of either these medications or antihistamines.
Antihistamines/ Ototoxic Medications: Symptoms of ototoxicity may be masked if antihistamines are used concurrently with ototoxic medications, particularly aminoglycoside antibiotics such as amikacin, dihydrostreptomycin, gentamicin, kanamycin, neomycin, streptomycin, tobramycin and viomycin.

Drug Interactions Involving Chlorpheniramine Maleate:
Antihistamines/Alcohol/CNS Depressants (including Tricyclic Antidepressants):
Antihistamines may have additive effects when used concurrently with alcohol or other CNS depressants, e.g. hypnotics, sedatives, tranquilizers, antianxiety agents, narcotic analgesics, anticonvulsants, general anesthetics, other antihistamines.
Antihistamines/Monoamine Oxidase Inhibitors: Concurrent administration of antihistamines and monoamine oxidase (MAO) inhibitors may prolong and intensify the anticholinergic (drying) effects of antihistamines. Therefore concurrent use of antihistamines with monoamine oxidase (MAO) inhibitor therapy or within 14 days of discontinuation of such therapy is

contraindicated (see Contraindications.

Antihistamines/Ototoxic Medications: Symptoms of ototoxicity may be masked if antihistamines are used concurrently with ototoxic medications, particularly aminoglycoside antibiotics such as amikacin, dihydrostreptomycin, gentamicin, kanamycin, neomycin, streptomycin, tobramycin, and viomycin.

Antihistamines/Anticholinergic Agents or Other Agents Possessing Anticholinergic Activity: Concurrent use may lead to a potentiation of the anticholinergic effects. Therefore caution should be exercised and patients should be advised to promptly report occurrence of gastrointestinal problems, since paralytic ileus may occur upon concurrent therapy of antihistamines and anticholinergic agents.

Drug Interactions Involving Phenylephrine Hydrochloride:

Phenylephrine/ β-Blockers: β-Blockers increase the effects of sympathomimetics.

Phenylephrine/α-Blockers: The vasopressor response to phenylephrine is decreased by prior administration of an adrenergic blocking agent.

Phenylephrine/Oxytocic Drugs: When a vasopressor, e.g. phenylephrine, is used in conjunction with oxytocic drugs, the pressor effect is potentiated.

Phenylephrine/Sympathomimetic Agents: Combination products containing phenylephrine and a bronchodilator sympathomimetic agent should not be used concomitantly with epinephrine or other sympathomimetic agents, because tachycardia or other serious arrhythmias may occur.

Phenylephrine/General Anesthetics: Rarely, administration of phenylephrine to patients who have received cyclopropane or halogenated hydrocarbon general anesthetics that increase cardiac irritability and seem to sensitize the myocardium to phenylephrine may result in arrhythmias. Vasopressors should therefore be used only with extreme caution or not at all with these general anesthetics.

Phenylephrine/ Monoamine Oxidase (MAO) Inhibitors: The cardiac and pressor effects of phenylephrine are potentiated by administration of monoamine oxidase (MAO) inhibitors because metabolism of phenylephrine is reduced. Oral administration of phenylephrine to patients receiving a MAO inhibitor should be avoided (see Contraindications).

Phenylephrine/Tricyclic Antidepressants: Tricyclic antidepressants may potentiate the vasopressor effects of phenylephrine.

Phenylephrine/Atropine: Atropine sulfate may block the reflex tachycardia caused by phenylephrine and enhances the pressor response to phenylephrine.

Phenylephrine/Injectable Ergot Alkaloids: An excessive rise in blood pressure may occur if phenylephrine is administered to patients receiving a parenteral injection of an ergot alkaloid such as ergonovine maleate.

Phenylephrine/Digitalis: The possibility that digitalis can sensitize the myocardium to the effects of sympathomimetic drugs should be considered. Phenylephrine/ Furosemide or Other Diuretics: Administration of furosemide or other diuretics may decrease arterial responsiveness to vasopressors such as phenylephrine.

4.6 Pregnancy and Lactation

Chlorphenamine maleate:

Pregnancy:

There are no adequate data from the use of chlorphenamine in pregnant women. The potential risk for humans is unknown, Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essential by a physician.
Lactation:
Chlorphenamine maleate and other antihistamines may inhibit lactation and may be secretedin breast milk. Not to be used during lactation unless considered essential by a physician.

Phenylephrine hydrochloride:

The safety of this medicine during pregnancy and lactaction has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of pre- eclampsia. In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.

Effects on ability to drive and usemachines

It is advisable not to drive or operate machinery when on treatment with capsule.

4.7 Undesirable effects

Chlorphenamine maleate:

Constipation; diarrhea; dizziness; drowsiness; dry mouth, nose, or throat; excitability; headache; loss of appetite; nausea; nervousness or anxiety; trouble sleeping; upset stomach; vomiting; weakness.

General disorders and administration site conditions:

Common: fatigue
Unknown: chest
tightness
*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness)

Phenylephrine hydrochloride:

High blood pressure with headache and vomiting, probably only in overdose. Rarely palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males.

4.8 Overdose

Chlorphenamine maleate:

Symptoms and signs

The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions,apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no

contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion.) Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

Phenylephrine hydrochloride: Phenylephrine overdose is likely to result in: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, mydriasis, acute angle closure glaucoma, tachycardia, palpitations, and allergic reactions. Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking medicinal products such as phentolamine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Chlorphenamine maleate: Antihistamines for Systemic Use
ATC Code: R06AB04

Phenylephrine Hydrochloride: Nasal Decongestants for Systemic Use
ATC Code: R01BA53

Chlorphenamine maleate:

Pharmacodynamics:

Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedma and wheal in hypersneitivity reactions such as allergy and anaphylaxis.

Phenylephrine Hydrochloride:

Pharmacodynamics:

Phenylephrine is a post-synaptic α-receptor agonist, with low cardioselective β-receptor affinity. It is has a recognised decongestant activity, by vasoconstriction to reduce oedema of the nasal mucosa .No additional pharmacodynamic studies have been presented

5.2 Pharmacokinetic properties

Chlorphenamine maleate:

Pharmacokinetics:

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Phenylephrine Hydrochloride:

Pharmacokinetics:

Phenylephrine has low bioavailability (~38%) from the gastrointestinal tract owing to variable absorption and first-pass metabolism. There is significant biotransformation in the intestinal wall. However, phenylephrine is active as a decongestant by the oral route, the drug distributes

through the systemic circulation to the vascular bed of the nasal mucosa.

5.3 Pre-clinical Safety:

None known.

6. PHARMACEUTICAL PARTICULARS

6.1 List ofexcipients

Magnesium Stearate	BP
Purified Talc	BP

6.2 Incompatibilities Nil

6.3 Shelflife

36 months from the date of manufacturing

6.4 Special precautions forstorage

Store below 30°C.Protect from light and moisture.

6.5 Natureandcontentsofcontainer<andspecialequipmentforuse,administrationor implantation>

10 x 10 Capsule in Alu - PVC Blister packed in a primary carton along with Pack insert.

6.6 Special precautions for disposal <and otherhandling>

No special requirements

7. <APPLICANT/MANUFACTURER>

UGOLAB PRODUCTIONS NIG. LTD. 31-A, Burma Road, Kano, Kano State, Nigeria.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Treasury Book No. 6

000036185

TREASURY RECEIPT

Station Lagos Dep

Date 26-04-2021

HEAD NAFDAC

Sub-Head

RRR No 2204-7865-9381

Received from YOLABS PRODUCTIONS NIG LTD

the sum of two million four thousand five hundred Naira

kobo being (description of payment)*

Oversea Cup Registration

Brussels Laboratories Pvt Ltd 33 charges for

and estate Sarkej Bavla Road Changodar

382210 Ahmedabad

gujarat India

*If space is insufficient further particulars must be inserted on back of Receipt

ORIGINAL

Name of Accounting Officer

Signature of Accounting Officer

Signature or Mark of Payer

Witness of Mark

NIGERIA 2000 YEARS OF NIG. ARTS N50 NIPOST 2010©

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL
NAFDAC

Receipt

#	N000026291	
Company Name	UGOLAB PRODUCTIONS NIGERIA LIMITED	
Application Number	RNW-PP-109702	
Product Name	ALKOLD CAPSULE	
Remita Reference Number	120362793622	
Pack Size	10*10pack Miligram (mg)	
Payment Type	Renewal	Late Renewal
Amount	850,500.00	135,000.00
Payment Date	12/24/2019	

Total Amount: **N985,500.00**

NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL
ACCOUNT OFFICE
RECEIVED
Sign.....

QTY 600

75X55X72 MM AUTO LOCK 1

10 x 10 CAPSULES

ALKOLD

Chlorpheniramine Maleate & Phenylephrine Hcl Capsules

10 x 10 CAPSULES

ALKOLD

Chlorpheniramine Maleate & Phenylephrine Hcl Capsules

ALKOLD

Each hard gelatin capsule contains :

Chlorpheniramine maleate B.P	4 mg.
Phenylephrine Hydrochloride B.P.	2.5 mg.
Excipients	q.s.

Approved colours used in empty hard gelatin capsule shell.

Dosage:
Adult: 1 capsule 3-4 times daily or as directed by Physician.
not for Children under 12 years.
Indications: for nasal and bronchial congestion.
Cold and flu symptoms etc.

Store below 30°C.
Protect from light and moisture.
Keep out of reach of Children.

Mfg. in India By: Brussels Laboratories Pvt.Ltd. 33,Changodar Industrial Estate,Sarkhej-Bavla Road,Changodar,Ahmedabad,Gujarat,India.

MANUFACTURED IN INDIA

10 x 10 CAPSULES

ALKOLD

Chlorpheniramine Maleate & Phenylephrine Hcl Capsules

NAFDAC Reg. No. : **B4-2113**

Mfg. Lic. No. : G/1369

Batch No. ;

Mfg. Date :

Exp. Date. :

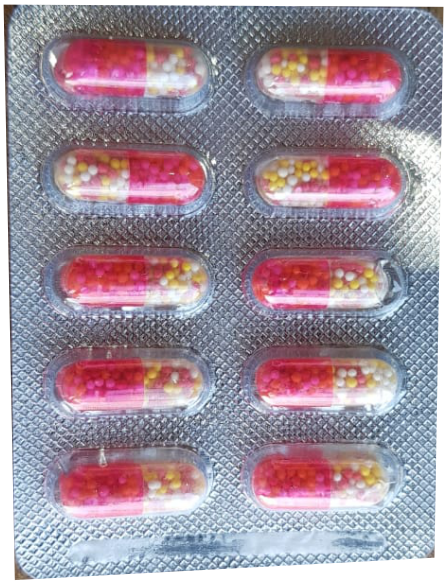
Manufactured For :
UGOLAB PRODUCTION NIG. LTD.
31-A, Burma Road, Sabon-Gari Kano,
Kano State, Nigeria.

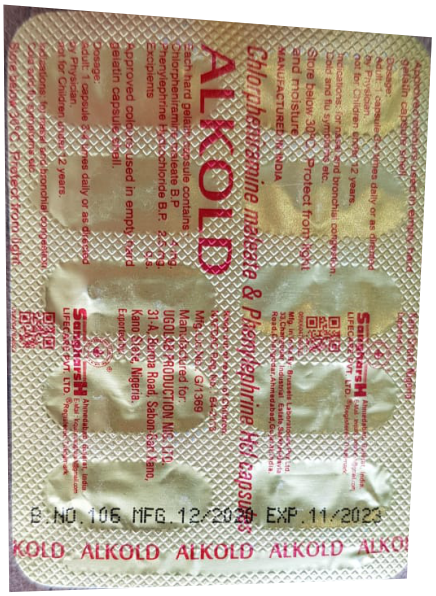
Exported by:

Sanghars H
LIFECARE PVT. LTD.
Ahmedabad, Gujarat, India.
E-Mail : Inquiry.sangharsh@gmail.com
® Registered Trademark

18906047650620

FOIL SIZE : 148MM
REPEAT : 35.33 MM
PACK SIZE : 53X70 MM
2+3+63+4+4+4+63+3+2=148 MM





95 X 260 MM

95 X 260 MM

Chlorpheniramine Maleate & Phenylephrine Hcl Capsules

ALKOLD

COMPOSITION
Each hard gelatin capsule contains:
Chlorpheniramine maleate B.P. 4 mg
Phenylepherine Hydrochloride B.P. 2.5mg

DOSAGE FORM
Oral Capsule

THERAPEUTIC CLASS
Antihistaminic and Nasal decongestant drug combination

PHARMACOLOGY
Chlorpheniramine Maleate is a phenothiazine derivative with properties of prolonged antihistamine action. It also has some anticholinergic, antiserotoninergic and marked local anaesthetic properties. Chlorpheniramine maleate diminishes the main actions of histamine in the body, probably by occupying the receptor sites in the effector cells to the exclusion of histamine, but does not prevent the production of histamine.
Chlorpheniramine Maleate is a H1-receptor antagonist and thereby mediates the contraction of smooth muscle and the dilation and increased permeability of the capillaries.
Phenylepherine Hydrochloride is a sympatho mimetic decongestant.

Pharmacokinetics
Chlorpheniramine maleate is well absorbed after oral dosing with extensive first-pass effect. It is highly bound to plasma proteins. It is slowly excreted via urine and bile. It is distributed widely in the body. It enters the brain and crosses the placenta. Antihistamines pass into the milk at low concentrations
Phenylepherine hydrochloride is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver; orally administered phenylepehrine has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

Dosage:
Adult: 1 capsule 3-4 times daily or as directed by Physician.
not for Children under 12 years.

Indications: for nasal and bronchial congestion. Cold and flu symptoms etc.

CONTRAINDICATIONS
Alkold is contra-indicated in individuals with known hypersensitivity to the product or any of its components. It is contra-indicated in patients with hypertension, acute ischemic heart disease, thyrotoxicosis, glaucoma or urinary retention. This drug is also contra-indicated in patients who are taking, or have taken, monoamine oxidase inhibitors within the preceding two weeks. The concomitant use of a phenylephrine and this type of product may occasionally cause a rise in blood pressure. The antibacterial agent Furazolidone is known to cause a dose-related inhibition of monoamine oxidase. Although there are no reports of hypertensive crises caused by the concurrent administration of ALKOLD and furazolidone, they should not be taken together.
Use in patients who are currently receiving other sympathomimetic drugs.
Do not exceed the stated dose

SIDE EFFECTS/ADVERSE REACTION
ALKOLD may cause drowsiness and impair performance in tests of auditory vigilance. Patients should be cautioned about engaging in activities requiring mental alertness, such as driving a car or operating machinery, until they have established their own response to the drug.
It is recommended that patients are advised not to undertake tasks requiring mental alertness whilst under the influence of alcohol or other CNS depressants. Concomitant administration of ALKOLD may, in some patients, produce additional impairment.
This product may act as a cerebral stimulant in children and occasionally adults giving rise to insomnia, nervousness, hyperpyrexia, tremors and epileptic convulsions. Care should be taken when used in epileptic patients.
Skin rashes, with or without irritation, tachycardia, dryness of mouth, nose and throat, and headache have occasionally been reported.
Urinary retention has been reported occasionally in men receiving phenylepherine ; prostatic enlargement could have been an important predisposing factor.

OVERDOSAGE AND TREATMENT
The treatment of over dosage is likely to be symptomatic and supportive. Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed up to 3 hours after ingestion if indicated.
Catheterisation of the bladder may be necessary. If desired, the elimination of phenylepherine can be accelerated by acid diuresis or by dialysis.

STORAGE
Store below 30°C. Protect from light and moisture.
Keep out of reach of Children.

PRESENTATION
Available in a blister pack of 10capsules.

Manufactured for
UGOLAB PRODUCTIONS NIGERIA LIMITED
Plot 157/159 Club Road,
Bompai industrial layout, Kano.
Nigeria.

NAFDAC Reg. No. : **B4-2113**
Mfg.Lic.No.: G/1369

Exported by:
SanghasH
LIFECARE PVT. LTD.
Ahmedabad, Gujarat, India.
E-Mail : Inquiry.sangharsh@gmail.com
® Registered Trademark

Mfg. in India By: Brussels Laboratories Pvt.Ltd. 33,Changodar Industrial Estate,Sarkhej-Bavla Road,Changodar,Ahmedabad,Gujarat,India.
MANUFACTURED IN INDIA

08906047650623

FEDERAL REPUBLIC OF NIGERIA
NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL
(NAFDAC)
(NARCOTICS AND CONTROLLED SUBSTANCES DIRECTORATE)
LAGOS

P.M.B 1016
e-mail:-ncs@nafdac.gov.ng

Ref. No. 2021000212
Date: 1ST JANUARY, 2021

Permit For Importation

(Psychotropic drugs, and other controlled substances)

In exercise of the powers conferred under the provisions of Section 5 (k), of Decree No. 15 1993, the National Agency for Food and Drug Administration and Control (NAFDAC) hereby authorises the Superintendent Pharmacist

OGBUJI EUGENE UGONNA (SUPERINTENDENT PHARMACIST)

of UGOLAB PRODUCTIONS (NIG.) LIMITED, 157/159 CLUB ROAD, BOMPAI INDUSTRIAL LAYOUT, KANO STATE

to Import into Nigeria from:

(i) Name of Address of Manufacturer BRUSSELS LABORATORIES PVT LIMITED 33, CHANGODAR INDUSTRIAL ESTATE, SARKHEJ BAVLA ROAD, CHANGODAR-382210, AHMEDABAD, GUJARAT, INDIA

(ii) Name and Address of Exporter or Forwarding Agent SANGHARSH LIFECARE PVT LIMITED A-502, SOLITAIRE CORPORATE PARK, NR DIVYA BHASKAR HOUSE, S.G HIGHWAY, MAKARBA, AHMEDABAD, GUJARAT, INDIA

the following controlled drugs:

Name	Quantity
PHENYLEPHRINE HCL 2.5mg (ALKOLD CAPSULES)	90,000x10x10x10x2.5mg =225kg

Date of Issue 1ST JANUARY, 2021
Valid till the end of the year

Signature .....
Name: MUSA UMAR
NAFDAC
For: Director General

This permit does not authorise the importer to clear the preparations from the Nigerian Ports without first obtaining a permit to clear from the Narcotics and Controlled Substances Directorate, National Agency for Food and Drug Administration and Control, Lagos.