Summary Product Characteristics

1. Name of the proprietary product: GONEKOLD

Name of the nonproprietary International Product: Chlorpheniramine Maleate and Phenylephrine HCl Capsule

Route of Administration: Oral

2. Qualitative and Quantitative composition:

Each Hard Gelatin Capsules contains.
Chlorpheniramine Maleate…….4 mg
Phenylephrine HCl……..……2.5 mg
Excipient …….. Q.S.

3. Pharmaceutical Form: Hard Gelatin Capsule.

4. Clinical Particulars:

4.1 Therapeutic Indications:
GONEKOLD is indicated for patients having problems related to nasal congestion, allergic condition such as perennial and seasonal allergic rhinitis, urticaria, contact dermatitis, pruritis, insect bite, drug rashes, menieres disease and motion sickness.

4.2 Posology and method of administration:
Adult: 1 to 3 capsules/ day in divided dosages.
This drug is not suitable for children below 12 years of age.

4.3 Contraindications
Phenylephrine HCl: Severe coronary heart disease and cardiovascular disorders, Hyperthyroidism. Contraindicated in patients with monoamine oxidase inhibitors.
Chlorpheniramine: Adverse effects caused by concomitant use with phenytoin, but drug interactions are rare. The most serious problem is the possible potentiation of the effects of alcohol.

4.4 Special warnings and precautions for use
Patients should be warned of possible adverse effects when driving and machine operation and the dangers of taking alcohol with antihistamines. It has to be used with caution on pregnant and breast feeding women.

4.5 Interaction with other medicinal products and other forms of interaction:
The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring.
To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval.
Some products that may interact with this drug include: antihistamines applied to the skin (such as diphenhydramine cream, ointment, spray), blood pressure medications (especially reserpine, guanethidine, methyldopa, beta blockers such as atenolol, or calcium channel blockers such as nifedipine).
Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction.
Avoid taking MAO inhibitors (isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and narcotic pain relievers (such as codeine). Check the labels on all your medicines (such as cough-and-cold products, diet aids) because they may contain ingredients that could affect your blood pressure or cause drowsiness. Ask your pharmacist about using those products safely.
This medication may interfere with certain medical/laboratory tests (including brain scan for Parkinson's disease), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

4.6 Pregnancy and Lactation:
It has to be used with caution on pregnant and breast feeding women.
During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.
This medication may pass into breast milk and the effect on a nursing infant is unknown. Consult your doctor before breast-feeding.

4.7 Effects on the ability to drive and use machines
This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely.

4.8 Undesirable effects:
Phenylephrine HCl may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin and Chlorpheniramine adverse effects may include hypotension, muscular weakness, incoordinatior, euphoria, visual disturbances, tremor, agitation, insomnia, palpitations, bronchoconstriction, facial swelling and intestinal disturbance.

4.9 Overdose
Severe overdose may produce hypertension and associated reflex bradycardia. The hypertensive effect may be treated with an alpha- receptor blocking agent (such as phentolamine mesylate 6-10 mg) and the bradycardia treated with atropine. Treatment of large oral dose should include gastric lavage followed by activated charcoal. In the event of CNS excitement or convulsions, edation and anticonvulsant treatment should be with diazepam.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Nasal decongestant, Anti histamine.

ATC code:
ATC code: Chlorpheniramine Maleate: R06AB04, Phenylephrine HCl: R01AA04

Mechanism of Action:
Mechanism of action
Phenylephrine act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the

mucous membrane lining the nasal and sinus passages. Chlorpheniramine is an antihistamine agent and produce effect by H1 receptor hence opposes action of histamine.

5.2 Pharmacokinetic properties

Chlorpheniramine Maleate :

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 HCl :

Absorption: Completely absorbed after oral administration. It has a reduced bioavailability (compared to pseudoephedrine) following oral administration due to significant first-pass metabolism in the intestinal wall. Compared to IV administration, bioavailability is approximately 38%. Peak serum concentrations are achieved approximately 0.75-2 hours following oral administration. Phenylephrine should be administered parenterally to achieve cardiovascular effects. Occasionally, systemic effects are observed following oral inhalation.

Protein binding: 95% binding-plasma proteins.

Metabolism: Undergoes extensive first-pass metabolism in the intestinal wall and extensive metabolism in the liver. Sulfate conjugation, primarily in the intestinal wall, and oxidative metabolism by monoamine oxidase (MAO) represent the principle routes of metabolism. Glucuronidation occurs to a lesser extent. Phenylephrine and its metabolites are mainly excreted in urine.

5.3 Pre-clinical Safety:

Chlorpheniramine Maleate:

The antihistaminic potency of Chlorpheniramine is confined mainly to its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)-isomer. The toxicity may therefore be non-specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic ^antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer.

The experimental data on the carcinogenicity and mutagenicity of Chlorpheniramine indicate lack of these adverse effects, but the racemate and the (+)-isomer have shown some embryotoxicity in fertility tests.

Effective antihistaminic concentrations of Chlorpheniramine in vitro are about 1-10pg/L and oral doses of 0.2-1 mg/kg antagonise histamine-induced bronchospasm in guinea pigs.

Phenylephrine Hydrochloride:

Phenylephrine has been used to induce cardiac myocyte hypertrophy in cultures of rat neonatal myocyte at doses of 100 μM and 10 μM. To the best of our knowledge there have been no human studies associating therapeutic phenylephrine use with the development of cardiac myocyte hypertrophy. The use of phenylephrine has been well-established for many years. No unexpected adverse safety issues were identified during the development.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Empty Hard Gelatin Capsule Pink/ Clear Transparent Size 2	In-house

6.2 Incompatibilities: Nil

6.3 Shelf life: 36 months

6.4 Special Precautions for storage:
Store at a temperature below 30ºC. Protect from light.

6.5 Nature and contents of container:
Alu- PVC blister of 10 capsules each, such 10 blisters are packed in a primary carton along with pack insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder: M/S. UGOLAB PRODUCTION (NIG) LTD
157/159 CLUB ROAD, BOMPAI INDUSTRIAL LAYOUT KANO STATE, NIGERIA

8. Marketing Authorization Number: --

9. Date of first Authorization /renewal of the authorization: Not Applicable

10. Date of Revision of text: July 2022