1. NAME OF THE MEDICINAL PRODUCT
Asylin Drop

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml of the drop contains:

- Pseudoephedrine Hydrochloride: 9.38 mg
- Chlorphenamine Maleate: 1 mg
- Dextromethorphan Hydrobromide: 3.12 mg

Excipients with known effects: [List here if applicable]

3. PHARMACEUTICAL FORM
Oral Drop.
A clear or slightly colored liquid presented in a 15 ml amber glass bottle with a dropper.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Asylin Drop is indicated for the relief of nasal congestion, runny nose, sneezing, cough, and related symptoms in upper respiratory tract infections, common colds, and allergic conditions.

4.2 Posology and Method of Administration
- Infants (3 months–12 months): 0.25 ml 2–3 times daily.
- Children (1–2 years): 0.5 ml 2–3 times daily.
- Administer orally using the dropper provided. Shake well before use.

Note: Dosage may be adjusted as directed by a healthcare professional.

4.3 Contraindications
- Hypersensitivity to pseudoephedrine, chlorphenamine, dextromethorphan, or any excipients.
- Severe hypertension or coronary artery disease.
- Patients on monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.
- Cough associated with asthma or excessive mucus.

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with glaucoma, urinary retention, prostatic hypertrophy, or severe renal or hepatic impairment.
- Not recommended for use in children under 3 months of age.
- Monitor for sedation or drowsiness due to chlorphenamine.
- Avoid use with other products containing pseudoephedrine or dextromethorphan.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Avoid concomitant use with MAOIs, tricyclic antidepressants, or other CNS depressants.
- Alcohol may enhance sedative effects of chlorphenamine.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Use only if clearly needed, as safety in pregnancy is not fully established.
- Lactation: Use with caution as the components may be excreted in breast milk.

4.7 Effects on Ability to Drive and Use Machines
May cause drowsiness. Patients should be cautioned about driving or operating machinery.

4.8 Undesirable Effects
- Common: Drowsiness, dry mouth, dizziness, gastrointestinal discomfort.
- Rare: Palpitations, urinary retention, or hypersensitivity reactions.

Note: Report adverse effects to the appropriate regulatory authority.

4.9 Overdose
Symptoms may include restlessness, nausea, vomiting, tachycardia, or CNS depression. Treat symptomatically with supportive care and contact a poison control center.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
- Pseudoephedrine Hydrochloride: Sympathomimetic decongestant that relieves nasal congestion by vasoconstriction.
- Chlorphenamine Maleate: H1 receptor antagonist with antihistaminic and anticholinergic properties.
- Dextromethorphan Hydrobromide: Cough suppressant that acts on the cough center in the medulla.

5.2 Pharmacokinetic Properties
- Absorption: Rapidly absorbed from the gastrointestinal tract.
- Metabolism: Primarily metabolized in the liver.
- Excretion: Excreted in urine.

5.3 Preclinical Safety Data
Preclinical studies show no significant risks for humans at therapeutic doses.

6. PHARMACEUTICAL PARTICULARS
6.1 List of Excipients
- Methyl
- Propyl
- Citric acid
- Sugar
- CMC
- Carmosin red
- Raspberry flavor

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
2 years from the date of manufacture.

6.4 Special Precautions for Storage
Store below 30°C. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and Contents of Container
1 bottle per packet

6.6 Special Precautions for Disposal
Dispose of unused product in accordance with local regulations.

7. MARKETING AUTHORISATION HOLDER
AC Drugs Limited
Plot C5/C6, Old Airport Road, Emene, Enugu State, Nigeria.

8. MARKETING AUTHORISATION NUMBER(S)
To be assigned by the regulatory authority.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
To be assigned by the regulatory authority.

10. DATE OF REVISION OF THE TEXT
[Insert date of latest revision]