SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

FENCLOR ® SYRUP

Strength

Each 5 ml contains:

Chlorpheniramine maleate BP…….2mg

Pharmaceutical/Dosage form

Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Chlorpheniramine maleate BP…….2mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

Clear yellow coloured syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fenclor Syrup is indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions, insect bites.

4.2 Posology and method of administration

Oral administration only

Do not exceed the stated dose or frequency of dosing

The minimum interval between the doses should be 4 hours.

Do not use continuously for more than two weeks without consulting a doctor.

Children:

6 - 12 years: one to two teaspoonful (5-10ml) 3-4 times daily.

1 - 5 years: half to one teaspoonful (2.5ml-5ml) 3 times daily.

Up to1 years: half to one teaspoonful (2.5ml) 2 times daily.

Adult (above 12 years): Two teaspoonful (10ml) 3-4 times daily.

Not recommended for children below 1 year

Populations

Patients with renal or hepatic impairment should seek doctor's advice prior to taking this medicine. (See Section 4.4 Special warnings and precautions for use).

4.3 Contraindications

Fenclor Syrup is contra-indicated in patients who are hypersensitive to antihistamines or to any of the syrup ingredients.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). **Fenclor Syrup** is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

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4.4 Special warnings and precautions for use

Chlorpheniramine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. Increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

The effects of alcohol may be increased and therefore concurrent use should be avoided.

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Fenclor syrup contains ethanol (alcohol), this should be taken into consideration as it is harmful for those suffering from alcoholism. To be taken into account in pregnant and breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Methyl, ethyl and propyl hydroxybenzoates (E218, E214 and E216) may cause allergic reactions (possibly delayed).

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects, concurrent use of alcohol may have a similar effect therefore medical advice should be sought before taking chlorpheniramine concurrently with these medicines.
Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
The anticholinergic effects of chlorpheniramine are intensified by MAOIs (see Contra-indications).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of chlorpheniramine 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

Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor **impairment**, which can seriously hamper the patients' ability to drive and use machinery.

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1000 to <1/100), rare (>1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse reactions identified during post-marketing use with chlorpheniramine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

System Organ Class	Adverse Reaction	Frequency
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness headache	Common
Eye disorders	Blurred Vision	Common
Gastrointestinal disorders	Nausea, dry mouth	Common
	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
Immune system disorders:	Allergic reaction, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown
Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrythmias	Unknown
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown

*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (eg

increased energy, restlessness, nervousness)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

Symptoms and signs

The estimated lethal dose of chlorpheniramine 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

Management should be as clinically indicated or as recommended by the national poisons centres where available. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorpheniramine is a potent antihistamine (H_1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H_1-receptor sites on tissues. Chlorpheniramine 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 chlorpheniramine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties

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

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

5.3 Preclinical safety data

No additional data of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

S. No	Composition	Reference
1.	Sucrose	BP
2.	Liquid Glucose	BP
3.	Methyl Paraben	BP
4.	Propyl Paraben	BP
5.	Glycerin	BP
6.	Ethanol 96%	BP
7.	Tartrazine Yellow	IHS
8.	Peppermint Oil	BP
9.	Purified Water	BP

6.2 Incompatibilities

None known.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store below 30°C. Protect from light

6.5 Nature and contents of container

Amber PET bottle with ROPP cap containing 60ml of Fenclor Syrup

Pack Size: 60ml

6.6 Special precautions for disposal and other handling

None.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

A11-0710

10. DATE OF REVISION OF THE TEXT

20/12/2028