SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

EXIPLON® EXPECTORANT

Strength

Each 5ml contains:

Diphenhydramine Hydrochloride BP…… 14mg
Sodium Citrate BP…..... 57mg
Ammonium Chloride BP……..135mg
Menthol BP……1.1mg

Pharmaceutical/Dosage form
Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Diphenhydramine Hydrochloride BP……14mg
Sodium Citrate BP…..... ……. 57mg
Ammonium Chloride BP……..135mg
Menthol BP……..1.1mg

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup.

A clear red syrup

4. Clinical particulars

4.1 Therapeutic indications

Exiplon Expectorant is indicated for the relief of coughs and nasal congestion.

4.2 Posology and method ofadministration

Posology

Children (2 – 5years): 2.5ml three times daily.

Children (6 – 12years): 5ml three times daily.

Adult: 10ml three times daily.

Method of administration
For oral use

4.3 Contraindications

Exiplon Expectorant is contraindicated in patients with hypersensitivity to any active ingredients.

4.4 Special warnings and precautions for use

Exiplon Expectorant may cause drowsiness. If affected do not drive or operate machinery.
Avoid alcoholic drink during the course of treatment with Exiplon Expectorant.

4.5 Interaction with other medicinal products and other forms of interaction

This product contains diphenhydramine and therefore may potentiate the effects of alcohol, codeine, antihistamines and other CNS depressants.

As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (eg, some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (eg, colic), urinary retention and headache.

4.6 Pregnancy and Lactation

Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. Exiplon Expectorant should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

4.7 Effects on ability to drive and use machines

Exiplon Expectorant may cause drowsiness. If affected, the patient should not drive or operate machinery

4.8 Undesirable effects

Side effects associated with the use of Exiplon Expectorant are uncommon.

Diphenhydramine may cause drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremors, convulsions or parasthesia.

Hypersensitivity reactions have been reported to have skin rashes, erythema, urticaria and angiodema.

4.9 Overdose

The symptoms and signs of the Exiplon Expectorant overdose may include drowsiness, hyperpyrexia and anticholinergic effects. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe antichlolinergic symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.2 Pharmacokinetic properties

Absorption

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached between 2 and 2.5 hours.

Distribution

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

Metabolism and Elimination

Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

The Elderly

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

5.3 Preclinical safety data

Mutagenicity

The results of a range of tests suggest that neither diphenhydramine nor menthol have mutagenic potential.

Carcinogenicity

There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

Teratogenicity

The results of several studies suggest that the administration of either diphenhydramine or menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility

There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

6. PHARMACEUTICAL PARTICULARS

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place below 30ºC.
Keep all medicines away from the reach of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

100ml amber PET bottles with tamper evident ROPP cap.

6.6 Special precautions for disposal <and other handling>

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

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

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
Ogun State, Nigeria.
Tel: +234 8097421000
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9. NAFDAC REGISTRATION NUMBER(S)

04-4252

10. DATE OF REVISION OF THE TEXT

28/03/2026