1. NAME OF THE MEDICINAL PRODUCT

Expelyn Syrup (Raspberry Flavour)

Strength:

Chlorpheniramine Maleate 2.2mg, Ammonium Chloride 110mg, Sodium Citrate 40mg and Menthol 1.1mg per 5 ml

Pharmaceutical Form:

Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration

Chlorpheniramine Maleate BP, Ammonium Chloride BP, Sodium Citrate BP,and

Menthol BP

Quantitative Declaration

Each 5ml contains:

- Chlorpheniramine Maleate 2.2mg
- Ammonium Chloride 110mg
- Sodium Citrate 40mg
- Menthol 1.1mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

A pink syrupy liquid with a sweet taste and pleasant aroma of raspberry and a burning sensation with pH of 4.0 to 6.0

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Expelyn Syrup (Raspberry Flavour) is indicated for relief of bronchial congestion, colds and allergic bronchial congestion.

4.2 Posology and Method of Administration

Posology

As directed by the Physician OR Use six hourly as below:-

- 0 – 1 year: 2.5mls every 6 hours
- 1 – 5 years: 5mls every 6 hours
- 5 – 12 years: 7.5mls every 6 hours
- Adults: 10mls every 6 hours

Method of Administration

Oral Administration

4.3 Contraindications

Expelyn Syrup (Raspberry Flavour) is contraindicated in:

- Patients who exhibit hypersensitivity to any of the components of the formula.
- Pregnant and breastfeeding mothers in high doses.
- Patients with metabolic or respiratory alkalosis.

4.4 Special Warnings and Precautions for Use

Special warnings

Expelyn Syrup (Raspberry Flavour) should be given with extreme caution to patients with heart failure, oedema, renal impairment, hypertension and eclampsia.

Do not take Expelyn Syrup (Raspberry Flavour) and drive a car or operate machinery because it can cause drowsiness and dizziness.

Precautions

If symptoms persist, medical advice should be sought.

Keep the medicine out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Expelyn Syrup (Raspberry Flavour) may lead to enhanced sedation with other CNS depressant. It is incompatible with Calcium Chloride, Phenobarbitone and Kanamycin.

Alcoholic drinks and certain other central nervous system depressants such as anxiolytics or hypnotics can potentiate the sedative effects of Chlorpheniramine Maleate.

4.6 Pregnancy and lactation

Pregnancy

Use of Chlorpheniramine Maleate during the third trimester may result in reactions in the unborn child. It should not be used during pregnancy unless considered essential by a physician.

Lactation

Antihistamines including Chlorpheniramine Maleate may be secreted in the breast milk. It should not be used unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

Expelyn Syrup (Raspberry Flavour) has influence on the ability to drive and use machines because it can cause drowsiness or dizziness.

4.8 Undesirable effects

Expelyn Syrup (Raspberry Flavour) can cause drowsiness, dizziness, vomiting or diarrhea.

Reporting of suspected adverse reactions

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

4.9 Overdose

Chlorpheniramine Overdose

Signs and Symptoms

A Chlorpheniramine overdose may cause the following symptoms: Dry mouth, eyes, nose, and throat, a rapid heart rate, nausea and vomiting, agitation, rapid breathing, drowsiness, dilated pupils, flushing, fever, slowing of the digestive tract, low blood pressure, an irregular heart rhythm, confusion, hallucinations, delirium, psychosis, seizures, coma, loss of life.

Treatment

If the overdose was recent, a healthcare provider may give certain medicines or place a tube into the stomach to "pump the stomach." It is not usually recommended to induce vomiting for a chlorpheniramine overdose. Treatment may also involve supportive care, which consists of treating the symptoms that occur as a result of the overdose. For example, supportive treatment options may include:

- Fluids through an intravenous line (IV)
- Medicines to increase blood pressure, control an irregular heart rhythm, or control seizures
- Close monitoring of the heart and lungs
- A breathing tube to help with breathing
- Other treatments based on complications that occur.

Ammonium Chloride Overdose

Signs and Symptoms

Overdosage of Ammonium Chloride has resulted in a serious degree of metabolic acidosis, disorientation, confusion and coma.

Treatment

Should metabolic acidosis occur following overdosage, the administration of an alkalinizing solution such as sodium bicarbonate or sodium lactate will serve to correct the acidosis.

Sodium Citrate Overdose

Signs and Symptoms

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

Treatment

If overdose occurs the patient should be monitored for evidence of toxicity and standard symptomatic and supportive treatment applied as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antitussive and expectorant combination

ATC Code: R06AA02

Mechanism of Action

Chlorpheniramine Maleate

It has weak antimuscarmic and moderate anti-serotonin and local anesthetic actions. Also it can cause CNS (Central Nervous System) stimulation or depression. These actions provide temporary relief of runny nose, sneezing and watery and itchy eyes.

Ammonium Chloride

It tends to lower the blood pH after being metabolized to urea and hydrochloric acid which provides hydrogen ions to acidify the blood or urine.

Sodium Citrate

It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

Pharmacodynamic Effects

Chlorpheniramine Maleate

Chlorpheniramine Maleate is a potent antihistamine (H_1- antagonist). It antagonizes various histamine-induced effects such as increased capillary permeability and dilation, formation of edema and the constriction of gastrointestinal and respiratory smooth muscle.

Ammonium Chloride

Ammonium chloride has irritant effect on mucous membrane and is considered to have expectorant properties.

Sodium Citrate

The effect of sodium citrate is that it renders the urine to become less acidic. It is an antitussive and mucolytic agent that breaks down the mucus so that coughing up phlegm becomes easier. It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

5.2 Pharmacokinetic Properties

Chlorpheniramine Maleate

i. Absorption

After oral administration, the absorption of chlorpheniramine maleate occurs. This is whereby plasma concentrations take place peak at about 2.5 to 6 hours. Then it is absorbed by the gastrointestinal tract.

The effects that may develop within 30 minutes are maximal within 1 to 2 hours and lasts 4 to 6 hours.

ii. Distribution

It is distributed in the body and taken to the CNS.

iii. Metabolism

It undergoes the first pass of metabolism and enterohepatic recycling. It is extensively metabolized, principally to inactive desmethylated metabolites which are excreted primarily in the urine.

iv. Excretion

Chlorpheniramine maleate is excreted in the urine and faeces. The mean elimination half-life has been reported to be about 30 hours with mean values ranging from 2 to 43 hours.

Ammonium Chloride

i. Absorption

Ammonium chloride is also absorbed by the gastrointestinal tract. Following oral administration, it is rapidly absorbed from the gastrointestinal tract whereby complete absorption occurs within 3 to 6 hours.

ii. Metabolism

In a test carried out on healthy male and female volunteers, they were orally administered with ammonium chloride. They produced transient increase in blood pH. Those who suffered from cirrhosis showed a greater and more prolonged increase over a higher baseline. This means that their livers metabolized ammonium chloride to from urea and hydrochloric acid.

iii. Excretion

Ammonium chloride is excreted by the kidneys in form of urine.

Sodium Citrate

i. Absorption and Excretion

Sodium citrate is absorbed and renally eliminated causing metabolic alkalosis and urinary alkalization in sufficient doses.

Menthol

i. Metabolism and Elimination

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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Colour Amaranth Powder
- Raspberry Flavour Liquid
- Glycerine
- Sodium Methyl Parabenzoate,
- Sodium Propyl Parabenzoate
- Citric Acid
- Rectified Spirit
- Sugar Syrup
- Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special Precautions for Storage

Store in a dry place below 30^0C.

Protect from light.

6.5 Nature and Contents of Container

Primary packaging: Amber coloured PET bottles.

Secondary packaging: Chipboard unit cartons.

Pack size(s); 100ml

6.6 Special Precautions for Disposal of a Used Medicinal Product or Waste Materials derived from such Medicinal Product and Other Handling of the Product

- Do not throw away any medicines you no longer use.
- Ask your pharmacist or medical facility how to properly dispose of any medicine you no longer use. These measures will help protect the environment.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Name: **ASPEN PHARMACARE NIGERIA LIMITED**

Address: **Plot 28, Infinity House, Ilupeju Bypass**

Country: **Nigeria**

Telephone: **+234 90 624 96814**

E-Mail: **info@aspennigeria.com**

8. DRUG PRODUCT MANUFACTURER

Name: **BETA HEALTHCARE INTERNATIONAL LTD**

Address: **Plot No. Nairobi/Block59/135, Mogadishu Road, Industrial Area, Nairobi**

P.O. BOX 42569-00100 Nairobi, Kenya

Country: **KENYA**

Telephone: **+254-20-2652042/89**

E-Mail: **info@ke.aspenpharma.com**

9. MARKETING AUTHORIZATION NUMBER

NAFDAC REG No. B4-4850

10. DATE OF FIRST REGISTRATION/RENEWAL OF REGISTRATION

Date of First Registration: 30th April 2015

Date of Renewal of Registration: 23rd November 2027

11. DATE OF REVISION OF THE TEXT

October 2024