1. NAME OF THE MEDICINAL PRODUCT

FEDALIS EXPECTORANT

Strength: Each 5ml containsChlorpheniramine Maleate 2mg, Ammonium Chloride 87mg, Sodium Citrate 43mg and Menthol 2mg,ephedrine hydrochloride 6mg

Pharmaceutical Form: Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Chlorpheniramine Maleate BP 2mg

Ammonium Chloride BP 87mg,

Sodium Citrate BP 43mg and

Menthol BP 2mg

Ephedrine hydrochloride 6mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fedalis Expectorant 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

4.3Contraindications

Expelyn Syrup (Pineapple Flavour)is contraindicated with patients hypersensitive to any of the components of the formula.

Expelyn Syrup (Pineapple Flavour)is contraindicated to pregnant and breastfeeding mothers in high doses.

Expelyn Syrup (Pineapple Flavour)should not be given to patients with metabolic or respiratory alkalosis.

4.4 Special Warnings and Precautions for Use

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

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

Keep the medicine out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Expelyn Syrup (Pineapple 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 (Pineapple Flavour) with each 5ml containing Chlorpheniramine Maleate 2.2mg, Ammonium Chloride 110mg, Sodium Citrate 40mg and Menthol 1.1mghas influence on the ability to drive and use machines because it can cause drowsiness or dizziness.

4.8 Undesirable effects

Expelyn Syrup (Pineapple Flavour) can cause drowsiness, dizziness, vomiting or diarrhoea

4.9 Overdose

Chlorpheniramine Overdose

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

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.

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

Particulars of its 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 Pharmacological Properties

Pharmacotherapeutic group and ATC Code

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 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

Tartrazine Yellow Colour, Pineapple Flavour Liquid, Glycerine, Sodium Methyl Parabenzoate, Sodium Propyl Parabenzoate, Citric Acid, Rectified Spirit, Sugar Syrup and 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 and special equipment for use, administration or implantation

Fedalis expectorant is packed in 100ml amber coloured PET bottles that are sealed with 25mm ropp aluminium caps and labelled. Then the filled, sealed and labelled bottles are packed in unit cartons made of chipboard.

6.6 Special precautions for disposal and other handling

No special requirements

7. APPLICANT/MANUFACTURER

Name of Applicant/Address: Marketing
FECCOX PHARMACY AND GENERAL ENTERPRISES LTD,
JABA LAYOUT OFF AIRPORT RD KANO KANO