SUMMARY OF PRODUCT CHARACTERISITCS

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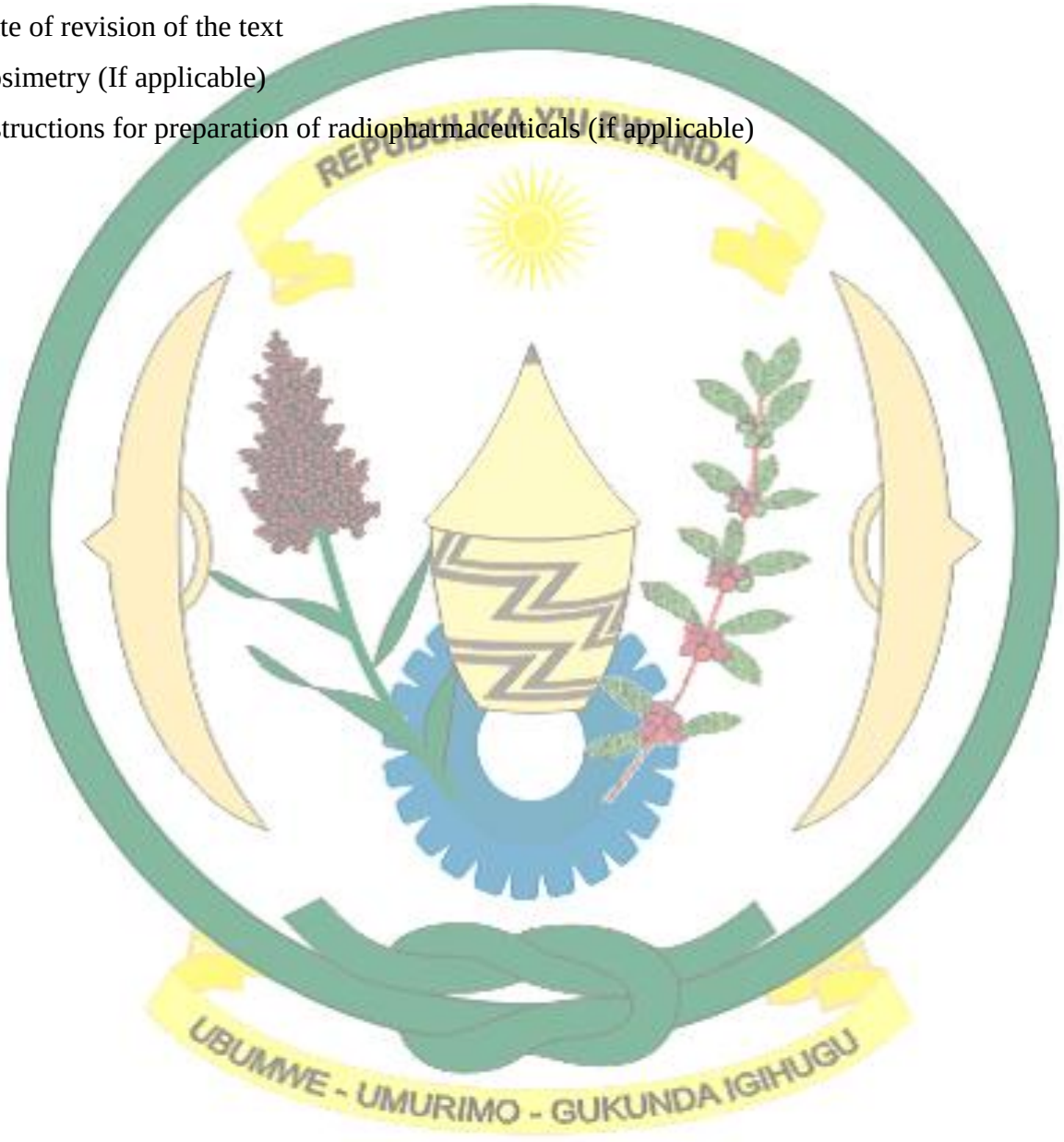

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Koflyn Raspberry Flavour Cough Expectorant

1.1 Strength

Each 5ml contains Chlorpheniramine Maleate 2.2mg, Ammonium Chloride 110mg and Sodium Citrate 40mg

1.2 Pharmaceutical Form

Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration

Chlorpheniramine Maleate, Ammonium Chloride and Sodium Citrate

2.2 Quantitative declaration

Each 5ml contains Chlorpheniramine Maleate 2.2mg, Ammonium Chloride 110mg and Sodium Citrate 40mg

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Koflyn Raspberry Flavour Cough 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

Specific Populations

Koflyn Raspberry Flavour Cough Expectorant is not indicated for specific populations especially elderly people

Paediatric Population

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

4.3 Method of Administration

Oral Administration

4.4 Contraindications

Koflyn Raspberry Flavour Cough Expectorant is contraindicated with patients hypersensitive to any of the components of the formula.

Koflyn Raspberry Flavour Cough Expectorant is contraindicated to pregnant and breastfeeding mothers in high doses.

Koflyn Raspberry Flavour Cough Expectorant should not be given to patients with metabolic or respiratory alkalosis.

4.5 Special Warnings and Precautions for Use

Koflyn Raspberry Flavour Cough Expectorant should be given with extreme caution to patients with heart failure, oedema, renal impairment, hypertension and eclampsia.

Do not take Koflyn Raspberry Flavour Cough and drive a car or operate machinery because it can cause drowsiness and dizziness.

Keep the medicine out of reach of children.

4.6 Paediatric Population

There are no specific special warnings and precautions for children under 3 years. However, if there are children who are hypersensitive or allergic to any of the components in the formula, they should avoid using Koflyn Raspberry Flavour Cough Expectorant.

4.7 Interaction with other medicinal products and other forms of interaction

Koflyn Raspberry Flavour Cough Expectorant 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.

4.8 Additional information on special populations

The contraindications, special warnings and precautions and interaction with other medicinal products of Koflyn Raspberry Flavour Cough Expectorant does not affect any special populations.

4.9 Paediatric Population

The interaction studies have only been performed in adults.

There are no known interaction studies that have been performed in children.

4.10 Fertility, 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.

4.11 Effects on ability to drive and use machines

It does affect the ability to drive and use machines because it can cause drowsiness or dizziness.

4.12 Undesirable effects

Can cause drowsiness, dizziness, vomiting or diarrhoea

4.13 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 for a Chlorpheniramine Overdose

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.

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

Treatment for Ammonium Chloride Overdose

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

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacological Properties

Pharmacotherapeutic group and ATC Code

Pharmacotherapeutic group: **Antitussive and expectorant combination**

ATC Code: **R06AA02**

Chlorpheniramine Maleate

Chlorpheniramine Maleate is a potent antihistamine (H1- 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.

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

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

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

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.

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.

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

Menthol, Colour Amaranth Powder, Raspberry Flavour Liquid, Glycerin, 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

Koflyn Raspberry Flavour Cough Expectorant is packed in 100ml amber coloured glass 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. Marketing Authorisation Holder & Manufacturing Site Addresses

Name: BETA HEALTHCARE INTERNATIONAL LTD

Address: Plot No. LR 209/6554, Mogadishu Road, Industrial Area, Nairobi

P.O. BOX 42569-00100 GPO Nairobi

Country: KENYA

Telephone: +25420530106/8

Telefax: +25420556198 / 2944

E-Mail: info@ke.betashelys.com

8. Marketing Authorisation Number

13241

9. Date of First Registration/Renewal of the Registration

Date of first authorisation: 22/11/2001

Date of latest renewal: Annual Retention

10. Date of revision of the text

May 2019

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals

Not Applicable