1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

EXICHEST 34 mg/36,33 mg per 10 ml syrup

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml syrup contains 34 mg ammonium chloride and 36,33 mg sorbimacrogol laurate 300.

Preservative: Sodium benzoate 0,12 % *w/v*

Contains sugar: Sucrose 6 g per 10 ml syrup

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

EXICHEST is a brown, clear syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

EXICHEST is indicated for the alleviation of cough.

4.2. Posology and method of administration

Posology

Adults:

One to two medicine measures (5 ml to 10 ml) three to six times a day.

Paediatric population

Children over three years old:

One medicine measure (5 ml) three to six times a day.

Children under three years of age:

The safety and efficacy of EXICHEST in children under 3 years of age has not yet been proven.

Method of administration

For oral administration.

EXICHEST should be kept in the mouth for a few minutes and it should not be taken together with food or beverages.

4.3. Contraindications

EXICHEST is contraindicated in:

- Patients with hypersensitivity to ammonium chloride, sorbimacrogol laurate 300 or to any excipients in EXICHEST (see section 6.1).
- Impaired hepatic function.
- Impaired renal function.

4.4. Special warnings and precautions for use

If symptoms persist consult your doctor.

Paediatric population

The safety and efficacy of EXICHEST in children under 3 years of age has not yet been proven.

Excipients

EXICHEST contains 6 g of sucrose per 10 ml dose. This should be taken into account in patients with diabetes mellitus.

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

4.5. Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Pregnancy

The safety of EXICHEST during pregnancy has not been established.

Breastfeeding

The safety of EXICHEST during lactation has not been established.

Fertility

No available data.

4.7. Effects on ability to drive and use machines

Since adverse reactions such as progressive drowsiness have been reported in patients receiving EXICHEST, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that EXICHEST does not adversely affect their ability to do so (see section 4.8).

4.8. Undesirable effects

Ammonium chloride

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Metabolism and nutrition disorders	Acidosis, hypokalaemia
Nervous system disorders	Headache, progressive drowsiness
Respiratory, thoracic and mediastinal disorders	Hyperventilation
Gastrointestinal disorders	Nausea, vomiting
General disorders and administrative site conditions	Thirst

Sorbimacrogol laurate 300

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Gastrointestinal disorders	Increased absorption of liquid paraffin and other fat-soluble substances

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

In overdose, side effects can be precipitated and/or be of increased severity.

Treatment

Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

4.1. Pharmacodynamic properties

Category and class: A 10.1 Antitussives and expectorants

Pharmacotherapeutic group: Other cough suppressants and expectorants

ATC code: R05FB02

Mechanism of action

Ammonium chloride and ammonium carbonate have an irritant effect on mucous membranes and are considered to have expectorant properties.

Polysorbates, such as sorbimacrogol laurate, are ethoxylated sorbitan ester non-ionic surfactants and are used in respiratory tract disorders for their surfactant properties.

5.2. Pharmacokinetic properties

Absorption

Ammonium salts are effectively absorbed from the gastrointestinal tract.

Distribution

The ammonium ion is converted into urea in the liver; the anion thus liberated into the bloodstream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine, this is followed by a transient diuresis.

5. PHARMACEUTICAL PARTICULARS

5.1. List of excipients

Aniseed flavour ID 28467, disodium edetate, Eurovit Caramel 009831, liquorice flavour 77890-33, propylene glycol, purified water, sodium benzoate, sucrose.

5.2. Incompatibilities

Not applicable.

5.3. Shelf life

36 months.

5.4. Special precautions for storage

Store at or below 25 °C.

5.5. Nature and contents of container

100 ml or 200 ml syrup in glass or PET bottles, with or without an outer carton.

Not all pack sizes may be marketed.

5.6. Special precautions for disposal and other handling

No special requirements.

6. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

7. REGISTRATION NUMBER

47/10.1/0752

8. DATE OF FIRST AUTHORISATION

19 November 2024

9. DATE OF REVISION OF TEXT

19 November 2024

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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