1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

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

Ammonium chloride, sorbimacrogol laurate 300

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

Contains sugar: Sucrose 6 g per 10 ml syrup

Read all of this leaflet carefully because it contains important information for you

EXICHEST is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use EXICHEST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EXICHEST with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What EXICHEST is and what it is used for
2. What you need to know before you take EXICHEST
3. How to take EXICHEST
4. Possible side effects
5. How to store EXICHEST
6. Contents of the pack and other information

1. What EXICHEST is and what it is used for

EXICHEST relieves cough.

2. What you need to know before you take EXICHEST

Do not take EXICHEST:

- if you are hypersensitive (allergic) to ammonium chloride, sorbimacrogol or any of the other ingredients of EXICHEST (listed in section 6).
- if you have liver disease.
- if you have kidney disease.

Warnings and precautions

If your symptoms persist, contact your healthcare provider.

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

EXICHEST should not be taken with food or drink.

Pregnancy, breastfeeding and fertility

The safety of EXICHEST in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking EXICHEST.

Driving and using machines

Side effects such as drowsiness have been reported in patients receiving EXICHEST (see section 4). You should ensure that you do not engage in the above activities until you are aware of the measure to which EXICHEST affects you (see section 4).

EXICHEST contains sucrose

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking EXICHEST.

3. How to take EXICHEST

Do not share medicines prescribed for you with any other person.
Always take EXICHEST exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

EXICHEST should be kept in the mouth for a few minutes.

Adults:

The usual dose of EXICHEST is one to two medicine measures (5 ml to 10 ml) three to six times a day.

Children:

Children over three years old:

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

Children under 3 years of age:

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

If you take more EXICHEST than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The following are signs of an overdose of EXICHEST:

- stomach discomfort and the sensation of wanting to vomit (nausea),
- vomiting,
- thirst,
- headache,
- you start to breathe very fast (hyperventilation),
- you start to feel sleepy and that need to sleep becomes worse over time (progressive drowsiness).

If you forget to take EXICHEST

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of EXICHEST, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

4. Possible side effects

EXICHEST can have side effects.

Not all side effects reported for EXICHEST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EXICHEST, please consult your healthcare provider for advice.

If any of the following happens, stop taking EXICHEST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EXICHEST. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- you experience rapid and shallow breathing, confusion, fatigue, sleepiness you could be suffering from a condition called acidosis,
- you experience weakness, fatigue, muscle cramps or spasms, heart palpitations you could be suffering from a condition called hypokalaemia,
- headache,
- you start to feel sleepy and that need to sleep becomes worse over time (progressive drowsiness),
- you start to breath very fast (hyperventilation),
- stomach discomfort and the sensation of wanting to vomit (nausea) or vomiting,
- thirst,
- increase the absorption of liquid paraffin and other fat soluble substances.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects 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

By reporting side effects, you can help provide more information on the safety of EXICHEST.

5. How to store EXICHEST

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EXICHEST contains

The active substances in 10 ml syrup are 34 mg of ammonium chloride and 36,33 mg sorbimacrogol laurate 300.

The other ingredients are aniseed flavour ID 28467, disodium edetate, Eurovit Caramel 009831, liquorice flavour 77890-33, propylene glycol, purified water, sodium benzoate, sucrose.

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

Contains sugar: Sucrose 6 g per 10 ml syrup

What EXICHEST looks like and contents of the pack

EXICHEST is a brown, clear syrup.

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

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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