

Package leaflet: Information for the user

PectoDrill sugar-free for chesty coughs 250mg/5 ml, oral solution

Carbocisteine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days

What is in this leaflet

1. What PectoDrill sugar-free is and what it is used for
2. What you need to know before you take PectoDrill sugar-free
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1. What PectoDrill sugar-free and what it is used for

PectoDrill sugar-free contains the active substance carbocisteine which belongs to a group of medicines known as mucolytics or expectorants.

PectoDrill sugar-free is an oral solution for the treatment of chesty coughs.

PectoDrill sugar-free is used for bronchial congestion associated with certain respiratory tract disorders.

PectoDrill sugar-free is used to treat adults and children over 6 years of age.

How PectoDrill sugar-free works

PectoDrill sugar-free promotes coughing by thinning the secretions. It helps clear your bronchi of secretions causing congestion.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take PectoDrill sugar-free

Do not take PectoDrill sugar-free:

- if you are allergic to carbocisteine or any of the other ingredients of this medicine (listed in section 6)
- if you currently suffer from an active peptic ulcer in your stomach
- in infants and toddlers under the age of 2.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking PectoDrill sugar-free:

- if you have loose and possibly infected mucus and phlegm, fever;
- if you suffer from a longterm illness of the bronchi or lungs
- if you have previously had ulcers in your stomach or intestine (duodenum)
- if you have been told by your doctor that you have an intolerance to some sugars.
- do not use any medicine for a dry cough or to dry secretions from your lungs while you are taking this medicine, as they suppress the cough. Chesty coughs are important for your pulmonary defences and

should not be suppressed. This medicine should always be accompanied by voluntary effort to cough to facilitate the evacuation of secretions.

- if you are on a controlled sodium diet

If you are unsure about any of the above special care points and their relevance to yourself, please consult your doctor or pharmacist.

Other medicines and PectoDrill sugar-free

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine contains carbocisteine. Other medicines contain this product. Do not use other carbocisteine-containing products with this product in order to not exceed the maximum recommended dose.

Pregnancy and breast-feeding

Use of this medicine is not recommended if you are pregnant or could become pregnant.

Use of this medicine is not recommended during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There are no or negligible risks with driving or using machines when using PectoDrill sugar-free.

PectoDrill sugar-free contains

- small amounts of ethanol (alcohol), less than 100mg per 15ml dose.
- methyl parahydroxybenzoate (E218) and may cause allergic reactions (possibly delayed).
- about 0.1 g of sodium per 15 ml dose. To be taken into consideration by patients on a controlled sodium diet.

3. How to take PectoDrill sugar-free

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For oral use.

Children 6 to 12 years:

The recommended dose is 5 mls three times a day.

The maximum daily dose for children aged 6 to 12 years is 15 ml (3 doses of 5 mls).

Adults and adolescents over 12 years of age:

The recommended dose is 15 mls three times a day initially. After a satisfactory response, this may be reduced to 10 mls three times a day.

The maximum daily dose for adults and children over 12 years of age is 45 ml.

Shake the bottle before use.

Always rinse the measuring cup with water after use.

Duration of treatment must be restricted to five days after which time if symptoms continue, medical advice must be sought.

Do not exceed the stated dose.

After taking this medicine you should try to cough, which helps to remove the mucus and phlegm from your lungs.

If you have the impression that the effect of PectoDrill sugar-free is too strong or too weak, talk to your doctor or pharmacist. You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

If you take more PectoDrill sugar-free than you should

In the event that you take more PectoDrill sugar-free than you should stop taking the medicine and consult a doctor or a pharmacist immediately.

Symptoms and signs of overdose can be: gastrointestinal disturbance (including nausea, vomiting, diarrhoea and abdominal pain).

If you forget to take PectoDrill sugar-free

Take your medicine as soon as you remember. If it is almost time for your next dose, wait until the next dose and continue as usual.

Do not take a double dose to make up for a forgotten dose. Continue your treatment as scheduled.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A few people can be allergic (hypersensitive) to some medicines:

Contact your doctor or go to the nearest hospital casualty department IMMEDIATELY if any of the following happen after taking your medicine:

- Wheezing, difficulty breathing or swallowing, dizziness
- Swelling of the eyelids, face, lips, tongue or throat
- Itchy skin rash affecting the whole body.

The following side effects may occur (frequency not known) with this medicine:

- Digestive disorders such as stomach pain, nausea, vomiting, diarrhoea.
- Skin rashes as well as allergic reactions caused by an ingredient called Methyl parahydroxybenzoate (E218) (possibly delayed). These may present as a red rash, itching, hives or a raised itchy rash and/or swelling of the skin (particularly the face and/or mouth).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517, Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store PectoDrill sugar-free

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Do not refrigerate or freeze.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What PectoDrill sugar-free contains

- The active substance is carbocisteine 5% (750 mg per 15 ml). Each 5 ml contains 250 mg of carbocisteine.
- The other ingredients are sodium saccharin, methyl parahydroxybenzoate (E218), hydroxyethylcellulose, aromatic flavour*, sodium hydroxide (for pH adjustment), purified water.

*Composition of the aromatic flavour: rum, honey, cocoa tincture, orange tincture, cherry tincture, hart's tongue leaves, tonka bean, liquorice, vanillin, ethylvanillin, maltol, acetylmethylcarbinol, ethyl acetate, caramel colouring, glycol propylene.

What PectoDrill sugar-free looks like and contents of the pack

PectoDrill sugar-free is an oral solution.

This medicine is a slightly brownish, clear solution.

This medicine is available in 150 ml or 200 ml amber glass bottles.

A 15 ml measuring cup may be supplied with some packages.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

PIERRE FABRE MEDICAMENT

45, place Abel Gance,

92100 Boulogne, FRANCE

Manufacturer :

PIERRE FABRE MEDICAMENT PRODUCTION

Site SIMAPHAC

Zone industrielle de Châteaurenard

45220 CHATEAURENARD

FRANCE

Or

PIERRE FABRE MEDICAMENT PRODUCTION

Site PROGIPHARM

Rue du lycée

45500 GIEN - FRANCE

This leaflet was last revised in 04/2016

Other sources of information

For further information on this product contact the local representative of the Marketing Authorisation

Holder: Tel: + 44 1962 874400

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio call: +44 (0)1733 375370

Be ready to give the following information:

Product Name: PectoDrill sugar-free for chesty coughs 250mg/5ml: PA 329/9/2

This is a service provided by the Royal National Institute of the Blind.