PACKAGE LEAFLET:
Information for the user

PEKTUSOL

Syrup – 15 mg / 5 ml (0.3 %)

(Dextromethorphan hydrobromide)

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

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. WHAT PEKTUSOL IS AND WHAT IT IS USED FOR

Dextromethorphan hydrobromide is used as a suppressant of non-productive cough. It has a central action on the cough centre in the medulla and is also an antagonist of N-methyl-D-aspartate (NMDA) receptors. Although structurally related to morphine, dextromethorphan has no classical analgesic properties but a little sedative activity.
Your doctor may have prescribed Pektusol for another intention. Ask your doctor if you want to know why Pektusol has been prescribed to you.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PEKTUSOL

Do not take Pektusol:

- in hypersensitivity to dextromethorphan hydrobromide;
- in hypersensitivity to any other excipients listed at the end of the leaflet;
- in concomitant treatment with MAO - inhibitors or if you have been treated with MAO - inhibitors in the last two weeks;
- in children under 6 years. In any case it is not recommended to be used even in higher pediatric ages.

If any of this applies to you, do not take this drug and consult with your doctor.

Warning and precautions
Dextromethorphan should not be given to patients at risk of developing respiratory failure. Caution is needed in patients with a history of asthma and it should not be given during an acute attack.

Taking other medicines

- Severe and sometimes fatal reactions have been reported after use of dextromethorphan in patients receiving MAOIs.
- Avoid concomitant use of dextromethorphan with moclobemide because CNS excitation or depression (hypertension or hypotension) is possible.
- Avoid concomitant use of dextromethorphan with rasagiline.
- Dextromethorphan is primarily metabolized by the cytochrome P450 isoenzyme CYP2D6; interactions with inhibitors of this enzyme, including amiodarone, fluoxetine, haloperidol, paroxetine, propafenone, quinidine, and thioridazine are possible.
- Antiarrhythmics.
  Quinidine can increase serum concentrations of dextromethorphan, and some patients have experienced symptoms of dextromethorphan toxicity when the two drugs have been used together.
  Amiodarone also increases serum concentrations of dextromethorphan.
- Antibacterials.
  Serotonin syndrome-like symptoms have occurred when dextromethorphan has been taken with *linezolid*.
- Antidepressants.
  Visual hallucinations have been reported after simultaneous use of *fluoxetine* and dextromethorphan.
- Dextromethorphan might exhibit additive CNS depressant effects when co-administered with alcohol and other CNS depressant drugs.
- Increased risk of CNS toxicity is possible when dextromethorphan is given with memantine.

Pregnancy and breast-feeding
Category C.
If you are pregnant or you are planning to have a baby, or if you are breast-feeding or planning to breast-feed, ask your doctor or pharmacist for advice before taking this medicine.
Even though teratogenic effects have not been demonstrated, dextromethorphan should not be taken during pregnancy.
Consult your doctor before taking this medicine during breast-feeding.

Driving and using machines
Take care while driving or using machines until you know how Pektusol affects you because this medicine may cause dizziness.

Important information about some of the excipients of Pektusol
Pektusol - syrup contains:

- about 5% v/v ethanol. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy;
- sucrose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Contains 5.2 g sucrose / 10 ml. This should be taken into account in patients with diabetes mellitus.

3. HOW TO TAKE PEKTUSOL

Pektusol acts within half an hour of an oral dose and exerts the effect for up to 6 hours.
It is given orally, preferably after meals in doses of 10 to 20 mg every 4 hours, or 30 mg every 6 to 8 hours, to a usual maximum of 120 mg in 24 hours.
Pektusol is not recommended for children.
It should not be taken by children under 6 years, while its use can be considered in 6-12 years old children when other alternatives have not been successful. This decision must be taken by the doctor and the doses must be suitable for children.
Do not take it for longer than five days without the advice of a doctor.
Your doctor may recommend to take Pektusol for a long period of time. Consult your doctor if you are not sure for the duration of treatment.

If you take more Pektusol than you should
If you take more Pektusol than you should or your child has taken it by mistake, contact your doctor. Naloxone may be effective as an antidote.

If you forget to take Pektusol
If you forget to take Pektusol, take the next dose at the normal time.
Do not take a double dose to make up the missed dose.
If you have any further questions, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they are serious, mostly they are not. Do not get worried from this list of possible side effects. None of them might appear to you.
Adverse effects with dextromethorphan are rare and may include dizziness and gastrointestinal disturbances. Hypersensitivity reactions including: urticaria, angioedema, erythema or shortness of breath are possible. Excitation, confusion, and respiratory depression may occur after overdosage. Dextromethorphan has been subject to abuse, but there is little evidence of dependence of the morphine type.
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PEKTUSOL

Keep this medicine out of the sight and reach of children!
Do not use this medicine after the expiry date which is stated on the package.
Do not store above 25ºC!
Keep in the original package to protect from light and humidity!

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pektusol contains
The active substance is dextromethorphan hydrobromide.
1 ml syrup contains 3 mg of dextromethorphan hydrobromide.
The other ingredients are: glycerin, citric acid, sodium citrate, sodium benzoate, sucrose, orange flavour, alcohol 96º, purified water.

Content of the pack
Carton box with 1 glass bottle of 100 ml.

Explanatory of the illustration icons on the packaging:

According to medical prescription.

Content.

Warning.

Syrup.

Marketing Authorisation Holder and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in May 2016.

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.