Package leaflet: Information for the patient

Etrilect 0.5 mg/ml + 1 mg/ml oral solution

bromhexine hydrochloride + ephedrine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Etrilect is and what it is used for

Etrilect contains bromhexine and ephedrine. Bromhexine is thought to thin the mucus in the airways. This may facilitate the expectoration of mucus. Ephedrine dilates the airways and acts to reduce mucous membrane swelling.

Etrilect is used to treat cough with viscous mucus when there is a simultaneous need for a bronchodilator.

2. What you need to know before you take Etrilect

Do not take Etrilect
- if you are allergic to bromhexine, ephedrine or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Etrilect.
In particular, tell your doctor before starting this medicine:
- if you have a history of heart disease, irregular heart rhythm or angina.
- if you have heart disease, high blood pressure, high levels of thyroid hormone in the blood (hyperthyroidism), enlarged prostate, glaucoma, diabetes or stomach ulcers.
- if you have bloody sputum.

Etrilect may cause a dry mouth. Good oral hygiene (e.g. brushing with fluoride toothpaste twice daily) is therefore necessary while using Etrilect.

There have been reports of severe skin reactions associated with the administration of bromhexine. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop taking Etrilect and contact your doctor immediately.

There is some risk of developing an addiction at high doses and with prolonged use.

Other medicines and Etrilect
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines may affect or be affected by treatment with Etrilect, such as:
- MAO inhibitors or tricyclic antidepressants (to treat depression)
- medicines to treat elevated blood pressure
- dexamethasone (a steroid)
- cardiac glycosides (to treat heart problems)
- quinidine (to treat heart rhythm problems)
- ergot alkaloids (to treat migraine)
- oxytocin (to induce labour)
- anaesthetics such as cyclopropane or halothane

Pregnancy, breast-feeding and fertility
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.
Pregnancy
No harmful effects on the foetus have been demonstrated, but normal caution should be observed, especially during the first three months of pregnancy.
Breast-feeding
Bromhexine probably crosses into breast milk and should be avoided during breast-feeding.
Therefore, you should not take Etrilect if you are breast-feeding.

Driving and using machines
Dizziness can occur during treatment with Etrilect. This should be considered when full alertness is required, for example when driving.

Etrilect contains ethanol
This medicine contains 30.26 mg of alcohol (ethanol) per ml.
The amount in 5 ml of this medicine is equivalent to less than 4 ml beer or 2 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

Etrilect contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to take Etrilect

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children 15 years and over:	15 ml, 3 to 4 times daily.
Children 11 to 14 years:	10–15 ml, 3 times daily.
Children 6 to 10 years:	10 ml, 3 times daily.
Children 2 to 5 years:	5 ml, 3 times daily.
Children over 6 months:	2.5 ml, 3 times daily.

If you take more Etrilect than you should
If you take more of this medicine than you should or if, for example, a child has taken the medicine accidentally, call your doctor or hospital to get an opinion of the risk and advice on the actions you should take.

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.

Stop taking this medicine and tell a doctor immediately if you experience any of the following serious side effects:

Rare (may affect up to 1 in 1,000 people):
- Spasm of the bronchial muscles, which may cause difficulty breathing (bronchospasm).

Frequency not known (cannot be estimated from the available data):
- Serious allergic reactions including anaphylactic shock and angioedema with symptoms such as rapidly developing swelling of face, tongue or throat; difficulty swallowing; hives, itching, dizziness and breathing difficulties.
- Severe skin reactions with symptoms such as:
  - circular, irregular red patches on the skin of the hands and arms (erythema multiforme),
  - skin rashes, commonly in the form of blisters or sores in the oral cavity and eyes, and other mucous membranes such as, for example, genitalia (Stevens-Johnson syndrome),
  - severe extensive skin damage with separation of the epidermis and superficial mucous membranes (toxic epidermal necrolysis),
  - skin rash with blisters and fever (acute generalised exanthematous pustulosis)..

Other side effects which may occur are:

Common (may affect up to 1 in 10 people):
- Dizziness
- Headaches
- Palpitations
- Tremor
- Anxiety
- Rash
- Urticaria (hives)
- Difficulty passing water

Uncommon (may affect up to 1 in 100 people):
- Nausea
- Diarrhoea
- Vomiting
- Insomnia

Rare (may affect up to 1 in 1,000 people):
- Hallucinations
- Confusion
- Aggression
- Transient elevations of certain liver enzymes
- Dry mouth
- Hypersensitivity reactions

Frequency not known (cannot be estimated from the available data):
- Reduced appetite

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 the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etrilect

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 carton and bottle label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.
Do not store above 25 °C.

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

6. Contents of the pack and other information

What Etrilect contains

- The active substances are bromhexine hydrochloride and ephedrine hydrochloride.
- 1 ml of Etrilect contains 0.533 mg bromhexine hydrochloride and 1.0 mg ephedrine hydrochloride.
- The other ingredients are glycerol, polysorbate 20, citric acid monohydrate, ethanol (96%), levomenthol, peppermint flavour, blood orange flavour, sodium hydroxide (E524), purified water.

What Etrilect looks like and contents of the pack
Etrilect is a clear, colourless to light-yellow solution.

Etrilect is available in amber glass bottles with a child-resistant plastic screw cap and in amber glass bottles with a temper-evident plastic screw cap and pouring ring.
Each pack contains a measuring device (plastic cup).

Pack sizes: 300 ml and 500 ml oral solution.

Not all pack sizes may be marketed.

Market Authorisation Holder and Manufacturer

[To be completed nationally]

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.
10/2020