

Package leaflet: Information for the patient

Hedelix® Effervescent Tablets

Active substance: ivy leaf dry extract

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.

What is in this leaflet

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1. What Hedelix® Effervescent Tablets are and what they are used for

Hedelix® Effervescent Tablets are a herbal medicinal product used as an expectorant in case of productive cough.

2. What you need to know before you take Hedelix® Effervescent Tablets

Hedelix® Effervescent Tablets must not be taken

- if you are allergic to ivy, plants belonging to the aralia family, such as Schefflera, or any of the other ingredients of this medicine (listed in section 6).
- by children under 2 years of age because of the risk of aggravation of respiratory symptoms.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hedelix® Effervescent Tablets.

When dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.

Concomitant use with opiate antitussives such as codeine or dextromethorphan is not recommended without medical advice.

Caution is recommended in patients with gastritis or gastric ulcer.

Macrogolglycerol hydroxystearate can cause a stomach upset and diarrhoea.

Children

Hedelix[®] Effervescent Tablets are not intended for use in children under 6 years of age.

Other medicines and Hedelix[®] Effervescent Tablets

None reported.

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines.

Hedelix[®] Effervescent Tablets with food and drink

No special precautions need to be taken.

Pregnancy and 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.

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

Hedelix[®] Effervescent Tablets contain sodium.

Each effervescent tablet contains 13.7 mmol (316 mg) sodium. This should be noted if you are required to follow a low-salt diet.

3. How to take Hedelix[®] Effervescent Tablets

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

Unless prescribed otherwise by your doctor, the recommended dose is:

Adolescents, adults and elderly should take one effervescent tablet twice daily (in the morning and evening) (equivalent to 600 mg herbal substance per day).

Children between 6 and 12 years of age should take half an effervescent tablet twice daily (in the morning and evening) (equivalent to 300 mg herbal substance per day).

Tube:

Store the second half of the effervescent tablet in the tube until the next application (max. 24 hours).

Close the tube tightly after intake of tablet.

Sachet:

Store the second half of the effervescent tablet in the closed sachet until the next application (max. 24 hours).

The open edge area of the sachet is closed by folding over twice.

The tablet can be divided into equal doses.

This medicine is not intended for use in children under 6 years of age.

The use in children under 2 years of age is contraindicated (see section 2. “Hedelix[®] Effervescent Tablets must not be taken”).

Insufficient data are available to permit specific dose recommendations in the case of impaired kidney/liver function.

Method of administration:

Oral use.

Dissolve the effervescent tablet in half a glass of water and drink after eating.

Duration of use:

If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted.

If you take more Hedelix[®] Effervescent Tablets than you should

There are normally no adverse effects if one effervescent tablet more than recommended is taken.

Nausea, vomiting, diarrhoea and restlessness can develop if considerably more tablets are taken.

One case of a 4-year-old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding to 1.8 g herbal substance has been reported. You should consult your doctor in such a case.

If you forget to take Hedelix[®] Effervescent Tablets

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

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.

The following list covers all the known side effects from treatment with extract of ivy leaf, including those from higher doses and long-term treatment.

The stated frequencies of the side effects are based on the following categories:

Very common: may affect more than 1 in 10 treated
Common: may affect 1 to 10 in 100 treated
Uncommon: may affect 1 to 10 in 1,000 treated
Rare: may affect 1 to 10 in 10,000 treated
Very rare: may affect less than 1 in 10,000 treated
Not known: cannot be estimated from the available data

Possible side effects:

Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.

Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hedelix® Effervescent Tablets

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 container after "EXP". The expiry date refers to the last day of that month.

Storage conditions:

Store in the original package in order to protect from moisture.

Shelf life after opening:

Hedelix® Effervescent Tablets can be used for 6 months after opening.

6. Contents of the pack and other information

What Hedelix® Effervescent Tablets contain

The active substance is ivy leaf dry extract.

Each effervescent tablet contains 50 mg ivy leaf dry extract (4-8:1), extraction solvent: ethanol 30% (m/m).

The other ingredients are:

Anhydrous citric acid, sodium hydrogen carbonate, mannitol, anhydrous sodium carbonate, saccharin sodium, sodium cyclamate, simeticone, medium-chain triglycerides, sodium citrate, macrogolglycerol hydroxystearate, beetroot powder (E 162), enocianin powder (E 163), cassis aroma.

What Hedelix® Effervescent Tablets look like and contents of the pack

Hedelix® Effervescent Tablets are round, flat tablets with purple speckles and a break-mark on one side.

Pack sizes: 20 effervescent tablets

Marketing Authorisation Holder and Manufacturer

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