

Package leaflet: Information for the patient

Hedelix® Cough Effervescent Tablets

50 mg

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® Cough Effervescent Tablets are and what they are used for

Hedelix® Cough Effervescent Tablets are a herbal medicine used to treat colds affecting the airways.

Hedelix® Cough Effervescent Tablets are used to relieve symptoms of chronic inflammatory bronchial conditions; for colds affecting the airways.

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

Hedelix® Cough Effervescent Tablets must not be taken

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

Warnings and precautions

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

Seek medical advice if you have any unexplained symptoms, symptoms that last more than one week, or you develop fever, shortness of breath, purulent or bloody sputum.

Hedelix[®] Cough Effervescent Tablets should not be used in combination with cough-relief medicines such as codeine or dextromethorphan without medical advice.

Particular caution must be exercised when taking Hedelix[®] Cough Effervescent Tablets if your stomach lining is inflamed (gastritis) or you have stomach ulcers, since ivy products can irritate the gastric mucosa.

Children

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

Other medicines and Hedelix[®] Cough Effervescent Tablets

Interactions with other medicines have not been investigated. No interactions have been reported to date.

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

Hedelix[®] Cough 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.

This medicine should not be used during pregnancy and when breast-feeding since sufficient studies are not available.

Driving and using machines

No special precautions are necessary.

Hedelix[®] Cough Effervescent Tablets contain sodium.

This medicine contains 316 mg sodium (main component of cooking / table salt) in each effervescent tablet. This is equivalent to 15.8 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 2 effervescent tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Hedelix[®] Cough Effervescent Tablets contain macroglycerol hydroxystearate. Macroglycerol hydroxystearate may cause stomach upset and diarrhoea.

Hedelix® Cough Effervescent Tablets contain glucose.

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

3. How to take Hedelix® Cough 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:

Adults and adolescents over 12 years of age 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.

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

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

Method of administration:

For oral use.

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

Duration of use:

Do not take Hedelix® Cough Effervescent Tablets for more than one week without medical advice. Please read the information in section 2 under “Warnings and precautions”.

If you take more Hedelix® Cough 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.

A four-year-old child became aggressive and developed diarrhoea after inadvertently taking ivy extract equivalent to 1800 mg of the herbal substance. You should consult your doctor in such a case.

If you forget to take Hedelix® Cough 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:

Common: gastrointestinal disorders (e.g. nausea, vomiting, diarrhoea).

Uncommon: allergic skin reactions, e.g. rash (exanthema), hives (urticaria), redness, itching, or serious systemic allergic conditions, e.g. involving swelling, shortness of breath, can occur after taking medicines that contain ivy.

Hedelix® Cough Effervescent Tablets must not be taken again if there are any signs of an allergic reaction. If necessary, consult a doctor.

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® Cough 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:

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

Shelf life after opening:

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

6. Contents of the pack and other information

What Hedelix® Cough Effervescent Tablets contain

The active substance is ivy leaf extract.

Each effervescent tablet contains 50 mg of dry extract from *Hedera helix* L., folium (ivy leaves) (4-8:1), extraction solvent: ethanol 30% (m/m).

The other ingredients are:

Citric acid, sodium hydrogen carbonate, mannitol (Ph. Eur.), sodium carbonate, saccharin sodium, sodium cyclamate, simeticone, medium-chain triglycerides, sodium citrate (Ph. Eur.), macroglycerol hydroxystearate (Ph. Eur.), beetroot powder (beetroot sap concentrate (E 162), maltodextrin, citric acid), enocianin powder (E 163) (anthocyanine, glucose syrup), blackcurrant flavour (contains i. a. menthol).

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

Hedelix® Cough Effervescent Tablets are round, flat, purple flecked tablets with a score line on one side.

Hedelix® Cough Effervescent Tablets are available in the following pack sizes:

PP tube with PP cap:

10 effervescent tablets

20 effervescent tablets (N1)

50 effervescent tablets (N2)

100 effervescent tablets (N3)

Sachet of laminated aluminium-paper-foil:

12 effervescent tablets

20 effervescent tablets

24 effervescent tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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