

Package leaflet: Information for the patient

Hedelix[®] s.a.
0.04 g/ml
oral drops

Extract of ivy leaves

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 have 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 a few days.

What is in this leaflet

1. What Hedelix[®] s.a. is and what it is used for
2. What you need to know before you take Hedelix[®] s.a.
3. How to take Hedelix[®] s.a.
4. Possible side effects
5. How to store Hedelix[®] s.a.
6. Contents of the pack and other information

1. What Hedelix[®] s.a. is and what it is used for

Hedelix[®] s.a. is a herbal medicinal product for use in common colds affecting the respiratory tract.

Hedelix[®] s.a. is used to treat common colds affecting the airways, for alleviation of symptoms in chronic inflammatory bronchial diseases.

If symptoms persist for prolonged periods or if laboured breathing, fever or expectoration of purulent or bloody sputum occur, please consult a doctor without delay.

2. What you need to know before you take Hedelix[®] s.a.

Do not take Hedelix[®] s.a.

- if you are allergic to ivy leaves, levomenthol, mint oil, eucalyptus oil or any of the other ingredients of this medicine (listed in section 6)
- if you have argininosuccinate synthetase deficiency (a metabolic disorder of the urea cycle)
- on infants of less than 2 years of age due to the risk of worsening of respiratory symptoms.

For infants and children less than 2 years of age, other preparations are available.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hedelix® s.a.

Other medicines and Hedelix® s.a.

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

There are no known interactions between Hedelix® s.a. and other medicines.

Hedelix® s.a. with food and drink

No special precautions are necessary.

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.

This medicinal product should not be used in pregnancy and breast-feeding as there are insufficient data.

Driving and using machines

No special precautions are necessary.

Hedelix® s.a. contains propylene glycol.

This medicine contains 837 mg propylene glycol per ml (= 31 drops).

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take Hedelix® s.a.

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 otherwise prescribed by the doctor, the recommended dose is:

Adults and children over the age of 10 years	31 drops three times daily (equivalent to 300 mg herbal substance per day)
Children aged 4 - 10 years	21 drops three times daily (equivalent to 200 mg herbal substance per day)
Children aged 2 - 4 years	16 drops three times daily (equivalent to 150 mg herbal substance per day)

Method of use

For oral use

Please take Hedelix[®] s.a. undiluted and ensure that you drink sufficient fluid (preferably drinking water).



Hold the bottle vertically while dripping. If necessary, tap the bottom of the bottle lightly to start dripping.

Duration of use

Do not take Hedelix[®] s.a. for more than a few days unless advised by a doctor. See also section 1. "What Hedelix[®] s.a. is and what it is used for".

If you have the impression that the effect of Hedelix[®] s.a. is too strong or too weak, please contact your doctor or pharmacist.

If you take more Hedelix[®] s.a. than you should

If you take a larger amount of this medicinal product as you should, please contact your doctor. He is able to decide about necessary measures. Below-mentioned side effects may occur more pronounced.

If you forget to take Hedelix[®] s.a.

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.

Possible side effects:

Very rarely allergic reactions (breathlessness, tumescences, erythema, itches) may occur after the ingestion of ivy-containing medicinal products.

Uncommonly gastric symptoms (nausea, vomiting, diarrhoea) may occur in sensitive persons.

Levomenthol, mint oil and eucalyptus oil may induce hypersensitivity reactions (including respiratory distress) in sensitized patients.

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® s.a.

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 label after “Exp:”. The expiry date refers to the last day of that month.

Storage conditions:

This medicinal product does not require any special storage conditions.

Information on shelf life after first opening of the container:

After first opening Hedelix® s.a. can be used for 6 months.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. More information is available at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Hedelix® s.a. contains

The active substance is extract of ivy leaves.

1 ml (= 31 drops) contains: 0.04 g of extract from ivy leaves in a drug to extract ratio (2.2–2.9:1). Extraction solvent: ethanol 50 % (V/V), propylene glycol (98:2).

The finished product contains no alcohol (ethanol).

The other ingredients are propylene glycol, glycerol, flavouring: star-anise oil, eucalyptus oil, levomenthol, mint flavour (contains mint oil).

What Hedelix® s.a. looks like and contents of the pack

Hedelix® s.a. is a clear greenish-brown, viscous solution.

Hedelix® s.a. is available in packs with 20 ml drops (N1), 50 ml (drops (N2) and 100 ml drops (N3).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in April 2021.

Further information

Hedelix® s.a. is free of sugar and alcohol and therefore suitable for diabetics and patients who have to avoid alcohol.

As Hedelix® s.a. contains plant-extracted substances, occasionally sediment may form in the bottle, turbidity of the fluid may occur and/or the taste may change a little bit.