

PATIENT INFORMATION LEAFLET FOR HEDELIX™ EFFERVESCENT TABLETS

Read all of this leaflet carefully before you start taking HEDELIX EFFERVESCENT TABLETS.

HEDELIX EFFERVESCENT TABLETS is a herbal expectorant and is available without a doctor's prescription. Nevertheless you still need to use HEDELIX EFFERVESCENT TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.

SCHEDULING STATUS

Not scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Heidelix™ Effervescent tablets 50 mg (Effervescent tablets).

Dry extract of ivy leaf.

Western Herbal Medicine.

WHAT HEDELIX EFFERVESCENT TABLETS CONTAIN

The active substance is: dry extract of ivy leaf (*Hedera helix*).

Each effervescent tablet contains: 50 mg dry extract of ivy leaf.

The other ingredients are: anhydrous citric acid, anhydrous sodium carbonate, macroglycolcerol hydroxystearate, mannitol (sugar alcohol), medium chain triglycerides, simethicone, sodium citrate, sodium hydrogen carbonate.

Sweetening agents: saccharin sodium, sodium cyclamate.

Colouring agents: beetroot powder E162, annocianin powder E163.

Flavouring Agent: blackcurrant flavour.

Each effervescent tablet contains 13,7 mmol (or 316 mg) sodium.

WHAT HEDELIX EFFERVESCENT TABLETS ARE USED FOR

HEDELIX EFFERVESCENT TABLETS contain the dry extract of ivy leaf which helps provide relief from a cough and thins and loosens phlegm (mucus) in the airways.

HEDELIX EFFERVESCENT TABLETS alleviate the symptoms of the common cold affecting the respiratory tract as well as the symptoms associated with chronic inflammatory bronchial diseases. HEDELIX EFFERVESCENT TABLETS with extract of ivy leaf helps to relieve bronchial spasms, thins the bronchial mucus and enables easy expectoration (coughing up and spitting out of mucus) thus relieving an irritated cough and helping you to breathe more easily.

BEFORE YOU TAKE HEDELIX EFFERVESCENT TABLETS

Do not take HEDELIX EFFERVESCENT TABLETS:

- If you are allergic (hypersensitive) to ivy leaves, herbs of the Araliaceae family or any of the other ingredients in HEDELIX EFFERVESCENT TABLETS.

Take special care with HEDELIX EFFERVESCENT TABLETS:

- In the presence of fever, shortness of breath, purulent sputum (off-white, yellow or green coloured mucus) production or if symptoms persist longer than one week, see your doctor immediately.
- Do not take HEDELIX EFFERVESCENT TABLETS together with antitussives (medicines for cough relief), such as codeine or dextromethorphan, without consulting your doctor.
- If you suffer with inflammation of the lining of the stomach (gastritis) or gastric diseases while taking HEDELIX EFFERVESCENT TABLETS, increased caution is necessary, as agents of ivy may cause irritation of gastric mucous membrane.
- This formulation is not suitable for children younger than 12 years of age.

Pregnancy and breast-feeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking HEDELIX EFFERVESCENT TABLETS.

Do not take HEDELIX EFFERVESCENT TABLETS if you are pregnant or breastfeeding, as its safety during pregnancy and breastfeeding has not been established.

Important information about some of the ingredients of HEDELIX EFFERVESCENT TABLETS:

HEDELIX EFFERVESCENT TABLETS contain mannitol (sugar alcohol). Products containing mannitol may have a laxative effect or cause diarrhoea.

HEDELIX EFFERVESCENT TABLETS contain macroglycolcerol hydroxystearate. Macroglycolcerol hydroxystearate may cause stomach upset and diarrhoea.

Each effervescent tablet contains 13,7 mmol (or 316 mg) of sodium. It is necessary to consider this if you have impaired kidney function or if you have been placed on a controlled sodium diet (diet low in sodium or sodium chloride).

Taking other medicines with HEDELIX EFFERVESCENT TABLETS:

Do not take HEDELIX EFFERVESCENT TABLETS together with antitussives (medicines for cough relief), such as codeine or dextromethorphan, without consulting your doctor.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

HOW TO TAKE HEDELIX EFFERVESCENT TABLETS

Always take HEDELIX EFFERVESCENT TABLETS exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose for adults and children older than 12 years of age is: One effervescent tablet, dissolved in half a glass of water, should be taken once daily before a meal.

Use in children under 12 years of age:

This formulation is not suitable for children under 12 years of age.

HEDELIX EFFERVESCENT TABLETS are for oral intake only.

Continue taking HEDELIX EFFERVESCENT TABLETS for at least 7 days (one week).

If symptoms worsen or do not improve after 7 days consult your doctor.

If you experience fever, shortness of breath or purulent sputum (off-white, yellow or green coloured mucus) production, please consult a doctor without delay.

If you take more HEDELIX EFFERVESCENT TABLETS than you should:

Do not exceed the recommended daily dose. If you take more than the recommended daily dose, you may experience nausea, vomiting, diarrhoea and restlessness.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take HEDELIX EFFERVESCENT TABLETS:

Do not take a double dose to make up for a missed dose. Continue to take HEDELIX EFFERVESCENT TABLETS as described in this leaflet. If you have any further questions on the use of this product ask your doctor or pharmacist.

If you seem to always have trouble remembering when to use/take your medicines, ask your pharmacist for some helpful hints.

POSSIBLE SIDE EFFECTS

HEDELIX EFFERVESCENT TABLETS can have side effects.

If any of the below side effects occur, stop taking HEDELIX EFFERVESCENT TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- shortness of breath
- skin rash
- red skin
- Itchy skin
- fluty retention

These are all very serious side effects. If you have them, you may have had an allergic reaction to HEDELIX EFFERVESCENT TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following:

- nausea
- vomiting
- diarrhoea

Not all side effects reported for HEDELIX EFFERVESCENT TABLETS are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. If you notice side effects that are not described in this leaflet, you should tell your doctor or pharmacist.

STORING AND DISPOSING OF HEDELIX EFFERVESCENT TABLETS

Store at or below 25 °C in the original packaging in a cool dry place. Keep the tube firmly sealed to protect the contents from moisture.

Do not use after the expiry date stated on the packaging. Once opened, use within 6 months.

KEEP OUT OF REACH OF CHILDREN.

Do not freeze or refrigerate.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF HEDELIX™ EFFERVESCENT TABLETS

10 or 20 effervescent tablets presented in a polyethylene tube with a polyethylene cap, contained in an outer cardboard carton.

IDENTIFICATION OF HEDELIX™ EFFERVESCENT TABLETS

Round flat effervescent tablets with purple speckles and a break-mark on one side.

NAME AND ADDRESS OF APPLICANT

Actor Pharma (Pty) Ltd¹
Unit 7, Royal Palm Business Estate
646 Washington Street
Halfway House, Midrand, 1685

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

TM: HEDELIX is a Trademark of Actor Pharma (Pty) Ltd.

¹ Company registration number: 2008/006787/07