

PATIENT INFORMATION LEAFLET: HEDELIX® EFFERVESCENT TABLETS**Complementary Medicine (Western Herbal Medicine).**

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

HEDELIX® 50 mg effervescent tablets.

Read all of this leaflet carefully because it contains important information for you.

HEDELIX EFFERVESCENT TABLETS are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use HEDELIX EFFERVESCENT TABLETS carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Do not share HEDELIX EFFERVESCENT TABLETS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT HEDELIX EFFERVESCENT TABLETS CONTAIN

The herbal substance is: dry extract of ivy leaves (*Hedera helix L.*, folium).

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

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

HEDELIX EFFERVESCENT TABLETS contain sweetener (saccharin sodium: 9,2 mg/tablet and sodium cyclamate 6,2 mg/tablet).

HEDELIX EFFERVESCENT TABLETS contain sugar (glucose: component of the enocianin powder).

The other ingredients are: anhydrous citric acid, anhydrous sodium carbonate, beetroot powder (beetroot sap concentrate E 162, maltodextrin, citric acid monohydrate), blackcurrant flavour (ethyl butyrate, raspberry ketone, linalool, hexenyl acetate c-3, menthol, L-, maltodextrin, propylene glycol E 1520, modified starch E 1450), enocianin powder (anthocyanin extract from grape skin E 163, glucose syrup), macroglycerol hydroxystearate, mannitol (sugar alcohol), medium chain triglycerides, simeticone, sodium citrate, sodium hydrogen carbonate.

HEDELIX EFFERVESCENT TABLETS are free from artificial colourants.

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 leaves help to relieve bronchial spasms, thin the bronchial

mucus and enable 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, to plants of the Araliaceae family (Schefflera, Panax ginseng or Eleutherococcus senticosus) or to any of the other ingredients in HEDELIX EFFERVESCENT TABLETS.

Take special care with HEDELIX EFFERVESCENT TABLETS:

This formulation is not suitable for children younger than 6 years of age.

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

If shortness of breath, fever or phlegm (mucus) containing blood or pus occurs, a doctor or pharmacist should be consulted.

Caution is recommended in patients with gastritis or gastric ulcer.

Pregnancy and breastfeeding:

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

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

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

HEDELIX EFFERVESCENT TABLETS are considered high in sodium. If you have been advised to follow a low salt diet, please consult your doctor or pharmacist before taking HEDELIX EFFERVESCENT TABLETS.

HEDELIX EFFERVESCENT TABLETS contain macrogolglycerol hydroxystearate. Macrogolglycerol hydroxystearate may cause stomach upset and diarrhoea.

HEDELIX EFFERVESCENT TABLETS contain glucose (as a component of the enocianin powder) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with HEDELIX EFFERVESCENT TABLETS:

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 described in this leaflet or as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose for adolescents aged 12 years and older, adults and the elderly is:

One effervescent tablet (corresponding to 50 mg of ivy leaves dry extract), dissolved in half a glass of water, taken twice daily after eating (i.e. one effervescent tablet in the morning and one in the evening).

The recommended dose for children from 6 to 11 years of age:

Half an effervescent tablet (corresponding to 25 mg of ivy leaves dry extract), dissolved in half a glass of water, taken twice daily after eating (i.e. half an effervescent tablet in the morning and half a tablet in the evening).

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

Close the tube tightly after intake of tablet.

The recommended dose for children under 6 years of age:

HEDELIX EFFERVESCENT TABLETS are not intended for use in children under 6 years of age.

HEDELIX EFFERVESCENT TABLETS are for oral intake only.

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

If shortness of breath, fever or phlegm (mucus) containing blood or pus occurs, a doctor or pharmacist should be consulted.

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.

Not all side effects reported for HEDELIX EFFERVESCENT TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking HEDELIX EFFERVESCENT TABLETS and contact your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty in breathing
- hives (raised, itchy areas of skin)
- skin rash
- anaphylactic reaction

These side effects may be serious.

If they occur 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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF HEDELIX EFFERVESCENT TABLETS

Store all medicines out of reach of children.

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.

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

HEDELIX EFFERVESCENT TABLETS are presented in a polypropylene tube with a polyethylene cap and contained in an outer cardboard carton.

Pack sizes: 10 / 20 / 50 / 100 effervescent tablets. Not all pack sizes may be marketed.

IDENTIFICATION OF HEDELIX EFFERVESCENT TABLETS

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

The tablet can be divided into equal doses.

NAME AND ADDRESS OF APPLICANT

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® HEDELIX is a registered trademark of Actor Pharma (Pty) Ltd.

¹ Company registration number: 2008/008787/07

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