

## **PATIENT INFORMATION LEAFLET: HEDELIX® COUGH SYRUP**

### **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® COUGH SYRUP** (0,8 g /100 ml)

Soft extract of ivy leaves

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

HEDELIX COUGH SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use HEDELIX COUGH SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share HEDELIX COUGH SYRUP 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 COUGH SYRUP CONTAINS**

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

100 ml syrup contains: 0,8 g of extract from ivy leaves.

The other ingredients are: glycerol, hydroxyethylcellulose, macrogolglycerol hydroxystearate, purified water, propylene glycol, sorbitol liquid (non-crystallising), star-anise oil.

HEDELIX COUGH SYRUP is sugar free, alcohol free and free from preservatives and colourants.

### **WHAT HEDELIX COUGH SYRUP IS USED FOR**

HEDELIX COUGH SYRUP contains the soft extract of ivy leaves which help provide relief from a cough and thin and loosen phlegm (mucus) in the airways. HEDELIX COUGH SYRUP alleviates the symptoms of the common cold affecting the respiratory tract as well as the symptoms associated with chronic inflammatory bronchial diseases. HEDELIX COUGH SYRUP with extract of ivy leaves 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 USE HEDELIX COUGH SYRUP**

#### **Do not take HEDELIX COUGH SYRUP:**

If you / your child is allergic (hypersensitive) to ivy leaves, to plants of the Araliaceae family or any of the other ingredients in HEDELIX COUGH SYRUP.

**Take special care with HEDELIX COUGH SYRUP:**

If your child aged from 0 to 4 years has persistent or recurrent cough, please consult your doctor. Your doctor will decide if this medicine is appropriate for your child.

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

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

Caution is recommended if you have stomach problems such as gastritis or gastric ulcer.

**Pregnancy and breastfeeding:**

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

The safety of HEDELIX COUGH SYRUP during pregnancy and breastfeeding has not been established. In the absence of sufficient data use during pregnancy and lactation is generally not recommended.

**Important information about some of the ingredients of HEDELIX COUGH SYRUP:**

HEDELIX COUGH SYRUP contains sorbitol. If you / your child has a rare hereditary condition of sorbitol intolerance do not use HEDELIX COUGH SYRUP.

HEDELIX COUGH SYRUP contains macrogolglycerol hydroxystearate. Macrogolglycerol hydroxystearate may cause stomach upset and diarrhoea.

**Using other medicines with HEDELIX COUGH SYRUP:**

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

**HOW TO TAKE HEDELIX COUGH SYRUP**

Always take HEDELIX COUGH SYRUP 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.

For the exact dosage a syringe is enclosed in this package. Follow the instructions indicated below.

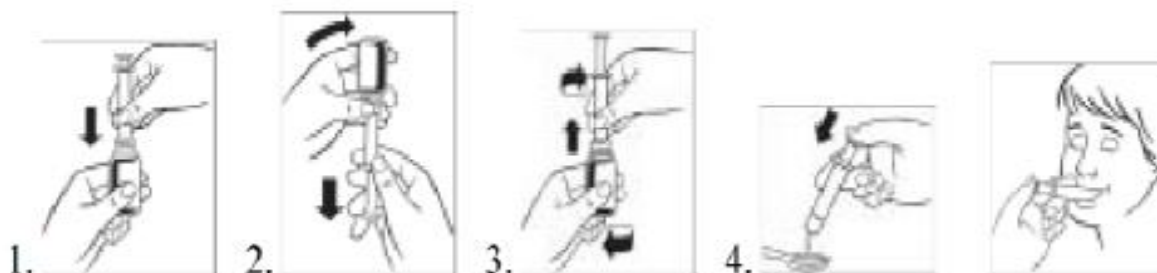
The amount of HEDELIX COUGH SYRUP to take depends on age. Do not exceed the recommended dosage.

- Infants 0 to 1 year:** 2,5 ml syrup once daily.  
**Children 1 to 4 years:** 2,5 ml syrup three times daily.  
**Children 4 to 10 years:** 2,5 ml syrup four times daily.  
**Adults and children older than 10 years:** 5 ml syrup three times daily.



Shake well before use.

**Instructions for the use of the dosing syringe:**



1. Insert the dosing syringe into the opened bottle and push down until it fits firmly. The plunger of the syringe should be pushed all the way in.
2. Carefully turn the bottle upside down and slowly pull the liquid into the syringe by pulling the plunger out to the desired marking.
3. Turn the bottle around again and pull the syringe out of the bottle neck by twisting carefully. Replace the bottle cap after removal.
4. Administer the cough syrup either directly with the syringe by emptying the syringe slowly on the inside of the cheek, or in a spoon.
5. After administering, pull the plunger out of the syringe, clean the parts with warm water and subsequently dry the syringe.



Close the bottle tightly after use.

HEDELIX COUGH SYRUP is for oral intake only. Ensure that you / your child drink sufficient fluid (preferably water) afterwards.

If symptoms persist longer than one week during the use of HEDELIX COUGH SYRUP, 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 COUGH SYRUP than you should:**

If you use more HEDELIX COUGH SYRUP than you should, you / your child may experience nausea, vomiting, diarrhoea and agitation.

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

**If you forget to take HEDELIX COUGH SYRUP:**

Do not take a double dose to make up for a missed dose. Continue to take HEDELIX COUGH SYRUP 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 COUGH SYRUP can have side effects.

Not all side effects reported for HEDELIX COUGH SYRUP are included in this leaflet.

Should you / your child's general health worsen or if you / your child 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 COUGH SYRUP 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 / your child may have had an allergic reaction to HEDELIX COUGH SYRUP.

You / your child 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 COUGH SYRUP**

Store in the original packaging in a dry place below 25 °C.

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

KEEP OUT OF REACH OF CHILDREN.

### **PRESENTATION OF HEDELIX COUGH SYRUP**

HEDELIX COUGH SYRUP is available in packs of 100 ml and 200 ml.

### **IDENTIFICATION OF HEDELIX COUGH SYRUP**

Clear, yellowish-brown syrup.

As HEDELIX COUGH SYRUP contains plant extracts, the preparation may occasionally exhibit cloudiness,

formation of a precipitate and/or slight variations in taste. This, however, does not affect the use of the preparation.

### **NAME AND ADDRESS OF APPLICANT**

Actor Pharma (Pty) Ltd<sup>1</sup>

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### **NAME AND ADDRESS OF MANUFACTURER**

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<sup>1</sup> Company registration number: 2008/008787/07

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