



## PATIENT INFORMATION LEAFLET FOR HEDELIX COUGH SYRUP

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

HEDELIX COUGH SYRUP is a herbal expectorant and is available without a doctor's prescription. 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 contact a doctor if your symptoms worsen or do not improve.

### SCHEDULING STATUS

Not Scheduled

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM HEDELIX™ COUGH SYRUP (syrup)

Extract of ivy leaves  
Western Herbal Medicine

### WHAT HEDELIX COUGH SYRUP CONTAINS

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

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

The other ingredients are: glycerol, hydroxyethylcellulose, macroglycerol hydroxystearate, propylene glycol, purified water, sorbitol solution 70 % (non crystallising), star-anise oil.

### WHAT HEDELIX COUGH SYRUP IS USED FOR

HEDELIX COUGH SYRUP contains the extract of ivy leaf which helps to provide relief from a cough and to 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 easier.

### BEFORE YOU USE HEDELIX COUGH SYRUP

#### Do not take HEDELIX COUGH SYRUP:

- If you / your child is allergic (hypersensitive) to ivy leaves or any of the other ingredients in HEDELIX COUGH SYRUP.
- If you / your child has argininosuccinate synthetase deficiency (a metabolic disorder of the urea cycle).

### Take special care with HEDELIX COUGH SYRUP:

If symptoms persist for prolonged periods or if laboured breathing, fever or expectoration (coughing up and spitting out) of purulent or bloody sputum occur, please consult a doctor without delay.

### Pregnancy and breast-feeding

Do not take HEDELIX COUGH SYRUP if you are pregnant or breast-feeding, as its safety during pregnancy and breast-feeding has not been established.

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

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

HEDELIX COUGH SYRUP contains sorbitol. If you have been told by your doctor that you / your child has an intolerance to some sugars, contact your doctor before you use HEDELIX COUGH SYRUP. Sorbitol may have a slight laxative effect.

### Using other medicines with HEDELIX COUGH SYRUP

There are no known interactions with other medicines. 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 your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

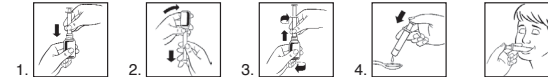
For the exact dosage a syringe is enclosed in this package. Follow the instructions indicated below. The amount of HEDELIX COUGH SYRUP to take depends on age. Do not exceed the recommended dosage.

<b>Infants 0 to 1 year:</b>	2,5 ml (1/2 measuring spoon) once daily
<b>Children 1 to 4 years:</b>	2,5 ml (1/2 measuring spoon) three times daily
<b>Children 4 to 10 years:</b>	2,5 ml (1/2 measuring spoon) four times daily
<b>Adults and children older than 10 years:</b>	5 ml (1 measuring spoon) 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.

Continue using HEDELIX COUGH SYRUP for at least 7 days (one week). It is recommended to continue with HEDELIX COUGH SYRUP for at least 2-3 days after symptoms have subsided. If symptoms persist for prolonged periods or if laboured breathing, fever or expectoration (coughing up and spitting out) of purulent or bloody sputum occur, please consult a doctor without delay.

You should consult a doctor if you / your child's condition worsens or does not improve.

### 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 and diarrhoea.

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.

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:

- breathlessness
- itchiness
- red skin rash

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

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

- nausea
- vomiting
- diarrhoea
- swelling of the penis (male) or clitoris (female) – resulting in sexual excitation.

### If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for HEDELIX COUGH SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HEDELIX COUGH SYRUP, please consult your doctor, pharmacist or other health care professional for advice. 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>  
Unit 7, Royal Palm Business Estate  
646 Washington Street  
Halfway House, Midrand, 1685

### NAME AND ADDRESS OF MANUFACTURER

Krewel Meuselbach GmbH, Krewelstr. 2, 53783 Eitorf, Germany

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

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

