

**PACKAGE LEAFLET\_rv16**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### HARPADOL hard capsules

*Devil's Claw Root 435 mg*

**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 has 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.*
- *You must talk to a doctor if you feel worse or do not feel better after 4 weeks.*

#### **What is in this leaflet.**

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

#### **1. WHAT HARPADOL IS AND WHAT IT IS USED FOR.**

Harpadol contains the active substance Devil's claw root (*Harpagophytum procumbens D.C. and / or H. zeyheri L. Decne*).

Harpadol is a traditional herbal medicinal product for the relief of minor joint pain in adults over 18 years of age, exclusively based on longstanding use.

You must talk to a doctor if you feel worse or do not feel better after 4 weeks.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HARPADOL.**

##### **Do not take Harpadol:**

- If you are allergic to Devil's claw (also known as Harpagophytum) or any of the ingredients of this product.
- If you are pregnant or breast-feeding.
- If you are under 18 years.

##### **Warnings and precautions :**

Talk to your doctor or pharmacist before taking Harpadol.

Talk to your doctor:

- if you have other symptoms such as swelling, redness of a joint, or fever in addition to joint pain.
- if new symptoms develop or if your symptoms worsen or last for more than 4 weeks
- if you have an ulcer (either a gastric and/or duodenal ulcer).
- if you have heart disease.

##### **Children and adolescents:**

Do not give this medicine to children or adolescents under the age of 18 years as it is not known if it is safe.

**Other medicines and Harpadol:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including any herbal medicines.

**Pregnancy, breast-feeding and fertility:**

Do not take Harpadol if you are pregnant, breast-feeding or planning to have a baby.

**Driving and using machines:**

In rare cases HARPADOL may cause dizziness and drowsiness. If it happens to you, do not drive or use machines.

**3. HOW TO TAKE HARPADOL.**

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.

For elderly and adults above 18 years only, the recommended dose is:  
one capsule morning, noon and evening during meals with a large glass of water.  
See your doctor if your symptoms worsen or if they do not improve after 4 weeks.

For oral short-term use only.

**If you take more HARPADOL than you should:**

If you take too much and feel ill, talk to your doctor.  
Taking too much is unlikely to be harmful.

**If you forget to take HARPADOL:**

Do not take a double dose to make up for a forgotten dose.

**If you stop taking HARPADOL:**

You can stop Harpadol at any time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS.**

Like all medicines, Harpadol can cause side effects, although not everybody gets them.

**Minor side effects:**

The following minor side effects can occur when using Harpadol:

- diarrhoea, feeling sick, vomiting, abdominal pain.
- headache, dizziness.
- rash, itching. Stop taking Harpadol if you experience any allergic skin reaction.

*Discontinue use if you find these symptoms are troubling you.*

*If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.*

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE HARPADOL.**

Keep this medicine out of the reach and sight of children.

Do not use HARPADOL after the expiry date which is stated on the carton and bottle after “Exp”. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION.**

### **What HARPADOL contains.**

- The active substance is Devil’s Claw root. Each capsule contains 435 mg Devil’s claw root (*Harpagophytum procumbens D.C. and/or H. zeyheri L. Decne*).
- The other ingredients are magnesium stearate (vegetable origin), hydrated colloidal silica and hypromellose (capsule shell).

### **What HARPADOL looks like and contents of the pack.**

Capsule, hard (hypromellose). Translucent colourless capsule filled with brown yellow powder. Brown polyvinyl chloride container of 45 or 150 capsules, with a security cap made of low-density polyethylene.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

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