

TEXT FOR HIRUDOID CREAM

LEAFLET

MA085/00101

PACKAGE LEAFLET: INFORMATION FOR THE USER

HIRUDOID CREAM

heparinoid 0.3% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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. See section 4.
- You must talk to a doctor if your signs of illness or injury do not improve.

What is in this leaflet:

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

1. WHAT HIRUDOID CREAM IS AND WHAT IT IS USED FOR

Hirudoid Cream contains the active substance heparinoid.

Hirudoid Cream is a local anti-coagulant preparation which, when applied to the skin, relieves pain and inflammation in addition to promoting healing in superficial thrombophlebitis (inflammation of the veins) and bruising (including haematoma).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HIRUDOID CREAM

Do not use Hirudoid Cream:

- if you are allergic (hypersensitive) to heparinoid or any of the other ingredients of Hirudoid Cream (listed in section 6)
- if you have broken skin, or on large areas of skin
- on or near sensitive areas such as the mouth, eyes or ano-genital regions.

Hirudoid Cream should **NOT** be used on children under the age of 5 years old.

Warnings and precautions

- Hirudoid Cream is for external use only. Do **NOT** swallow.
 - Do not exceed the dose stated in section 3.
 - Talk to your doctor if your signs of injury or illness do not improve or get worse.
- See section 4 for information about possible side-effects.

Other medicines and Hirudoid Cream

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Hirudoid Cream contains cetostearyl alcohol

This may cause local skin reactions (for example contact dermatitis).

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Hirudoid Cream contains the preservatives propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218).

These ingredients may cause allergic reactions (possibly delayed).

3.HOW TO USE HIRUDOID CREAM

External use only. Do not swallow.

- Always use 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.
- Before use, pierce the tube seal with the spiked top of the cap.
- The amount of cream you use will depend on the size of the area being treated.
- Between 2 and 6 inches (5-15 cm) of cream should be gently massaged into the affected area at any one time.
- You can apply Hirudoid Cream up to four times a day.
- Do not exceed this dose.
- If the area is tender to touch, you can massage the cream into the skin surrounding the affected area.
- Remember to wash your hands after applying Hirudoid Cream, unless this is the area being treated.
- If you accidentally swallow some of this cream, it is unlikely to be serious. However, you should contact your doctor or a hospital casualty department.

4.POSSIBLE SIDE-EFFECTS

Like all medicines, Hirudoid Cream can cause side-effects, although not everybody gets them.

Rarely, Hirudoid Cream can cause a rash in sensitive individuals. If this occurs, STOP using the cream and tell your doctor or pharmacist.

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 the ADR reporting website at:

www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5.HOW TO STORE HIRUDOID CREAM

Keep out of the sight and reach of children.

Do not use Hirudoid Cream after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month. Store below 25°C.

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 protect the environment.

6.CONTENTES OF THE PACK AND OTHER INFORMATION

What Hirudoid Cream contains

The active substance is 0.3% w/w heparinoid.

The other ingredients are anhydrous eucerine, emulsifying cetostearyl alcohol type A, glycerol, isopropyl alcohol, methyl parahydroxybenzoate (E218), myristyl alcohol, potassium hydroxide, propyl parahydroxybenzoate (E216), purified water, stearic acid and thymol.

What Hirudoid Cream looks like and the contents of the pack

Hirudoid Cream is a white cream available in aluminium lacquered tubes of 50 grams.

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MA085/00101 Hirudoid Cream

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturers:

Mobilat Produktions GmbH, Luitpoldstrasse 1, 85276 Pfaffenhofen, Germany.

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany.

This leaflet was last revised in May 2016.