

TEXT FOR HIRUDOID GEL

LEAFLET

MA085/00102

PACKAGE LEAFLET: INFORMATION FOR THE USER

HIRUDOID GEL

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

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

Hirudoid Gel contains the active substance heparinoid.

Hirudoid Gel 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 GEL

Do not use Hirudoid Gel:

- if you are allergic (hypersensitive) to heparinoid or any of the other ingredients of Hirudoid Gel (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 Gel should **NOT** be used on children under the age of 5 years old.

Warnings and precautions

- Hirudoid Gel 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 Gel

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 Gel contains propylene glycol

This may cause skin irritation.

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3. HOW TO USE HIRUDOID GEL

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 gel you use will depend on the size of the area being treated.
- Apply 2-6 inches (5-15 cm) of gel as a thin layer to the affected area at any one time.
- You can apply Hirudoid Gel up to four times a day.
- Do not exceed this dose.
- If the area is tender to touch, you can apply the gel to the skin surrounding the affected area.
- Remember to wash your hands after applying Hirudoid Gel, unless this is the area being treated.
- If you accidentally swallow some of this gel, 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 Gel can cause side-effects, although not everybody gets them.

Rarely, Hirudoid Gel can cause a rash in sensitive individuals. If this occurs, STOP using the gel 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 GEL

Keep this medicine out of the sight and reach of children

Do not use Hirudoid Gel 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hirudoid Gel contains

The active substance is 0.3% w/w heparinoid.

The other ingredients are isopropyl alcohol, polyacrylic acid, propylene glycol, purified water and sodium hydroxide.

What Hirudoid Gel looks like and the contents of the pack

Hirudoid Gel is a colourless gel available in aluminium lacquered tubes of 50 grams.

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Hirudoid Gel

Marketing Authorisation Holder and Manufacturer:

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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.