

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription

Traumaplant Cream

Active ingredient:

Each 100 gram contains:

Comfrey (Symphytum) concentrate 10 g
(ex. Herba Symphyti recente 25 g).

Inactive ingredients and allergens in the preparation – see section 6 "Further Information."

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is not intended for children and infants under 4 years of age.

Use in the correct manner. Consult the pharmacist if you need further information. Consult the doctor if symptoms worsen or if they do not improve after 3-4 days.

Traumaplant cream contains an extract of the Comfrey plant. This plant is one of the prominent plants in natural medicine. The plant is characterized by its constricting (reduces swelling) and anti-inflammatory activity. The Comfrey plant also has components that aid in accelerating wound healing.

Traumaplant cream is absorbed and does not leave an oily residue on the skin.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- For the treatment of ankle sprains due to sports or accidental injuries.
- For the treatment of muscle pain.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are pregnant or breastfeeding.
- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients which the medicine contains.
- the medicine is not intended for children and infants under 4 years of age.

Special warnings regarding use of the medicine

- If you are sensitive to any type of food or medicine, inform the doctor before commencing treatment with the medicine.
- If there is no improvement in your condition within 3-4 days, refer to the doctor.
- If you feel that the effect of the medicine is too strong or too weak, refer to the doctor.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use this medicine, since no sufficient studies were conducted on this subject.

Important information about some of the medicine's ingredients

The medicine contains sorbic acid which may cause local irritation of the skin (e.g., contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding the manner of use.

Apply as necessary, several times a day, on the affected area and rub in gently.

The preparation is also suitable for use with an occlusive dressing. For this purpose, apply a larger amount of the cream on the desired area, cover with a dressing and leave it on for several hours (for instance, overnight).

Do not use the medicine for more than 3 weeks.

Do not exceed the recommended dose.

Do not swallow, for external use only. Avoid contact with the eyes and mucosal tissues.

If a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Traumaplant may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Contact the doctor if the following effects develop:

Redness, rash or irritation of the skin, especially in users with sensitive skin or prone to allergy (these effects usually disappear within a short time after adapting to the medicine).

If any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiration date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Use within 6 months after first opening.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Purified water, glycerol monostearate, macrogol-20 glycerol monostearate, isopropyl myristate, propylene glycol, octyldodecanol, hydroxyethyl salicylate, dimethicone, sorbic acid, rosemary oil, alpha tocopherol acetate, citric acid anhydrous.
- **What does the medicine look like and what are the contents of the package?**
A tube containing 10, 30 50 or 100 gram of cream (not all package sizes may be in the market).
- **License holder and address:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- **Manufacturer and address:** Gehrlicher Pharmazeutische Extrakte GmbH, Eurasburg, Germany.
- **Rights-holder:** Harras Pharma Curarina Arzneimittel., Munchen, Germany.
- Revised in April 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140.61.31480.00.

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