PRESCRIBING INFORMATION

Traumaplant®

1. NAME OF THE MEDICINAL PRODUCT

Traumaplant®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g of cream contains 10 g Comfrey (Symphytum) concentrate

For the complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traumaplant® is a phytodrug (extract of plants) for external treatment of muscle pains (in case of sports and accidental injuries) and ankle sprains.

4.2 Posology, method and duration of administration

Traumaplant® is intended for the use of adults, adolescents and children above 4 years old.

Traumaplant® can be applied several times a day on the affected tissue of the skin.

The patient should spread the cream generously over the entire affected area, than rub it gently and allow it to be thoroughly absorbed.

This preparation is especially suitable for occlusive dressings – should be applied on the skin and then covered with a dressing for several hours.

The patient is instructed to consult a doctor if improvement does not occur after 3-4 days.

Treatment duration should not be more than 3 weeks and it is dependent on the pattern of symptoms.

4.3 Contraindications

Traumaplant® must not be used if there is any hypersensitivity to comfrey or to other ingredients of this medicine.

4.4 Special warnings and special precautions for use

General instructions:

Contact with the eyes and mucosa should be avoided.

4.5 Interactions with other medicinal products and other forms of interaction

When used as directed, interactions with other medicines are unknown to date.

4.6 Pregnancy and lactation

No adequate data are available concerning use of **Trauma**plant® during pregnancy and lactation. **Trauma**plant® should not be given to a pregnant or breastfeeding woman.

4.7 Effects on the ability to drive and use machines

No special precautions are required.

4.8 Undesirable effects

The following categories are taken as the basis for assessment of side effects:

Very common (≥1/10)
Common (≥1/100 and <1/10)
Uncommon (≥1/1,000 and <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Unknown (frequency not assessable based on the available data)

Possible undesirable effects:

In very rare cases, erythema may occur, which depends on the sensitivity of the skin or on allergic response to one of the ingredients of **Trauma**plant®.

These skin symptoms are generally rapidly resolved.

Symptoms of irritation such as skin inflammation (dermatitis) may occur since the medicine contains sorbic acid.

The patient is instructed to consult a doctor in case of a specific allergic reaction.

4.9 Overdosage

No cases of overdosage have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: herbal preparations for topical use against muscle and joint pain.

ATC code: M02AP06

The active substance complex contained in **Trauma**plant® is obtained from freshly harvested plants (symphytum x uplandicum).

Traumaplant® reduces pain (analgesic), fever and inflammation. It also reduces swelling.

Traumaplant® helps in a better recovery of wounds.

No studies concerning the bioavailability of **Trauma**plant® are available.

5.2 Pharmacokinetic properties

No pharmacokinetic studies concerning **Trauma**plant® are available.

5.3 Preclinical safety data

No harmful pyrrolizidine alkaloid contents are detectable in **Trauma**plant® (limit of detection: 0.1 ppm; officially established safety limit: 10 µg of pyrrolizidine alkaloids per daily dose). Consequently, **Trauma**plant® is not subject to the restrictions on use for drugs containing pyrrolizidine alkaloids.

According to the current status of scientific knowledge, **Trauma**plant® cannot result in acute or chronic poisoning when used as directed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, glycerol monostearate, macrogol 20 glycerol monostearate, isopropyl myristate, propylene glycol, octyldodecanol, hydroxyethyl salicylate, dimethicone, sorbic acid, rosemary oil, α-tocopherol acetate, citric acid anhydrous.

6.2 Incompatibilities

Not applicable.

6.3 Special precautions for storage

None.

6.4 Nature and contents of container

Package sizes: 10 g, 30 g, 50 g, 100 g
It is possible that not all pack sizes are marketed.

6.5 Instructions for use and handling and disposal

Shelf-life after opening is 6 months.

7. MANUFACTURER

Gehrlicher GmbH, Eurasburg, Germany
For Harras Pharma Curarina Arzneim. Munchen, Germany

8. MARKETING AUTHORISATION HOLDER

Trima Trading (1961) Ltd., Maabarot 40230, Israel

9. REGISTRATION NUMBER

140 61 31480 00

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it.

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