

Patient information leaflet

Scheduling status

Schedule 0

Proprietary name, strength and pharmaceutical form

Traumeel[®] S Ointment

Read all of this leaflet carefully because it contains important information for you

Traumeel[®] S is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Traumeel[®] S carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Traumeel[®] S with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. What Traumeel[®] S contains

For each 100 g of ointment:

The active substances are: Arnica montana D3 1.5 g; Calendula officinalis Ø 0.45 g; Hamamelis virginiana Ø 0.45 g; Echinacea angustifolia Ø 0.15 g; Echinacea purpurea Ø 0.15 g; Chamomilla recutita Ø 0.15 g; Symphytum officinale D4 0.1 g; Bellis perennis Ø 0.1 g; Hypericum perforatum D6 0.09 g; Achillea millefolium Ø 0.09 g; Aconitum napellus D1 0.05 g; Atropa belladonna D1 0.05 g; Mercurius solubilis Hahnemanni D6 0.04 g; Hepar sulfuris D6 0.025 g.

The other ingredients are: Cetostearyl alcohol (type A), emulsifying; Ethanol (96 per cent); Paraffin, liquid; Paraffin, white soft; Water, purified.

Preservative: 13.8 % v/v ethyl alcohol.

2. What Traumeel[®] S is used for

Pharmacological classification: D.33.2. Homeopathy.

Discipline of the medicine: Homeopathy.

Traumeel[®] S is indicated in injuries of all kinds (sports, accidents) such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures, etc; inflammatory processes and degenerative processes associated with inflammation on the various organs and tissues (e.g. periodontitis, suppuration of the gingival pockets, periodontosis), including, in particular, on the support and mobility apparatus (tendovaginitis, bursitis, scapulohumeral peri arthritis); arthrosis of the hip, knee and small joints.

3. Before you use Traumeel[®] S Do not use Traumeel[®] S:

- if you are hypersensitive (allergic) to
 - the active substance or any of the other ingredients of Traumeel[®] S
 - the plants of the daisy (compositae) family (e.g. Arnica, Chamomilla, Achillea millefolium).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Important information about some of the ingredients of Traumeel[®] S:

Preservative: 13.8 % v/v ethyl alcohol.

Taking other medicines with Traumeel[®] S:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Traumeel[®] S with these medicines may cause undesirable interactions. Always tell your healthcare professional if you are taking any other medicine.

4. How to use Traumeel-S

Do not share medicines prescribed for you with any other person.

Always take Traumeel® S exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults, children and infants: apply ointment generously to the affected area 2 to 3 times daily.

Traumeel® S should be rubbed gently into the skin. Traumeel® S may be applied using mild compression bandaging and/or occlusive bandaging. Sufficient ointment should be applied to cover the affected area, but should not be applied over large areas. Avoid contact with eyes, mucosae, open wounds or broken skin.

If you take more Traumeel-S than you should:

Due to the low concentration of active ingredients in homeopathic preparations such as Traumeel® S, adverse reactions following over dosage are extremely unlikely. However, care must be taken not to exceed the recommended dosage. In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use Traumeel-S:

Do not use a double dose to make up for forgotten individual doses.

5. Possible side effects

Traumeel® S can have side effects.

Hypersensitivity reactions may occur in individual cases. Local allergic reactions (cutaneous inflammation, redness, swelling and pruritus) have been reported. In this case the product should be discontinued.

Not all side effects reported for Traumeel® S are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. Storing and disposing of Traumeel-S

Keep all medicines out of the reach and sight of children.

- Store in a cool (below 25 °C) place.
- Replace cap tightly.

7. Presentation of Traumeel-S

Tubes containing 50 g of ointment.

Sachets containing 4 g of ointment.

8. Identification of Traumeel-S

White ointment.

9. Registration number/reference number

U 5684 (Act 101/1965)

10. Name and address of registration holder

ModHomCo (Pty) Ltd

96 Amsterdam Street, Clubview, 0157 Centurion

11. Date of publication

July 2018

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.