

Patient Information Leaflet

Scheduling status

Schedule 0

Proprietary name, strength and pharmaceutical form

Traumeel® S Tablets

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

1 tablet contains:

The active substances are: Arnica montana D2 15 mg; Calendula officinalis D2 15 mg; Hamamelis virginiana D2 15 mg; Achillea millefolium D3 15 mg; Atropa belladonna D4 75 mg; Aconitum napellus D3 30 mg; Mercurius solubilis Hahnemanni D8 30 mg; Hepar sulfuris D8 30 mg; Chamomilla recutita D3 24 mg; Symphytum officinale D8 24 mg; Bellis perennis D2 6 mg; Echinacea angustifolia D2 6 mg; Echinacea purpurea D2 6 mg; Hypericum perforatum D2 3 mg.

The other ingredients are: lactose monohydrate (approx. 300 mg), magnesium stearate.

2. What Traumeel® S is used for

Pharmacological classification: D.33.2. Homeopathy.

Discipline of the medicine: Homeopathy

This medicine is prepared in accordance with homeopathic principles and is proposed for use in injuries such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures; post-operative and post-traumatic oedema and swelling of the soft tissues; inflammatory processes and degenerative processes associated with inflammation on the various organs and tissues, including, in particular, on the support and mobility apparatus (tendovaginitis, styloiditis, epicondylitis, bursitis, scapulohumeral peri-arthritis); arthrosis of the hip, knee and small joints; commotion cerebri acuta.

3. Before you take Traumeel® S

Do not take Traumeel® S:

- if you are hypersensitive (allergic) to
 - active substances or any of the other ingredients of Traumeel® S to members of the Compositae family.
- Principally contraindicated for patients with progressive systemic disease such as tuberculosis, leukose, collagen disorders, multiple sclerosis, AIDS, HIV infection, and other autoimmune disorders.

Pregnancy and Breastfeeding

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

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

This preparation contains natural lactose. Although the quantity of lactose present is probably not sufficient to cause discomfort, a health professional should be consulted in strong cases of lactose intolerance.

A temporary aggravation of the existing symptoms is possible after taking a homeopathic preparation.

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. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. How to take 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 and children over 3 years of age: Dissolve 1 tablet in the mouth 3 times daily.

Infants: Half the adult dose.

If you take more Traumeel® S than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take Traumeel® S:

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

5. Possible side effects

Traumeel® S can have side effects.

Increased flow of saliva may occur after taking this medication; in such an event, do not continue therapy with this preparation. Hypersensitivity reactions may occur in individual cases. The following have been observed among patients taking medication containing preparations from *rudbeckia*: rashes, itching, facial swelling (rare), acute respiratory distress, vertigo, and acute hypotension.

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) dry place.

7. Presentation of Traumeel® S

Containers of 50 and 250 tablets.

8. Identification of Traumeel® S

White to light yellow tablets, sometimes small orange dots.

9. Registration number / Reference number

U 5514 (Act 101/1965).

10. Name and business address of the holder of the certificate of registration

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.