

Patient information leaflet

Scheduling status

Schedule 0

Proprietary name, strength and pharmaceutical form

Traumeel[®] S Gel

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

10 g gel contains:

The active substances are: Arnica montana D3 0,15 g, Calendula officinalis D0 0,045 g, Hamamelis virginiana D0 0,045 g, Echinacea angustifolia D0 0,015 g, Echinacea purpurea D0 0,015 g, Chamomilla recutita D0 0,015 g, Symphytum officinale D4 0,01 g, Bellis perennis D0 0,01 g, Hypericum perforatum D6 0,009 g, Achillea millefolium D0 0,009 g, Aconitum napellus D1 0,005 g, Atropa belladonna D1 0,005 g, Mercurius solubilis Hahnemanni D6 0,004 g, Hepar sulfuris D6 0,0025 g.

The other ingredients are: Purified water, Ethanol (96 per cent), Carbomers, Sodium hydroxide solution 18 % (m/m).

Preservative: 17.9 % v/v ethyl alcohol.

2. What Traumeel[®] S is used for

Pharmacological classification: D. 33.2 Homeopathy.

Discipline of the medicine: Homeopathy

For the temporary relief of arthritic pain, of symptoms associated with injuries (i.e. sports injuries, sprains, bruises) and inflammations of all kinds (i.e. tennis elbow).

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
 - botanicals of the Compositae family (Arnica).

Pregnancy and Breastfeeding

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

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

Preservative: 17.9 % m/m ethyl alcohol.

Using other medicines with Traumeel[®] S:

If you are using 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 use Traumeel[®] S

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

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

For external use only.

The usual dose is:

Apply to the affected parts 1-2 times daily, or more often if necessary. A dressing may be applied.

Replace cap tightly.

Do not use on open wounds.

If you use 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 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.

In isolated cases, hypersensitivity reactions may occur.

Local allergic reactions (skin inflammation) have been reported.

Not all side effects reported for Traumeel® S are included in this leaflet. Should your general health worsen 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.

7. Presentation of Traumeel-S

Tubes containing 50 g of gel.

8. Identification of Traumeel-S

Clear gel.

9. Registration number / Reference number

To be allocated by the SAHPRA.

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

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11. Date of publication

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