



Traumeel®

ointment

Homeopathic medicinal product

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or qualified healthcare practitioner. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you feel worse, or do not feel better after 7 days.

What is in this leaflet

1. What Traumeel is and what it is used for
2. What you need to know before you use Traumeel
3. How to use Traumeel
4. Possible side effects
5. How to store Traumeel
6. Contents of the pack and other information

1. What Traumeel is and what it is used for

Traumeel is a homeopathic medicinal product used within the homeopathic tradition to relieve symptoms such as **pain and swelling** which may result from minor injuries such as **sprains, muscular strains and bruising**.

2. What you need to know before you use Traumeel

Do not use Traumeel:

- if you are allergic (hypersensitive) to
 - active substances or any of the other ingredients of this medicine (listed in section 6).
 - plants of the Asteraceae (Compositae) family such as daisies, marigolds or artichokes.
- if skin is broken, sore, red or irritated.

Warnings and precautions

There is a possible risk of allergic/hypersensitivity reactions in sensitive or atopic patients. Those patients should consult their doctor before using Traumeel.

A doctor should be consulted if joint pain, with swelling of the joint, redness or fever occurs.

Children and adolescents

The use in children under 2 years of age is not recommended.

Other medicines and Traumeel

Traumeel is not reported to affect any other medicines.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This product is not reported to affect driving or operating machines.

Traumeel contains cetostearyl alcohol

It may cause local skin reactions (e.g. contact dermatitis).

3. How to use Traumeel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This product is to be applied on the skin only.

The hands should be washed before and after applying the ointment.

The recommended dose is:

Adults, elderly and children over 2 years of age	Apply a thin layer to the affected area 2 times daily and then massage into the skin until absorbed Can be applied up to 4 times daily if needed.
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Do not apply more than the recommended dose.

Tamper evident

Do not use if inner protective seal under cap is broken. To open, push the spike that is affixed to the cap through this seal.

Method of use

Discontinue use if redness, irritation or dry skin occurs. Avoid contact with the eyes and mucous membranes.

If the ointment is accidentally swallowed and you feel unwell, contact your doctor or pharmacist.

If the ointment gets into the eyes, rinse the affected area well and consult your doctor or pharmacist if irritation persists.

Duration of use

If the condition worsens, or if symptoms do not improve within 7 days, consult a doctor or qualified healthcare practitioner.

If you use more Traumeel than you should

If you apply more than the recommended dose, wipe off the excess with a tissue. If you feel unwell, contact your doctor.

If you forget to use Traumeel

Apply the next dose when it is due. Do not apply a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or qualified healthcare practitioner.

Mat.no.: 0XXXXX
Version: XXXX
Code: 24
Size: 210 x 300 mm
Type size: ≥ 9 Pt
Colours: ■ Pantone 432

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- Correction necessary
- Approved for submission
- Approved for printing
 - Valid until _____
 - Valid until further note

Date/Signature

-Heel

4. Possible side effects

Like all medicines, Traumeel ointment can cause side effects, although not everybody gets them.

There have been a small number of post-marketing reports of allergic skin reactions with symptoms such as; redness, itching, rash, blisters or swelling, unusual skin sensation. There have been isolated cases reports of tachycardia (fast or irregular heart rate), heart problems, vertigo, headache, fatigue, pain and throat tightness.

The frequency of these effects is not known.

Stop the treatment and consult your doctor if skin rash or other allergic reactions occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Traumeel

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Store in the original package.
- Use within 1 year after first opening.
- Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
- Ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Traumeel contains

The active substances of 1 g Traumeel ointment are:

Achillea millefolium 3X
Aconitum napellus 4X
Arnica montana 4X
Atropa belladonna 4X
Bellis perennis 3X
Calendula officinalis 2X
Echinacea angustifolia 2X or Echinacea pallida 2X, or a mixture of both species
Echinacea purpurea 2X
Hamamelis virginiana 2X
Hepar sulfuris 9X
Hypericum perforatum 9X
Matricaria recutita 2X
Mercurius solubilis Hahnemanni 9X
Symphytum officinale 7X

The other ingredients are: emulsifying cetostearyl alcohol (type A), ethanol (96 per cent), liquid paraffin, white soft paraffin, purified water.

What Traumeel looks like and contents of the pack

Traumeel ointment is white to yellow-white.

The ointment is supplied in a tube in a cardboard box.

Tubes contain either 25, 50 or 100 g ointment.

NR Holder and Manufacturer

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A copy of this Patient Information Leaflet (PIL) for the blind or partially sighted may be obtained from Bio Pathica Ltd., P.O. Box 217, Ashford, Kent TN23 6ZU, +44 1233 636678, <http://www.biopathica.co.uk>