

Package leaflet: Information for the user

Tyrosur[®]

Wound Healing Powder

Powder for use on the skin

Active substance: Tyrothricin 1 mg/g

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

This medicine is available without a prescription. Nevertheless, you still need to use Tyrosur[®] Wound Healing Powder correctly to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your

doctor or pharmacist.

The package leaflet includes:

1. WHAT TYROSUR[®] WOUND HEALING POWDER IS AND WHAT IT IS USED FOR
2. BEFORE YOU USE TYROSUR[®] WOUND HEALING POWDER
3. HOW TO USE TYROSUR[®] WOUND HEALING POWDER
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE TYROSUR[®] WOUND HEALING POWDER
6. FURTHER INFORMATION

1. WHAT TYROSUR[®] WOUND HEALING POWDER IS AND WHAT IT IS USED FOR

Tyrosur[®] Wound Healing Powder is a wound treatment agent.

Tyrosur[®] Wound Healing Powder is used

For treatment of small-area, superficial wounds that are not weeping very much with a bacterial superinfection with tyrothricin-sensitive pathogens such as lacerations, scratches and abrasions.

2. BEFORE YOU USE TYROSUR[®] WOUND HEALING POWDER

Tyrosur[®] Wound Healing Powder must not be used if you are hypersensitive (allergic) to the active substance or any of the other ingredients of Tyrosur[®] Wound Healing Powder.

Take special care with Tyrosur[®] Wound Healing Powder

Other medicines and Tyrosur[®] Wound Healing Powder:

There are no known interactions of Tyrosur[®] Wound Healing Powder with other medicines and no other medicines are known that can influence the effect of Tyrosur[®] Wound Healing Powder.

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, even those obtained without a prescription.

Pregnancy:

No safety data are available regarding use of Tyrosur[®] Wound Healing Powder during pregnancy. As it is not known to what extent tyrothricin, the active substance in Tyrosur[®] Wound Healing Powder, is absorbed through the skin into the bloodstream, if you are pregnant you should use Tyrosur[®] Wound Healing Powder only for a short time and on a small area of skin and only if your doctor instructs you to do this.

Breastfeeding:

It is not known if tyrothricin, the active substance of Tyrosur[®] Wound Healing Powder passes into breast milk enter the mother's milk. If you are breastfeeding, Tyrosur[®] Wound Healing Powder must not be used in the breast region. If you are breastfeeding, Tyrosur[®] Wound Healing

Powder must only be used for a short period of time on a small area of skin and only at the express instruction of your doctor. Avoid contact of the infant with the treated skin areas.

Driving and using machines:

No special precautions are required.

3. HOW TO USE TYROSUR[®] WOUND HEALING POWDER

Always use Tyrosur[®] Wound Healing Powder exactly as instructed in this package leaflet. Check with your doctor or pharmacist if you are not sure. Unless otherwise prescribed by your doctor, the usual dosage is:

Apply Tyrosur[®] Wound Healing Powder once to twice a day on the affected skin areas

Route of administration:
Powder for use on the skin.

Apply a thin layer of powder in the morning (and evenings) to the areas of skin to be treated and, if necessary, cover with a dressing.

Duration of administration:
The duration of administration depends on the severity and disease course. After the symptoms have subsided, Tyrosur® Wound Healing Powder should be used for about a week after the symptoms have subsided, to stop them from recurring.

If you have the impression that the effect of Tyrosur® Wound Healing Powder is too strong or too weak, talk to your doctor or pharmacist.

If you use more Tyrosur® Wound Healing Powder than you should:
No consequences are to be expected. Continue the treatment as described above.

However, if you should notice unusual symptoms, please contact your doctor.

If you forget to use Tyrosur® Wound Healing Powder:
Continue the treatment as stated in the dosage instructions.

Effects when treatment with Tyrosur® Wound Healing Powder is stopped:

The duration of treatment depends on the severity and course of the clinical condition.

If you discontinue treatment with Tyrosur® Wound Healing Powder too soon the desired effect may not occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tyrosur® Wound Healing Powder can cause side effects, although not everybody gets them.

The following frequencies are used for evaluating adverse reactions:

Very common:	more than 1 out of 10 persons treated
Common:	1 to 10 out of 100 persons treated
Uncommon:	1 to 10 out of 1000 persons treated
Rare:	1 to 10 out of 10000 persons treated
Very rare:	fewer than 1 out of 10,000 persons
Not known:	Frequency cannot be estimated from the available data

Possible side effects

Skin and subcutaneous tissue disorders
In very rare cases, hypersensitivity reactions may occur.

Reporting of side effects

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

You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices), Pharmacovigilance Dept.
Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn
Website: www.bfarm.de

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

5. HOW TO STORE TYROSUR® WOUND HEALING POWDER



Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the container and the folding box! The expiry date refers to the last day of that month.
Close the powder dispenser carefully after use!

Do not store above 25°C

6. FURTHER INFORMATION

What Tyrosur® Wound Healing Powder contains

The active substance is tyrothricin.

100 g powder for use on the skin contains 0.1 g tyrothricin.

The other ingredients are:

Lactose monohydrate, macrogol 6000, highly dispersed silicon dioxide.

What Tyrosur® Wound Healing Powder looks like and contents of the pack:

Tyrosur® Wound Healing Powder is available in packs with 5 g (N1) and 20 g (N2) powder for use on the skin.

Marketing Authorisation Holder and Manufacturer

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