

Package leaflet: Information for the user

Tyrosur® Wound Healing Gel

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 Gel 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 GEL IS AND WHAT IT IS USED FOR

2. BEFORE YOU USE TYROSUR® WOUND HEALING GEL

3. HOW TO USE TYROSUR® WOUND HEALING GEL

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TYROSUR® WOUND HEALING GEL

6. FURTHER INFORMATION

1. WHAT TYROSUR® WOUND HEALING GEL IS AND WHAT IT IS USED FOR

Tyrosur® Wound Healing Gel is a wound treatment agent.

Tyrosur® Wound Healing Gel is used

For the soothing 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 GEL

Do not use Tyrosur® Wound Healing Gel:
• if you are hypersensitive (allergic) to the active substance or any of the other ingredients of

Tyrosur® Wound Healing Gel.

- on the mucus membrane of the nose.

Take special care with Tyrosur® Wound Healing Gel

- When used near the eyes: the gel must not get into the eyes, as this may lead to a burning sensation.

Other medicines and Tyrosur® Wound Healing Gel:

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

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 Gel during pregnancy. The potential risk for humans is not known due to the lack of animal studies. Therefore, Tyrosur® Wound Healing Gel should not be used during pregnancy.

Breastfeeding:

It is not known whether tyrothricin or cetylpyri-

dinium chloride passes into breast milk, therefore do not use Tyrosur® Wound Healing Gel during breastfeeding.

Driving and using machines:

No special precautions are required.

Important information about some of the ingredients of Tyrosur® Wound Healing Gel:

Tyrosur® Wound Healing Gel contains propylene glycol and can therefore cause skin irritations.

3. HOW TO USE TYROSUR® WOUND HEALING GEL

Always use Tyrosur® Wound Healing Gel 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 a sufficient amount of gel 2 to 3 times a day.

Route of administration:

To be applied to the skin. Apply the gel in the morning, (afternoon) and evening so that the affected skin area is covered. A dressing is not usually required for minor injuries or skin inflammation on uncovered body parts. For weeping wounds it is recommended to apply a protective dressing, which should be renewed after 1-2 days or according to your doctor's instructions.

Duration of administration:

The duration of administration depends on the clinical picture.

If the symptoms worsen or if there is no improvement within one week, you must see a doctor.

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

If you use more Tyrosur® Wound Healing Gel than you should:

No consequences are to be expected. Continue the treatment as stated in the dosage instructions. However, if you should notice unusual symptoms, please contact your doctor.

If you forget to use Tyrosur® Wound Healing Gel:

Continue the treatment as stated in the dosage instructions.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tyrosur® Wound Healing Gel 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 treated
Not known:	Frequency cannot be estimated from the available data

Possible side effects

Skin and subcutaneous tissue disorders

In very rare cases, hypersensitivity reactions such as a burning sensation on the skin may occur.

Reporting of side effects

If you notice any side effects, please inform your doctor or pharmacist. This includes any possible 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 GEL

 **Keep out of the reach and sight of children.**

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

Do not store above 25°C
Do not use for longer than 3 months after the first use.

6. FURTHER INFORMATION

What Tyrosur® Wound Healing Gel contains

The active substance is tyrothricin.
100 g gel contain 0.1 g tyrothricin.

The other ingredients are:

Cetylpyridinium chloride 1 H₂O, propylenglycol, ethanol 96%, carbomer (40.000–60.000 mPa·s), trometamol, purified water.

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

Tyrosur® Wound Healing Gel is available in packs with 5 g (N1), 15 g and 25 g (N3) gel.

Marketing Authorisation Holder and Manufacturer

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