

Summary of product characteristics

1. NAME OF THE MEDICINAL PRODUCT

Tyrosur[®]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g gel contain 0.1 g Tyrothricin.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tyrosur[®] is used for the treatment of small, superficial and slightly weeping wounds with bacterial superinfection with tyrothricin-sensitive pathogens, such as lacerations, scratches, abrasion.

4.2 Posology, method and duration of administration

Tyrosur[®] should be applied 2-3 times daily in an adequate amount to cover the affected parts of the skin. For minor wounds or skin inflammations on uncovered parts of the body a dressing is usually not necessary. In case of weeping wounds a protective bandage is recommended, which should be renewed every 1-2 days or as instructed by the doctor.

The period of treatment depends on the clinical manifestation. If there is no improvement after one week, treatment should be re-evaluated. Where applicable a verification of the pathogens should be carried out.

4.3 Contraindications

Known hypersensitivity to the active ingredient or any of the other ingredients.
Not to be used on the nasal mucosa; there are reports that this may lead to an impairment of the olfactory sense.

4.4 Special warnings and precautions for use

Care should be taken when using close to the eyes as this may lead to a burning sensation.

Tyrosur[®] contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No medicinal products are known which affect the activity of Tyrosur[®] and the product is not known to affect the activity of any other medicinal product.

4.6 Pregnancy and lactation

Pregnancy

No data are available concerning the use of Tyrosur[®] in pregnancy. Adequate animal studies concerning the reproductive toxicity of tyrothricin and cetylpyridinium chloride have not been carried out (see 5.3). The potential risk for human beings is not known. Therefore Tyrosur[®] should not be used during pregnancy.

Lactation

It is not known whether tyrothricin or cetylpyridinium chloride pass into breast milk. Therefore Tyrosur[®] should not be used during lactation.

4.7 Effects on ability to drive and use machines

No special precautions are needed.

4.8 Undesirable effects

Incidence of side effects:

Very common:	≥ 1/10
Common	≥ 1/100 - < 1/10
Occasional	≥ 1/1000 - < 1/100
Rare	≥ 1/10.000 - < 1/1.000
Very rare	< 1/10.000
Not known	Frequency on the basis of available data not assessable

Cutaneous and subcutaneous tissue disorders

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

4.9 Overdose

Overdose has not been reported so far.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical antibiotic
ATC code: D06AX08

Tyrothricin is a compound of various cyclic and linear, antibacterially effective polypeptides, formed as endotoxin by the anaerobic spore-forming *Bacillus brevis*. The compound contains up to 70-80 % tyrocidins (basic cyclic decapeptides) and up to 20-30 % gramicidins (neutral linear pentadecapeptides).

The spectrum of activity mainly comprises gram-positive bacteria, but also a few gram-negative bacteria and various fungal species, including *Candida albicans*.

Tyrothricin has a dose-dependent bacteriostatic or bactericidal action on the following micro-organisms

	inhibitory value (µg/ml):
Staph. aureus MSSA	4
Staph. aureus MRSA	4
Staph. haemolyticus	4
Strep. pyogenes	0.5
Strep. viridans	1 - 5
Enterococcus faecalis	2
Diplococcus pneumoniae	1
Corynebact. spp.	2
Clostridia	0.1 - 10
Candida albicans	16
Candida parapsilosis	32

Inhibitory values of ≥ 50 µg/ml:

Neisseria meningitidis, some species of *Neisseria gonorrhoeae*, some fungi, *Trichomonas*.

Tyrocidin acts by releasing substances which contain nitrogen and phosphate from the bacterial cells. Similar to cationic detergents tyrocidin destroys the osmotic barrier of the bacterial cell membrane. Since this is a direct attack on the bacterial cell wall, the action is not limited to growing or self-dividing bacteria, and this explains the bactericidal effect of the tyrocidin component.

Gramicidins, on the other hand, form cation-bearing channels into the bacterial cell membrane, and as a result in particular of potassium loss particular this leads to changes in the intracellular cation concentration and finally to cytolysis. The gramicidin component further leads to an decoupling of the respiratory chain phosphorylation.

Due to the special mechanism of action of tyrothricin, which is not known in systemically used antibiotics, no cross-resistances have been observed.

In the treatment of wounds Tyrosur[®] is characterised not only by an outstanding antimicrobial action, but also by further properties that favour the healing process. Thus, it was shown in clinical studies that Tyrosur[®] –accelerates wound healing by cleansing the base of the wound as well as by stimulating tissue granulation and epithelialisation.

5.2 Pharmacokinetic properties

The extent to which tyrothricin is absorbed systemically is not known. High concentrations have been found in the stratum corneum (after application on intact skin) or directly in the wound.

5.3 Preclinical safety data

No toxic effects could be detected after s.c. or oral application of tyrothricine in mice and rats. However, tyrothricin shows a haemolytic potential in vitro and in dogs in vivo after i.v. application.

Investigations regarding a genotoxic potential, long-term-studies in animals concerning the tumorigenic potential of tyrothricin and studies concerning the reproductive toxicity have not been carried out.

In acute toxicity studies cetylpyridinium chloride caused convulsions and paralysis of the respiratory system and the somatic muscles. No relevant hints can be drawn from the present in vitro and in vivo studies that cetylpyridinium chloride might have a genotoxic potential. No long-term-studies concerning the carcinogenic potential of cetylpyridinium chloride have been carried out.

The reproductive toxicity potential of cetylpyridinium chloride is not sufficiently examined.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetylpyridinium chloride 1 H₂O, propylene glycol, ethanol 96%, carbomer (40 000 – 60 000 mPa s), trometamol, purified water.

6.2 Incompatibilities

No compatibility studies have been carried out. Therefore this product should not be mixed with other medicinal products.

6.3 Shelf life

Tyrosur[®] remains stable for a minimum of 3 years.

After first opening of the tube: 3 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 25 ° C.

6.5 Nature and contents of container

Aluminium tubes of 5 g and 25 g gel for topical administration.

6.6 Instructions for handling and disposal

None

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

N 16046

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25.07.2011

Date of latest renewal: 17.10.2016

10. DATE OF REVISION OF THE TEXT

November 2020

11. CLASSIFICATION

Pharmacy only medicine