

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tonsilotren

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet (250 mg) contains:

Active substances:

Atropinum sulfuricum trit. D5	12.5 mg
Hepar sulfuris trit. D3	10.0 mg
Kalium bichromicum trit. D4	50.0 mg
Silicea trit. D2	5.0 mg
Mercurius bijodatus trit. D8	25.0 mg

Excipients with known effect: lactose monohydrate, sucrose
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute tonsillitis, chronic or recurrent acute tonsillitis and enlargement of tonsils. To enhance the healing process after surgical removal of the tonsils.

4.2 Posology and method of administration

Posology

Adults: in *acute conditions*, 1 tablet is taken every hour, up to a maximum of 12 tablets per day, until improvement occurs. For *subsequent treatment* or in *chronic conditions*, 1-2 tablets are taken 3 times per day.

Paediatric population

Children aged 6 to under 12 years: in *acute conditions*, 1 tablet is taken every two hours, up to a maximum of 6 tablets per day, until improvement occurs. For *subsequent treatment* or in *chronic conditions*, 1 tablet is taken 3 times per day.

Children aged 12 years and older: in *acute conditions*, 1 tablet is taken every hour, up to a maximum of 12 tablets per day, until improvement occurs. For *subsequent treatment* or in *chronic conditions*, 1-2 tablets are taken 3 times per day.

Adults and children with *enlarged tonsils* take 1 tablet 3 times per day. It is recommended to continue the treatment for 6-8 weeks.

In *chronic and recurrent acute conditions*, several treatment cycles per year, each 6-8 weeks proved to be beneficial.

Method of administration

Tablets should be allowed to dissolve slowly in the mouth.

For young children, tablets can be crushed and then dissolved in a little bit of water.

An interval of at least half an hour to meals should be kept.

4.3 Contraindications

Hypersensitivity to chromium, mercury, any other of the active substances or any of the excipients listed in section 6.1.

Contraindicated in children under 6 years of age.

4.4 Special warnings and precautions for use

This medicinal product contains lactose and sucrose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Also patients with rare hereditary problems of fructose intolerance or sucrase-isomaltase insufficiency should not take this medicinal product.

A reassessment of the therapy is necessary

- if acute condition does not improve or worsens within first 2 days of treatment,
- if additional complaints arise, e.g. fever above 39°C.

Patients suffering from a thyroid disease are advised to consult a doctor before taking Tonsilotren.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with other medicinal products have not been observed. The use of this homeopathic medicinal product does not exclude the use of other medicinal products.

Patients are advised to consult a doctor if they are taking, have recently taken or might take any other medicinal products.

Note: The action of homeopathic medicinal products may be adversely affected by generally negative factors of living habits as well as by stimulants or drink and tobacco.

4.6 Pregnancy and lactation

Patients are advised to consult a doctor before using this medicinal product.

Like all pharmaceuticals, Tonsilotren must be taken during pregnancy and lactation only under consideration of the benefit-risk ratio assessment.

4.7 Effects on ability to drive and use machines

Tonsilotren has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Very rare (<1/10,000) or not known (frequency cannot be estimated from the available data): hypersensitivity reactions, e. g. skin rashes. In these cases, Tonsilotren should be discontinued and appropriate treatment measures have to be taken. If increased salivation appears, the dosage should be reduced or the medication discontinued.

Note: Existing complaints may temporarily become worse when homeopathic medicines are taken (initial homeopathic aggravation). In such cases, patients are advised to discontinue the medication and consult a doctor.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Homeopathic medicinal product.

Homeopathic therapy differs markedly from conventional medicine with regard to the understanding of disease and the use of medicinal substances. Homeopathic remedies stimulate the organism's own defence mechanisms and thereby activate its self-healing power. The response of the organism to a homeopathic remedy is highly individual. For these reasons dose-specific pharmacological effects, pharmacodynamic or pharmacokinetic data cannot be determined.

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable. Tonsilotren as a homeopathic pharmaceutical has not gone through preclinical testing.

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Sucrose, lactose monohydrate, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

Do not use after the expiration date indicated on the package.

6.4 Special precautions for storage

Store at a temperature not exceeding 25 °C. Store out of reach and sight of children.

6.5 Nature and contents of container

40 tablets. 2 blisters with 20 tablets and PIL in a box.

6.6 Special precautions for disposal

No special requirements.

7. MANUFACTURER

Dr. Gustav Klein GmbH & Co. KG
Steinenfeld 3, 77736 Zell am Harmersbach, Germany
Telephone: +49 (0) 7835 635530
www.klein-naturarznei.de

8. MARKETING AUTHORISATION HOLDER

Alpen Pharma GmbH, Steinenfeld 3,
77736 Zell am Harmersbach, Germany
Telephone: +49 (0) 7243 200 49 10
www.alpenpharma.com

9. MARKETING AUTHORISATION NUMBER(S)

[To be completed]

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1978

11. DATE OF REVISION OF THE TEXT

November 2023