

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tyrozets Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lozenge contains:

Tyrothricin 1 mg
Benzocaine 5 mg

Excipients with known effect:
Sucrose 989.19 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge
Pink, aniseed flavoured, flat bevelled-edge lozenges imprinted on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antibiotic and local analgesic-anaesthetic. For minor mouth and throat irritations; secondary irritation following tonsillectomy and other mouth and throat surgery.

4.2 Posology and method of administration

Adults and children 12 years and older: One lozenge to be dissolved slowly in the mouth every three hours. Do not exceed 8 lozenges in 24 hours.

Children aged 3 to 11 years: dosage should be reduced in children aged 3-11. Maximum 6 lozenges in 24 hours. Do not use this medicine in children less than 3 years of age.

If an adequate response is not evident within two days, consider stopping Tyrozets lozenges. Do not use for longer than five consecutive days.

To allow maximum contact with inflamed tissues, Tyrozets lozenges should not be chewed or swallowed whole, but allowed to dissolve slowly in the mouth.

4.3 Contraindications

Hypersensitivity to tyrothricin, benzocaine or to any of the excipients listed in section 6.1. If evidence of sensitivity occurs during therapy, Tyrozets lozenges should be discontinued.

4.4 Special warnings and precautions for use

The use of antibiotics may cause over-growth of non-susceptible organisms. If new infections due to bacteria or fungi appear during therapy, Tyrozets lozenges should be stopped and appropriate measures taken.

Topical use of Tyrozets lozenges as an aid to prevention of local infection in no way alters the need for adequate systemic

therapy if an infection should develop.

Benzocaine may cause methaemoglobinaemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. Patients should stop use and seek immediate medical attention if they develop pale, grey or blue coloured skin, lips and nail beds; headache; tachycardia; shortness of breath; dizziness or light-headedness; confusion; fatigue or lack of energy. Symptoms may occur at any time after using benzocaine.

Those most at risk of developing methaemoglobinaemia are children aged two or younger, the elderly and patients with certain inborn errors of metabolism such as glucose-6-phosphodiesterase deficiency, haemoglobin-M disease, NADH-methaemoglobin reductase (diaphorase 1) deficiency, and pyruvate-kinase deficiency. Patients who have breathing problems such as asthma, bronchitis, or emphysema, patients with heart disease, and patients who smoke are at greater risk for complications related to methaemoglobinaemia. In the most severe cases, methaemoglobinaemia can result in death.

Due to the local anaesthetic property of benzocaine food and drink should be avoided directly after taking a lozenge, to prevent any further trauma to the mucous membranes.

Tyrozets lozenges contain sucrose, which may produce dental caries and destabilise otherwise well-controlled diabetes.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

There have been no reports of any interactions.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of benzocaine and tyrothricin in pregnant women.

It is unknown whether benzocaine or tyrothricin or their metabolites are excreted in human milk.

This product should not be used during pregnancy and lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or nursing infant.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Blackness or soreness of the tongue may occur, but usually disappears when therapy is stopped.

Skin rashes have been reported to occur after benzocaine administration.

Methaemoglobinaemia has been reported to occur rarely in infants and children after benzocaine absorption.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms

Tyrozets lozenges should only be sucked in the mouth. Insertion into the nasal cavity can damage the sensory epithelium with risk of prolonged loss of smell.

There are no reports found in the literature describing the overdose potential of the combination of benzocaine and tyrothricin.

No adverse events were identified from the analysis of post-marketing data for the combination of benzocaine and tyrothricin.

Parenteral use of tyrothricin may result in haemolysis, liver and kidney damage.

Management

No antidote to either tyrothricin or benzocaine is available. Treatment of overdosage should be symptomatic and supportive; emesis should be induced or gastric lavage performed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat preparations, Antibiotics ATC code: R02AB02.

Tyrothricin from *Bacillus brevis* is a complex mixture of several polypeptides and its main action stems from the content of neutral gramicidins (20%), which neutralise the phosphorylation of the respiration chains. It is effective mainly against gram positive bacteria and cocci, against some fungi and some gram negative bacteria.

Benzocaine is a local anaesthetic of the ester type which remains localised for long periods of time to produce anaesthetic action. It is poorly soluble in water.

5.2 Pharmacokinetic properties

Tyrozets lozenges act locally in the mouth and throat and it is expected that only small amounts are absorbed by the buccal tissues.

5.3 Preclinical safety data

No specific information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acacia spray dried
Magnesium stearate
Maize starch
Sodium chloride
Sucrose
Anethole
Erythrosine (E127)
Peppermint oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from light.

6.5 Nature and contents of container

Packs of 12, 24 and 36 lozenges as one, two or three plastic tubes of 12 in cardboard cartons.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

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10 DATE OF REVISION OF THE TEXT

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