GERVETIN

INSTRUCTIONS FOR THE MEDICINAL PRODUCT

Trade name: Gervetin.
International Nonproprietary Name: Benzydamine hydrochloride.
Dosage form: Oromucosal solution.
Composition: 1 g oromucosal solution contains:
Active substance:
Benzydamine hydrochloride 1,5 mg.
Excipients: Methyl parahydroxybenzoate, glycerol, ethanol 96%, saccharin sodium, sodium hydrogen carbonate, polysorbate 60, aroma peppermint liquid 27198/14, color quinoline yellow 70 E 104, color indigotine 85 E 132, water purified.
Pharmacotherapeutic group: Other agents for local oral treatment.
ATCClassification: A01AD02.
Pharmacologic property:
Pharmacodynamics:
Benzydamine is a nonsteroidal anti-inflammatory drug with analgesic and antiexudative properties. Locally applied benzydamine also acts as an antiseptic and local anesthetic. In painful inflammatory conditions benzydamine exerts an analgesic effect. After local application action of benzydamine is enabled by its ability to penetrate through the epithelial layer, and required concentrations are achieved in inflamed tissue.
Pharmacokinetics:
Absorption through the mucous membranes of the mouth and pharynx is determined by the presence of measurable amounts of benzydamine in human serum, which, however, is not sufficient to cause systemic pharmacological action.
Excretion is mainly in the urine, mostly in form of inactive metabolites or products of conjugation.
Indications for use:
Symptomatic treatment of painful inflammatory conditions and oropharyngeal tract irritations (gingivitis, stomatitis, pharyngitis) and as a supplement to conservative dental treatment and after tooth extraction.
Contraindications:
Gervetin oromucosal solution is contraindicated in patients with:

- Known hypersensitivity to benzydamine or to any of the excipients;
- Known hypersensitivity to salicylic acid and/or nonsteroidal anti-inflammatory medicines;
- Problems with swallowing.

Pregnancy and Nursing Mother:
Gervetin oromucosal solution can be used during pregnancy and lactation only after evaluation of the possible risks/benefits ratio of therapy for each patient individually.

Dosage and directions for use:
Adults: Rinse or gargle with 15 ml (approximately 1 tablespoonful) every 1½ to 3 hours as required for pain relief.
The solution should be expelled from the mouth after use.
Children: Not suitable for children aged 12 years or under.
Elderly: No special dosage recommendations are made for elderly patients.
Gervetin should generally be used undiluted, but if 'stinging' occurs the rinse may be diluted with water.
Uninterrupted treatment should not exceed seven days, except under medical supervision.
Side-effects:
The frequency of undesirable effects is classified according MeDRA, as follows: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10000, <1/1000), very rare (<1/10000), frequency unknown (can not be estimated from available data).
According to System Organ Class, following undesirable effects are reported:

System Organ Class	Frequency	Undesirable effects
Gastrointestinal disorders	unknown (can not estimated from available data)	burning sensation in the mouth, dry mouth, nausea, vomiting
Immune system disorders	unknown (can not estimated from available data)	hypersensitivity reactions, anaphylactic reactions

Immediately after application of the medicine, numbness sensations in the mouth and throat may occur, as a result of the pharmacodynamic effect of benzydamine. Local undesirable effects usually are transient and completely reversible and rarely require additional treatment.
After local application Benzydamine is absorbed in small amounts in the bloodstream and therefore systemic undesirable effects are rarely possible.
Overdose:
Accidental ingestion of small quantities of oromucosal solution is harmless. In case of ingestion of large amounts of solution the following symptoms can occur: vomiting, abdominal pain, anxiety, fear, hallucinations, convulsions, ataxia, fever, tachycardia and respiratory paralysis. In the event of these symptoms symptomatic treatment is recommended, eg maintenance of respiration, elimination of the medicine (gastric lavage) etc.
Drug interactions:
No interactions have been observed.
Cautions:
Long term treatment with Gervetin can cause hypersensitivity. In this case treatment should be terminated and appropriate medical therapy should be applied.
If the improvement is not achieved after 7 days of therapy, it is necessary to seek medical advice.
The medicine should be kept out of the rich of children.
Effects on ability to drive and use machines.
The local use of Gervetin at the recommended dose does not affect the ability to drive and use machines.
Presentation:
Box with glass bottle with solution of 100 g and instruction leaflet.
Storage:
Keep in cool and dry place, protected from light at a temperature below 25°C.
Keep out of reach of children!
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

SPEY
The holder of Trade Mark and Marketing Authorization is:
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