**APPROVED**

Order of the Ministry

of Health of Ukraine

 No. 760 dated 04.07.2017

**Marketing Authorization**

# No. UA/16107/01/01

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## INSTRUCTION

## for medical use of medicinal product

**ZIPELOR**

***Composition:***

*active ingredient*: benzydamine;

1 ml of spray contains 1.5 mg of benzydamine hydrochloride;

*excipients*: ethanol 96%, glycerol, methylparaben (E 218), sodium saccharin, sodium bicarbonate, polysorbate 20, peppermint flavour, purified water.

**Pharmaceutical form**

Mouth spray.

*Basic physical and chemical properties*: transparent, colourless liquid with a characteristic peppermint odour.

**Pharmacotherapeutic group**

Stomatological preparations. Other agents for local oral treatment. ATC Code A01A D02.

**Pharmacological properties**

*Pharmacodynamics*

Benzydamine is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antiexcudative properties.

In clinical studies, benzydamine has been proven to be effective for the relief of the symptoms associated with local irritating pathological processes in the oral cavity and pharynx. In addition, benzydamine has an anti-inflammatory and local anesthetic effect on the mucous membrane of the oral cavity.

*Pharmacokinetics*

The absorption through the mucous membrane of the oral cavity and pharynx was proven by the presence of detectable amounts of benzydamine in human blood plasma. However, they are not sufficient to have any systemic pharmacological effect. The drug is mainly eliminated with the urine, mainly in the form of inactive metabolites or conjugated compounds.

It has been shown that its local use results in the accumulation of an effective concentration of benzydamine in the inflamed tissues due to its ability to penetrate through the mucosa.

**Clinical particulars**

*Indications*

Symptomatic treatment of irritations and inflammations of the oropharynx; pain caused by gingivitis, stomatitis, pharyngitis; in dentistry after tooth extraction or for prophylaxis.

***Contraindications***

Hypersensitivity to the active ingredient or other components of the drug.

***Interaction with other medicinal products and other types of interactions***

No studies of drug interactions have been conducted.

**Special warnings and precautions for use**

If sensitivity occurs during prolonged use, discontinue treatment and consult a doctor for appropriate treatment.

In some patients, ulcers of the mucosa of the cheeks/pharynx may be caused by serious pathological processes. Therefore, patients whose symptoms have worsened or not relieved within 3 days or who have fever or other symptoms should seek advice of a doctor or dentist, if necessary.

Benzydamine should not be used in patients with hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.

The drug may cause bronchospasm in patients with bronchial asthma or history of bronchial asthma. Such patients should be warned about this.

For athletes: the drugs containing ethyl alcohol may give positive results of anti-doping tests.

*Use during pregnancy or breastfeeding*

No reliable data is available on the use of benzydamine in pregnant and breastfeeding women. The ability of this drug to penetrate into breast milk has not been studied. Animal studies are not sufficient to draw any conclusions on the effects of this drug during pregnancy and breastfeeding. The potential risk to humans is unknown.

Zipelor should not be used during pregnancy or lactation.

***Effects on ability to drive and use machines***

When used in recommended doses, the drug has no effect on the ability to drive or operate machinery.

***Posology and method of administration***

Before use a nebulizer should be attached.

When the pump is pressed, an aerosol is formed containing 1 dose of a spray, 0.17 ml, which equals to 0.255 mg of benzydamine hydrochloride.

*Dosage*

Adults: 4 - 8 sprays 2 - 6 times a day.

Children (6-12 years): 4 sprays 2 - 6 times a day.

Children (4 to 6 years): 1 spray for every 4 kg of body weight. The maximum dose is equivalent to 4 sprays 2 - 6 times a day.

Do not exceed the recommended dose.

*Children*

The drug can be used in children over 4 years.

***Overdose***

There were no reports on overdose of benzydamine during local use.

However, it is known that benzydamine, when ingested in high doses (which is hundreds of times higher than the possible doses of this dosage form), especially in children, may cause excitation, convulsions, tremors, nausea, excessive sweating, ataxia and vomiting. Such an acute overdose requires immediate gastric lavage, treatment of water-electrolyte balance disorders, symptomatic treatment and adequate hydration.

***Undesirable effects***

Adverse reactions are classified according to the frequency of occurrence: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10000 to <1/1000); very rare (<1/10000); unknown (cannot be estimated from available data).

In each group the adverse effects are indicated in order of decreasing severity.

*Gastrointestinal disorders*: rare - a burning sensation in the mouth, dry mouth; frequency unknown - hypoesthesia of the oral cavity, nausea, vomiting, swelling and discoloration of the tongue, dysgeusia.

*Immune system disorders*: rare - hypersensitivity reactions; frequency unknown - anaphylactic reactions.

*Respiratory, thoracic and mediastinal disorders*: very rare - laryngospasm; frequency unknown - bronchospasm.

*Skin and subcutaneous tissue disorders*: uncommon - photosensitivity; very rare - angioedema; frequency unknown - rash, itching, urticaria.

*Nervous system disorders*: frequency unknown - dizziness, headache.

***Shelf life***

2 years.

Do not use after the expiry date stated on the package.

**Storage**

Store in the original package. Store below 25° C.

Keep out of the reach of children.

**Nature and contents of container**

15 ml or 30 ml in a bottle. 1 bottle in a pack.

**Prescription status**

Without prescription.

**Manufacturer**

JSC Farmak.

**Location**

74, Frunze St., Kyiv 04080, Ukraine

**Date of the last revision**

04.07.2017.