

The instruction on use of medicinal product
(for patients)

METROGYL DENTA® stomatological gel

International non-proprietary name: Metronidazole + Chlorhexidine

Composition

Active ingredients: 1 g of gel contains 16,0 mg metronidazole benzoate (equivalent to metronidazole 10 mg), 2,5 mg chlorhexidine digluconate 20% solution (equivalent to chlorhexidine digluconate 0,5 mg).

Auxiliary substances: propylene glycol, carbomer-940, disodium edetate, sodium saccharine, levomenthol, sodium hydroxide.

Description

Opalescent, white or almost white homogeneous gel.

Pharmacotherapeutic group

Antimicrobial remedy.

ATC code: A01AB11

Pharmacological properties

The formulation is effective because it contains two antibacterial components:

a) **metronidazole** has antibacterial action against anaerobic bacteria, which cause diseases of the parodontium: *Porphyromonas gingivalis*, *Prevotella intermedia*, *Fusobacterium fusiformis*, *Wolinella recta*, *Eikenella corrodens*, *Borrelia vincenti*, *Bacteroides melaninogenicus*, *Selenomonas spp.*

b) **chlorhexidine** is an antiseptic and antibacterial, which is effective against gram-positive and gram-negative aerobic and anaerobic bacteria (*Treponema spp.*, *Neisseria gonorrhoeae*, *Trichomonas spp.*, *Chlamydia spp.*, *Ureaplasma spp.*, *Bacteroides fragilis*). Some strains of *Pseudomonas spp.* and *Proteus spp.* are slightly sensitive to this formulation. Acid-resistant forms of bacteria and spores of bacteria are also resistant to this formulation. The formulation does not damage the functional activity of lactobacilli.

When used locally, **Metrogyl Denta®** gel is practically not absorbed.

Indications for use

Infectious-inflammatory diseases of the parodontium and mucosa of the oral cavity:

- acute and chronic gingivitis;
- acute necrotizing ulcerative gingivitis (Vincent's gingivitis);
- acute and chronic parodontitis;
- juvenile parodontitis;
- parodontosis complicated by gingivitis;
- aphthous stomatitis;
- pulpitis;
- cheilitis;
- inflammation of the mucosa in the oral cavity caused by use of dentures;
- post-extraction alveolitis (inflammation of the cavity after removal of the tooth);
- periodontitis, periodontal abscess (as part of combination therapy).

Contraindications

Individual intolerance of metronidazole, chlorhexidine, as well as of nitroimidazole derivatives. Intolerance to any components included in the composition of remedy. Children under 6 years old.

Special instructions

Use of **Metrogyl Denta®** gel does not replace the hygienic cleaning of teeth. Therefore, patients must continue to clean their teeth during the course of treatment.

If the drug has come into disrepair or expired - do not throw it in the waste water or on the street! Place the drug in the package and put it in the dumpster. These measures will help protect the environment!

Drug interaction

Systemic interaction of **Metrogyl Denta®** gel with other drugs has not been observed when it is used locally at the recommended dosage.

Use during pregnancy and lactation

This formulation should not be prescribed for pregnant women in the first trimester of pregnancy. It is

necessary to consider discontinuation of breast feeding, if the formulation is to be prescribed during the lactation period.

Directions for use and dosage

Local, only for stomatological use.

Adults and children over 6 years for inflammation of the gums (gingivitis): apply **Metrogyl Denta**[®] as a thin layer on the gums twice daily using a finger or swab. Avoid drinking and eating for 30 minutes after applying the gel. Do not remove the gel by rinsing. The average duration of treatment is 7-10 days.

In parodontitis: after removing the dental deposits, treat the parodontal pockets with **Metrogyl Denta**[®] gel and apply the gel on the gums. The exposure time should be 30 minutes. The number of treatments depends upon the severity of the disease. Further application of the gel can be carried out by the patient independently: apply **Metrogyl Denta**[®] gel on the gums twice daily during 7-10 days.

In aphthous stomatitis: apply **Metrogyl Denta**[®] gel on the affected part of the mucosa in the oral cavity twice daily during 7-10 days.

Prophylaxis of aggravation of chronic gingivitis and parodontitis: apply **Metrogyl Denta**[®] gel on the gums twice daily during 7-10 days. Prophylactic courses of treatment can be conducted 2-3 times yearly.

Prophylaxis of post-extraction alveolitis: after the extraction of a tooth the cavity treated with **Metrogyl Denta**[®] gel, then gel applied outpatient 2-3 times daily during 7-10 days.

Adverse effects

When **Metrogyl Denta**[®] gel is used locally there may be allergic reaction (skin rash, itching, urticaria), as well as headache.

Overdose

Accidental or deliberate ingestion of large amounts of gel may be reason increasing of side effects, mainly due metronidazole (chlorhexidine is practically not absorbed from the gastrointestinal tract). May be occur: nausea, vomiting, dizziness, in more severe cases - paresthesias, and seizures. Treatment: gastric lavage, as necessary symptomatic therapy.

Presentation

- 20 g gel in a plastic laminated tube with nozzle sealed with aluminium foil laminated with polyethylene and screw cap made of polypropylene. One tube with instructions for use is put in a cardboard packing.

- 20 g gel in a plastic laminated tube with nozzle sealed with aluminium foil laminated with polyethylene and screw cap made of polypropylene with a spike for piercing the foil. One tube with instructions for use is put in a cardboard packing.

Storage conditions

Store at a temperature not exceeding 25°C.

Keep out of the reach and sight of children.

Shelf life

3 years.

Do not use after expiry date.

Conditions of sale from pharmacies

Without prescription.

Manufacturer

Unique Pharmaceutical Laboratories

(A division of «J.B. Chemicals and Pharmaceuticals Ltd.»)

Worli, Mumbai - 400 030, India

Address of manufacturing site

Plot № 304-308, G.I.D.C. Industrial Area, Panoli 394 116, Gujarat State, India.

The organization that receives a claim

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