

FOGUM GEL FOR HEALTHY GUMS

COMPOSITION:

Chlorhexidine Gluconate.....0.25%
Metronidazole.....10mg

DESCRIPTION:

FOGUM GEL contains metronidazole, at a concentration of 10mg per gram (1%). Metronidazole is classified therapeutically as an antiprotozoal and antibacterial agent. The mechanism by which topical metronidazole acts, is not known but appears to include an antimicrobial and/or anti-inflammatory effect.

FOGUM GEL also contains Chlorhexidine at a concentration of 0.25%. Chlorhexidine is a bisbiguanide antiseptic and disinfectant which is bactericidal or bacteriostatic against a wide range of Gram-positive and Gram-negative bacteria. Chlorhexidine gluconate is also active against some viruses, bacterial spores and fungi especially *Candida* spp.

Chlorhexidine kills the microorganisms associated with various mouth and throat infections. These include the *Candida albicans* fungi that causes thrush infection in the mouth, and bacteria that may infect mouth ulcers or other sore areas in the mouth, e.g. after dental surgery. Infection of these areas increases discomfort and delays healing.

Chlorhexidine has also been shown to prevent the formation and build up of plaque on teeth and helps prevent gingivitis. It can therefore be used as an aid to oral hygiene, particularly in instances where tooth brushing is a problem, e.g. following dental surgery or in physically or mentally handicapped people. Chlorhexidine gel may be used to brush the teeth, or for direct application to sore areas in the mouth.

INDICATIONS AND USAGE:

- Prevent and treat Gingivitis (gum disease)
- Promote gum healing after surgery
- Manage recurring mouth ulcers
- Manage denture sore mouth
- Oral thrush
- Prevent plaque build-up on the teeth

CONTRAINDICATIONS:

FOGUM GEL is contraindicated in individuals with a history of hypersensitivity to chlorhexidine, metronidazole or other ingredients of the formulation.

PRECAUTIONS:

General:

FOGUM GEL has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided. If a reaction suggesting local irritation occurs, patients should be directed to use the medication less frequently or discontinue use.

Metronidazole in **FOGUM GEL** is a nitroimidazole and should be used with care in patients with evidence of, or history of blood dyscrasias.

FOGUM GEL is incompatible with certain ingredients of some toothpastes. Toothpastes should be used first and the mouth (and toothbrush also if necessary) rinsed before using **FOGUM GEL**, or they should be used at different times of the day.

When treating mouth ulcers or oral thrush infections, treatment should be continued for two days after the symptoms have cleared up. When treating inflammation caused by denture rubbing, the dentures should be cleaned and soaked for 15 minutes twice a day in chlorhexidine mouthwash.

DRUG INTERACTIONS:

Oral metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin resulting in a prolongation of prothrombin time. The effect of topical metronidazole on prothrombin time is not known.

PREGNANCY:

Teratogenic effects: Pregnancy category B:

There has been no experience to date with the use of **FOGUM GEL** (metronidazole –chlorhexidine gel) in pregnant patients. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. No fetotoxicity was observed after oral metronidazole in rats or mice. However, because animal reproduction studies are not always predictive of human response and since oral metronidazole has been shown to be a carcinogen in some rodents, this drug should be used during pregnancy only if clearly needed.

NURSING MOTHERS:

After oral administration, metronidazole is secreted in breast milk in concentrations similar to those found in the plasma. Even though **FOGUM GEL** blood levels are significantly lower than those achieved after oral metronidazole, a decision should be made whether to discontinue nursing or to discontinue the gel, taking into account the importance of the gel to the mother.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

The following adverse experiences have been reported with the topical use of Metronidazole-Chlorhexidine combination: burning, irritation, dryness, transient redness, metallic taste, staining of teeth, tingling or numbness of extremities and nausea.

DOSAGE AND ADMINISTRATION:

Apply a thin film of **FOGUM GEL** 3-4 times daily, morning and evening, to the entire affected area after rinsing mouth. Areas to be treated should be cleansed before application of **FOGUM GEL**.

HOW SUPPLIED:

FOGUM GEL is available in a 10gm tube.