



Mouthwash

Helps the process of regeneration of the **oral mucosa**

DO NOT USE FOR INDICATIONS OR APPLICATIONS THAT ARE NOT SPECIFICALLY NOTED IN THE INSTRUCTIONS FOR USE

INTENDED USE

Mucosamin® Mouthwash is a medical device which conforms to EU Directive 93/42/EEC and has a predominantly protective action on the oral mucosa. The product contains hyaluronic acid, a key component of connective tissue, and amino acids intended to promote the formation of collagen. The protective action of the ingredients is intended to help the process of regeneration of the oral mucosa in order to promote the rapid healing of areas of ulceration, resulting in a simultaneous reduction in pain.

Mucosamin® Mouthwash is specifically for use: at the start of radiological therapy or chemotherapy to help reduce the incidence of mucositis; in the treatment of mucositis due to radiotherapy or chemotherapy; in ulcerative pathologies of the oral cavity (e.g. pemphigus, pemphigoid, erosive lichen planus); in recurrent aphthous stomatitis; following surgical operations on the tongue and oral mucosa; and in burning mouth syndrome also secondary to Sjogren's syndrome.

DESCRIPTION

Mucosamin® Mouthwash is a topical oral solution that can be used to hydrate the oral mucosa, on which it exerts a protective effect. It helps to prevent and alleviate the irritation of the oral cavity that is usually caused by mucositis. Mucosamin® Mouthwash also aids the process of repair of damaged mucosal tissues of the oral cavity, helping to reduce local sensitivity within the mouth while at the same time promoting maintenance and restoration of physiological conditions.

COMPOSITION

PURIFIED WATER, SODIUM HYALURONATE, GLYCINE, L-PROLINE, L-LEUCINE, L-LYSINE HCl, METHYL PARAHYDROXYBENZOATE, PROPYL PARAHYDROXYBENZOATE, PROPYLENE GLYCOL, POLYVINYLPIRROLIDONE K90, MINT LIQUORICE FLAVOURING, SODIUM SACCHARIN, POLYSORBATE 20, E131 85% PATENT BLUE COLOURING, TETRASODIUM EDTA.

PACKAGING

250 ml bottle.

MODE OF ACTION

Lesions of the oral cavity are characterised by erythema and ulcers of the mucosa with recurrent burning pain of varying severity. Severe forms of mucositis have a heavy impact on quality of life and can compromise the ability of a patient to tolerate the scheduled therapeutic treatment plan. Oral mucositis caused by radiotherapy or chemotherapy is a common side effect in patients with cancer. The damage to the mucosa develops with an initiation phase followed by a phase of damage amplification: the outcome is a phase of ulceration followed by a phase of tissue repair. Mucosamin® Mouthwash, because of its ability to hydrate and protect the oral mucosa, is intended for use at the start of radiotherapy or chemotherapy, in order to reduce the incidence of mucositis. Mucosamin® Mouthwash, when used in the treatment of lesions of the oral cavity, has a dual action. The first action forms a film that covers and protects the ulcerated mucosa, which helps to reduce the pain and burning sensations. The second action is where hyaluronic acid and amino acids help to promote the repair of the oral mucosa during the regenerative phase.

INSTRUCTIONS FOR USE

After cleaning the oral cavity as described in the section on 'precautions' below, rinse with the product throughout the oral cavity, concentrating on the damaged area. It is always appropriate to combine the use of Mucosamin® Mouthwash with a diet free of acidic or spicy foods.

PRECAUTIONS FOR USE

Before treatment, remove any foreign matter from the ulcerated area by rinsing or gently cleaning with gauze. Do not stop using any antifungal therapies that may have been prescribed.

CONTRAINDICATIONS

Contraindicated in the event of known hypersensitivity to the ingredients. There have been no reports of overdose. There have been no reports of side effects. There have been no reports of interactions with drugs or medicinal substances. Although there are no known secondary effects during pregnancy and breastfeeding, it is left to the physician to decide whether prescribing is appropriate. Mucosamin® Mouthwash is generally well tolerated.

WARNINGS

Expiry refers to product that is sealed and properly stored. Do not use after the expiry date. Do not sterilise. Do not use if the packaging is opened or damaged. Do not use in the event of known hypersensitivity to the ingredients. Keep out of reach of children. In the event of adverse reactions, stop using the treatment and consult a physician.

DOSAGE AND ADMINISTRATION

Gently pour 5-10 ml of Mucosamin® Mouthwash into the mouth, distributing the product evenly throughout the oral cavity and keeping it in your mouth for at least one minute. Use Mucosamin® Mouthwash three or four times a day. Do not rinse after treatment. For the rear sections of the oral cavity, the product can be gargled. The product may be diluted with water, according to the severity of symptoms, if required.

DISPOSAL

Please dispose of carefully.

STORAGE

Mucosamin® Mouthwash should be stored between 8 °C and 30 °C. Do not keep in the refrigerator. Store in a cool dry place, away from damp and sources of heat.

MANUFACTURER

Professional Dietetics S.p.A. - Via Ciro Menotti, 1/A - 20129 Milan - Italy



Read instructions for use



Do not use if package is damaged



Do not dispose into the environment



Temperature limit between 8°C and 30°C



Keep away from moisture



Keep away from heat



CE mark accompanied by Notified Body identification no. (0373: ISS) - signifies European technical conformity

BARCODE 8021756001808

Document code

IFI MUMI VS 240829 REV.05



Via Ciro Menotti, 1/A - 20129 Milan - Italy