



SOLUMIUM® DENTAL

ANTIMICROBIAL SOLUTION FOR DENTISTS

30 ml

INSTRUCTIONS FOR USE

BASIC FACTS

SOLUMIUM® DENTAL is an antimicrobial agent for therapeutical and preventive purposes in dentistry and oral surgery. It is equally suitable for professional or home use.

SOLUMIUM® DENTAL kills all pathogenes including bacteria, fungi, protozoa, and viruses, including those in microbial biofilms responsible for various infections. At the same time, SOLUMIUM® DENTAL is not harmful to humans (see paragraph "SCIENTIFIC BACKGROUND").

SOLUMIUM® DENTAL does not sting, and may freely come into contact with the teeth, the skin, and the mucous membrane. The product does not discolor teeth. It does not induce a hardening or metaplasia of the mucous membrane of the mouth.

Chemically, SOLUMIUM® DENTAL is an aqueous solution of high purity chlorine dioxide (ClO₂), the compound responsible for the liquid's yellow color, and characteristic smell. There are no other ingredients in it. SOLUMIUM® products are made using a new, patented method [2].

The product is highly volatile, allowing it to move through air pockets (e.g. during root canal disinfection). After treatment, it evaporates with no residues, enabling the treated region to heal naturally.

Because of the product's volatility, please close bottle cap tightly, immediately after use. Fading of its yellow color indicates depletion of the solution. If the liquid becomes colorless, it is ineffective.

Please avoid spilling the product on clothes, as it may discolor them.

There are some applications which are simple to perform but need the product to be used several times a day or for several days (like in sections 3, 4 and 5). In those cases the dentist may choose to provide the patient with the required SOLUMIUM® product, so that the patient can apply the product at home.

Please note that shelf life of the product is guaranteed only in its original packaging.

SOLUMIUM® DENTAL - HOW TO APPLY:

1. Endodony (root canal treatment)

Use SOLUMIUM® DENTAL for the sterilization of the root canal cavity system, during mechanical exploration of the pulp, after each instrument change, and before root canal filling.

Rinsing method: Take up 0.4 - 0.5 ml of SOLUMIUM® DENTAL concentrate into a 2 ml syringe, and use it to flush the root canal. Use a thin (0.4 mm) needle, and rinse using mild pressure, for 0.5 to 1 min. That period is sufficient for the product to penetrate and sterilize all regions of the cavity system.

After rinsing with the concentrate, it is advisable to flush the treated area with a diluted solution of SOLUMIUM® DENTAL. Take up cca. 0.1 ml of SOLUMIUM® DENTAL into the 2 ml syringe, and fill the rest of the syringe with water. Use that liquid for a fast rinsing of the root canal. This method removes most of the concentrate together with the smear layer that formed during root canal treatment.

After the above process, root canal filling can be performed safely.

2. Oral surgery

For oral sterilization before surgery, dilute 1 part of SOLUMIUM® DENTAL with 15-20 parts of lukewarm water. Rinse with the freshly diluted liquid for about 15-20 seconds to decrease microorganism number very effectively. For children under 4 it is advisable to apply the diluted solution by brushing. Suggested device for brushing: plastic stick cotton buds.

3. Periodontology (diseases of the supporting structures of teeth)

SOLUMIUM® DENTAL prevents supralingual colonization of plaque bacteria, maintains intraoral ecological balance, and prevents proliferation of bacteria.

Methods: brushing, spraying, impregnated band insertion.

Isolate the area of the mouth to be treated, and use the concentrate for 1-2 minutes on the infected soft tissues. Repeat the procedure every 2 days until the symptoms disappear.

4. Contagious mouth diseases

To treat oral or facial herpes, canker sore, and bacterial or fungal infections of the mouth, brush using undiluted SOLUMIUM® DENTAL. Use once a day, or once in every 2 days, until the symptoms disappear.

5. Acute infectious tooth illnesses with pain and inflammation

To treat and extinguish a bacterial inflammation, apply a small gauze pad impregnated with SOLUMIUM® DENTAL, and press it against the infected area, for 30 seconds to 1 minute. Apply once or two times a day until the toothache is gone.

SOLUMIUM® DENTAL has no known long-term side effects.

If applied at an acute injury area on the mucous membrane, a temporary and mild feeling of burning, and an increased secretion of saliva might occur. Directly after treatment, a temporary feeling of drought and a reduced sense of taste might arise. These mild symptoms cease completely within a few hours.

SCIENTIFIC BACKGROUND

SOLUMIUM® DENTAL is an aqueous solution of high purity chlorine dioxide (ClO₂). Chlorine dioxide is an ideal local antiseptic: it is typically more effective than any other antimicrobial agent or disinfectant, while it is harmless to humans [1]. The use of chlorine dioxide as an antimicrobial agent in dentistry has previously been stalled because it was not available in a clean and stable solution. SOLUMIUM® products contain chlorine dioxide in very high purity made possible by a new patented invention [2]. The high purity of SOLUMIUM® means that it is harmless to human tissues, and its storage time is greatly extended. Chlorine dioxide is a so-called size-selective antimicrobial agent: in the concentration needed for treatment it kills all the microbes rapidly but cannot harm the much larger humans during the few minutes of a treatment [1].

[1] "CHLORINE DIOXIDE IS A SIZE-SELECTIVE ANTIMICROBIAL AGENT" (Plos One, November 5, 2013)

[2] "PERMEATION METHOD AND APPARATUS FOR PREPARING FLUIDS CONTAINING HIGH PURITY CHLORINE DIOXIDE" (WO/2008/035130)

INGREDIENTS:

High purity chlorine dioxide (ClO₂) (CAS: 10049-04-4) (0,12% / 1200ppm), water.

ANTIMICROBIAL SPECTRUM:

Bactericide, fungicide, virucide.

DO NOT MIX WITH OTHER ANTIMICROBIAL AGENTS.

KEEP OUT OF REACH OF CHILDREN.

STORAGE:

Close the bottle firmly, immediately after use. Keep the bottle in a dark, cool place, like a refrigerator, above freezing point. If not placed in a refrigerator, the bottle should be put back into its box, to protect it from light. Do not expose the bottle to strong sunlight for a longer time, as that can decrease its concentration. It is advisable to remove the bottle from refrigeration well before treatment, so that the patient is not disturbed by the coldness of the liquid.

BEST BEFORE:

Potency of the unopened, properly stored product is guaranteed for 2 years from date of manufacture.

See date of expiry on packaging. Please note that the product may still be effective even after several years of storage as long as it is yellow.

ECOTOXICITY:

Toxic to aquatic life. Must be diluted to a concentration below 0.8 ppm before discharging to surface water or ground water.

MANUFACTURED BY:

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PATENTS:

EP2069232; US 8,512,671; CN101605720

MEDICAL DEVICE



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MADE IN HUNGARY

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