

Rev. 4 - 11/2019

SPORIGERM' PERACETIC PLUS

Cold steriliser disinfectant

active in 10 minutes on spores, HIV, HCV, HBV, TBC, fungi and bacteria

Medical Device Class Ilb CE n° 0546

INDICATIONS

SPORIGERM PERACETIC PLUS

is a disinfecting/sterilising powder for invasive surgical instruments.

The active ingredient, the peracetic acid, is formed "in situ" after having dissolved the powder in water to obtain an aqueous solution of peracetic acid.

SPORIGERM PERACETIC PLUS can also be used on endoscope reprocessors and is effective for the fast disinfection and sterilisation of: endoscopes, optic fibre, surgical and dental instruments, transducers.

INSTRUCTIONS FOR USE

Dilute SPORIGERM PERACETIC PLUS using lukewarm fresh water at a temperature of approx. 35° C; the solution thus obtained will appear clear, light blue in colour and ready for use after 15 minutes. The solution, once completely colourless, can be used to immerse tools previously washed in the following way:

To decontaminate/disinfect:

Use 8 g of powder (equal to one dosing spoon) for each litre of water for 10 minutes. After contact time, remove and rinse thoroughly.

To sterilise:

Use 16 g of powder (equal to two dosing spoons) for each litre of water for 10 minutes. Subsequently remove the instruments and rinse in sterile water.

For aseptic storage use suitable product.

The solution is active for a maximum time of 24 hours from preparation.

After use, the diluted product can be disposed of as non-hazardous waste.

PACKAGING

Sporigerm Peracetic Plus

Code 502002......2 jars, 500 g each

Primary packaging in compliance with the technical specifications established by Farmacopea. These materials do not contain latex and are fully compatible with all the components of the formulated.

COMPOSITION 100 g of product

Tetraacetylethylenediamine......25.00 g; Sodium percarbonate...........42.00 g; Co-formulants q.s. at100.00 g; Bacteria with Spores

Protozoa with Cysts

Mycobacteria

Non-Enveloped Viruses

Fungi

Vegetative Bacteria

Enveloped Viruses

INFORMATION FOR THE EXCLUSIVE USE OF HEALTHCARE PROFESSIONALS

Manufactured by:

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Distributed by:

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Disinfettante sterilizzante a freddo

Cold sterilizer disinfectant



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PATHOGENIC AGENTS CLASSIFIED ACCORDING TO THEIR RESISTANCE TO DISINFECTANTS

ACTION

Results of the antimicrobial effectiveness tests are summarised in the following table:

CHARACTERISTICS

Granular powder white in colour,

might have light blue shades.

EN13727; EN14561

Bactericidal 0.4% 10 min

EN13624: EN14562

Yeasticidal (C. Albicans)0.4% 10 min EN14563

Mycobactericidal/Tuberculocidal.... 0.4% 10 min EN13704

Sporicidal0.8% 10 min

EN13624; EN14562

Fungicidal (A. brasiliensis)1.6%.....10 min EN14476

EN14937

Cold steriliser 1.6% 10 min

Bacteria with Spores

B. subtitles, C. tetani, C. difficile, C. botulinum

Protozoa with Cysts

Giardia lablia, Cryptosporidium parvum

Mycobacteria

M. tubercolosis, M. Avium intracellulare, M. chelonae

HIGH LEVEL DISINFECTANTS

CHEMICAL

STERILISERS

PRODUCT VALIDITY

The product has a validity of 2 years from the manufacturing date, it is to be stored in its original package. The product is affected by moisture

Non-Enveloped Viruses

Coxsachievvirus, Poliovirus, Rhinovirus, Norwalk-like virus, Hepatitis A virus, Murine norovirus, Adenovirus

Fungi

Candida species, Cryptococcus species, Aspergillus species, Dermatophytes

MID-LEVEL DISINFECTANTS

Vegetative Bacteria

Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginosa, Coliforms Legionella pneumophila, MRSA, VRE, Enterococcus hirae

LOW LEVEL DISINFECTANTS

Enveloped Viruses

Herpex simplex, Varicella-zoster virus, Cytomegalovirus, Measles virus, Mumps virus, Rubella virus, Influenza virus, Respiratory syncytial virus, Hepatitis B & C viruses, Hantavirus, HIV, Rotavirus, Coronavirus (SARS, MERS), Herpesviridae, Filoviridae (Ebola), Rabies, Human T Cell Leukemia Virus

STORAGE

To be stored in cool, dry areas away from heat sources.

QUALITY CONTROL

All components (raw materials, containers, labels etc.) together with the processing phases of each batch are punctually and thoroughly checked internally according to the corporate UNI EN ISO 9001 and UNI EN ISO 13485 certified Quality Management System.

AUTHORISATIONS

Class IIb CE 0546 medical device complying with Directive 93/42/EEC as amended by directive 2007/47/EEC

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