Instructions for Use

HYDROCYN[®]

Solution

INGREDIENTS

Active − HOCl (0.003%) Inactive − NaOCl + NaCl (≤ 0.1%) Purified Water (99.9%)

INDICATION

HYDROCYN aqua Solution is indicated as a wound wash, debridement agent & cleaning solution for acute and chronic wounds in stage I- IV ulcers, venous stasis & diabetic ulcerations, surgical wounds, burns ($1^{\rm st}-2^{\rm nd}$ degree) and bed sores. It also helps in moistening wound and control malodour. It is possible to use HYDROCYN aqua Solution in peritoneal and for instillation in Negative Pressure Wound Therapy (NPWT), provided compatibility against the NPWT devices has been verified by medical professionals.

HYDROCYN aqua Solution has ancillary antimicrobial properties that support wound healing. It is also proven to be effective against biofilm.

HYDROCYN aqua Solution meets the US Pharmacopoeia 41 NF 36, Chapter 51 – Antimicrobial Effectiveness Test. The solution contains hypochlorous acid and sodium hypochlorite acting as preservatives to reduce/prevent the growth of microorganisms within the solution.

DIRECTION FOR USE

HYDROCYN aqua Solution is ready for use with no mixing or dilution required. Apply directly to the affected area. Use at each wound dressing change. Saturation of the dressing with HYDROCYN aqua Solution will assist with dressing removal.

NOTE

Soak/saturate dressing with HYDROCYN aqua Solution at each dressing change and when required. Immersion is allowed for a maximum of 15 minutes, daily, during initial treatment.

STORAGE CONDITION

HYDROCYN aqua Solution should be stored in a cool, dry place (recommended storage temperature is 4°C to 30°C) away from direct sunlight/extreme weather condition, in its original packaging. After use, the container should be closed again, before storing.

STABILITY

Product is stable for 24 months from the date of manufacture if unopened and in its original packaging. However, it can only be used within 30 days once the bottle is opened. Stability is affected if the container is not stored or closed properly after use.

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RESTRICTION OF USE

Pregnancy and lactation period: There is no evidence of mutagenic or embryo toxicity associated with the ingredients of this product. Due to the lack of relevant clinical trials and clinical experience with pregnant and breast-feeding women, HYDROCYN aqua Solution should only be used after careful medical consultation in these cases.

Newborns and infants: Due to insufficient clinical data, HYDROCYN aqua Solution should only be used selectively on newborns and infants after consulting health care professional.

CAUTION

Do not use the product if the tamper proof seal is damaged or tampered with. Packaging has to be discarded if signs of contaminants are seen. Do not dilute or use the product in combination with other topical solutions unless with the advice of a health care specialist. Consult your health care specialist if wound persists to deteriorate even after use of solution. Notify your health care specialist in case of any adverse effect. In case of deep or serious wounds, or if you have any other treatment concerns consult a health care professional. If signs of infection occur (increased pain, bleeding, pus) or if the wound does not show signs of healing, consult a health care professional. Do not use if hypersensitive to product components. This device is intended for "Single Patient Use".

RISK OF RE-USE

HYDROCYN aqua Solution cannot be re-used if it is poured outside the container. Always use fresh solution.

SYMBOLS USED ON LABELLING

REF

Catalogue Number

LOT

Batch Code



Medical Device



Caution, see instructions for use



Temperature limit (Storage temperature 4°C - 30°C)



Keep away from sunlight



Do not use if package is damaged



Date of manufacture (YYYY-MM-DD)



Use by, expiry date (YYYY-MM-DD)



Manufacturer



Authorized representative in the European Community



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Manufacturer:

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