Trifectiv[®] Plus Wound & Burn Care 100 mL (3.4 FL. OZ) Instructions/package insert

Trifectiv® Plus Wound & Burn Care is ideal to treat burns, wounds, bites, scrapes, skin infections and other trauma to the skin. The active ingredient is hypochlorous acid (HOCI).

Trifectiv[®] Plus Wound & Burn Care helps to cleanse the wound and accomplish the goals of wound bed preparation in a safe, effective, and natural way. This solution of hypochlorous acid (HOCI) is antibacterial and soothes the wound. This ensures better, faster wound healing with a lower risk of infection and a marked improvement in pain and odour in chronic non-healing wounds. The potential for scarring as the wound heals is also reduced.

Composition

Sterile solution of hypochlorous acid 380 mg/L and water (Aqua)

Medical Device Classification

Medical device Class C (ZA). Suitable for use on open wounds. Wound irrigation solution, antimicrobial.

Indications

Any condition where the skin's integrity is compromised.

Contra Indications

Do not use on the face for prolonged periods.

Expect diminished efficacy in the presence of cortisone and antiinflammatory gel.

Warning

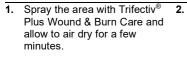
If the condition does not improve within 48-96 hours, consult with your health care practitioner.

Do not use the solution if it is beyond the expiry date.

Safety

The product is safe to use during pregnancy and lactation, as well as on children, babies and animals.

Quick Guide



Spray 5 mL* of Trifectiv[®] Plus Wound & Burn Care onto 3-5 sheets of clean non-sterile woven gauze and place onto the wound area.



- **3.** Cover the wet gauze with a crepe bandage or breathable dressing to secure the dressing.
- 4. Change dressing every day or every other day.



Usage Directions for Specific Conditions

Fungal Infections/fungal nail infections & athlete's foot

Spray Trifectiv[®] Plus onto the affected areas after cleaning and drying the feet. Allow to dry naturally. Repeat twice per day. For infected nails, start by cleaning the nails with an appropriate nail cleaning solution such as nail polish remover. Spray the clean nails with Trifectiv[®] Plus Wound & Burn Care. Allow to air dry naturally. Repeat twice a day.

*Note: infection should clear within two weeks, however it is important to continue use of Trifectiv[®] Plus Wound & Burn Care until healed nails have grown out completely.

Nappy rash

Clean nappy area with warm water or wet wipes. Do not use soap. Gently pat dry with a clean dry towel. Once dry, spray the affected area with Trifectiv[®] Plus Wound & Burn Care and allow to air dry completely. Once the skin is dry apply a barrier cream to the skin. Do not use an ointment such as petroleum jelly. Repeat above steps with every nappy change or at least once every 2 hours until the nappy rash has healed.

Sore throat

Spray Trifectiv[®] Plus directly into the throat every 2 hours until the pain has subsided. It is completely safe if swallowed.

Inflamed or infectious skin conditions, sunburn, bites

Spray Trifectiv[®] Plus 4 x per day over the area and allow to dry naturally.

Cuts, scrapes, grazes

Wounds should be cleaned prior to application of the first dressing of Trifectiv[®] Plus Wound & Burn Care being applied. Do this by washing the wound with a sponge and warm water and a little bubble bath. Ensure that no cleanser remains on the wound after rinsing with clean water (do not use saline). Pat the wound dry with a clean towel. No further cleaning of the wound will be necessary when using Trifectiv® Plus Wound & Burn Care. Thoroughly spray the affected area with Trifectiv® Plus and allow to dry naturally. Do not rub the solution into the skin. Continue to spray the wound 3 to 4 times a day. If necessary, you may cover the wound with a breathable dressing.

<u>Burns</u>

Remove any dead skin or other debris. Spray Trifectiv[®] Plus Wound & Burn care onto the affected area. Wet 3-5 layers of clean nonsterile woven gauze with 5 mL* of Trifectiv[®] Plus Wound & Burn Care and apply directly over the wound, making sure that the entire area is covered. Secure with a crepe bandage or breathable dressing. Change the dressing daily following the steps above.

Open & chronic wounds, pressure sores

Spray over the affected area until moist. Spray 5 mL* of Trifectiv[®] Plus Wound & Burn Care onto 3-5 sheets of clean non-sterile woven gauze until the gauze is wet but not drenched. Apply the wet gauze directly onto the wound, ensuring that the entire wound bed is covered. For deeper wounds, ensure that the gauze is plugged into the wound so that the wet gauze has direct contact with all surfaces of the wound. Cover the wet gauze dressing with a crepe bandage or breathable dressing. Change dressings every day or if not possible, on alternative days. Clean the wound at least twice per week under running water for 2-3 minutes before applying a new dressing. If the area can be left open, spray Trifectiv[®] Plus every 2-3 hours onto the wound and let it dry naturally. Patients should exercise regularly, to the extent that their condition allows.

A special note about paraffin gauze

If, after removing the surgical gauze dressing, bleeding occurs then a single layer of non-medicated paraffin gauze can be applied before applying the gauze dressing **BUT ONLY if ALL** necrotic material (dead tissue, dead biofilm, foreign bodies) has already been removed through wet-to-moist debridement. In paediatric burns a single layer of non-medicated paraffin gauze can be used before the gauze layers wet with Trifectiv[®] Plus Wound & Burn Care are applied. This will minimise discomfort during dressing changes.

Side Effects and Special Precautions

Slight stinging may occur for the first day of use. Do not use with waterproof or silver-impregnated dressing. Do not mix into or use with or after disinfectants like saline, chlorhexidine, iodine, or any other branded disinfectant. In some cases, additional sharp debridement of visible necrotic tissue may be required before the first application of Trifectiv[®] Plus Wound & Burn Care, for optimal results. Please consult with a medical professional if necessary.

THE BOTTLE IS GLASS please take care not to drop it.

Known Symptoms of Overdose

None known

Identification

Clear, colourless fluid

Presentation

100 mL (3.4 FL OZ) in a white **GLASS** bottle with atomiser pump.

Storage Instructions

Store at room temperature. Protect from direct sunlight. Discard any unused product 12 months after opening.

Name and Address of Manufacturer

Thoclor Labs (Pty) Ltd Unit E1 Stellenbosch Agri-Park, Baden Powell Drive, Lynedoch, Stellenbosch 7600, South Africa

Bar code No. 6009900445885 Nappi 1029852-001 SAHPRA 733MD Medical Device Class C (ZA) ISO 13485:2016

For more information on specific applications please visit <u>www.trifectiv.com/usage</u> or scan the QR code

