

Trifectiv® Plus Wound & Burn Care 450 mL (15.22 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 (HOCl).

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 (HOCl) is anti-bacterial 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 anti-inflammatory 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

1. Spray the area with **Trifectiv® Plus Wound & Burn Care** and allow to air dry for a few minutes.
2. 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 Wound & Burn Care** 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**. 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.*

Sore throat

Spray **Trifectiv® Plus Wound & Burn Care** directly into the throat every 2 hours until the pain has subsided. It is safe if swallowed.

Inflamed or infectious skin conditions, sunburn, bites

Spray **Trifectiv® Plus Wound & Burn Care** 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 Wound & Burn Care** 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.

Surgical wounds & stitches

Remove any surgical dressing the day following your surgery or as soon as possible there-after. Apply a single layer of non-medicated paraffin gauze over the stitches. Wet 3-5 layers of clean non-sterile woven gauze with 5 mL* of **Trifectiv® Plus Wound & Burn Care** and place this over the paraffin gauze. Hold in place with a breathable dressing. Change all dressings daily. Once the stitches are removed continue to spray the wound with **Trifectiv® Plus Wound & Burn Care** and allow to dry naturally (don't rub). Repeat the application twice a day. If necessary cover with a breathable dressing.

If you don't have stitches follow the directions below for open wounds.

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 Wound & Burn Care** every 2-3 hours onto the wound and let it dry naturally. Patients should exercise regularly, to the extent that their condition allows.

Burns

Remove any dead skin or other debris. Spray **Trifectiv® Plus Wound & Burn Care** care onto the affected area. Wet 3-5 layers of clean non-sterile 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.

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

450 mL (15.22 FL OZ) in a white **GLASS** bottle with trigger 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, ZA

Bar code No. 6009900474472

Nappi 1102811-001

SAHPRA 733MD

Medical Device Class C (ZA)

ISO 13485:2016

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



*Each dressing of 3-5 layers of woven gauze requires 5 mL of product – this equates to 10 pumps of the 450 mL bottle per dressing. This ensures optimal wetting of the gauze for debridement and healing. This is approx. 90 dressings per bottle.

Trifectiv® Plus Wound & Burn Care 450 mL (15.22 FL. OZ)

Instruksie/insetel

Trifectiv® Plus Wound & Burn Care is ideaal om brandwonde, oop wonde, byte, skrape, velinfeksies en ander beserings van die vel te behandel. Die aktiewe bestanddeel is hipochloorsuur (HOCl).

Trifectiv® help met die skoonmaak van die wond en berei die wond voor vir genesing op 'n natuurlike en effektiewe manier. Die oplossing van HOCl het 'n sterk antimikrobiële werking en kalmeer die wond. Dit verseker beter, vinniger genesing met 'n baie laer risiko vir infeksie en 'n verbetering in pyn en reuk in voorheen nie-genesende wonde.

Samstelling

Steriele oplossing van hipochloorsuur 380 mg/L en water (Aqua)

Mediese toestel klassifikasie

Mediese Toestel Klas C (ZA). Geskik vir gebruik op oop wonde.

Steriele wond uitspoel middel met antimikrobiële eienskappe.

Indikasies vir gebruik

Enige toestand waar die vel se integriteit versteur is.

Kontraindikasies

Vermy langtermyn aanwending op die gesig vel.

Verwag verminderde effektiwiteit in die teenwoordigheid van kortison en anti-inflammatoriese jel.

Waarskuwing

Indien die toestand waarvoor die produk gebruik word nie verbeter binne 48 tot 96 uur nie, spreek asb. u mediese praktisyn.

Moenie gebruik indien die produk se vervaldatum oorskrei is nie.

Veiligheidsaspekte

Die produk is veilig om te gebruik gedurende swangerskap en borsvoeding. Dit kan ook op kinders, babas & diere aangewend word.

VINNIGE GIDS

1. Sproei die Trifectiv® Plus Wound & Burn Care oor die beseerde area en laat dit natuurlik droog word.
2. Maak 3-5 lae skoon geweefde gaas nat* met Trifectiv® Plus Wound & Burn Care en gebruik dit om die wondarea te bedek.



3. Bedek die wond en nat gaasdeppers met 'n kruipverband.
4. Vervang die wondbedekking daaglik, of ten minste elke tweede dag.



GEBRUIKSAANWYSINGS VIR SPESIFIEKE TOESTANDE

Atleetsvoet

Wend Trifectiv® Plus aan oor die infeksie area 2 x per dag. Maak seker dat die voete skoon en droog is voor aanwending.

Swam naelinfeksies

Maak die naels eers skoon met 'n toepaslike produk soos naellak verwyderaar. Suiet die skoon naels met Trifectiv® Plus Wound & Burn Care.

Laat dit natuurlik droog word. Herhaal twee keer per dag.

* Opmerking: infeksie sal gewoonlik binne twee weke opklaar, maar dit is belangrik om voort te gaan met die gebruik van Trifectiv® Plus Wound & Burn Care totdat gesonde naels heeltemal uitgegroe het.

Seer keel

Suiet Trifectiv® Plus direk in die keel elke 2 ure totdat die seer keel beter voel. Dit is heeltemal veilig as dit ingesluk word.

Ontsteekte of aansteeklike veltoestande, sonbrand, insek byte

Suiet Trifectiv® Plus 4 x per dag oor die area en laat dit natuurlik droog word.

Snye, skrape, skaafwonde

Wonde moet skoongemaak word voordat die eerste verband van Trifectiv® Plus Wound & Burn Care toegedien word. Gebruik 'n spons, warm water, en 'n bietjie borrelbad seep om die wond skoon te was. Maak seker geen reiniger bly op die wond nadat dit met skoon water afgespoel is (moenie soutwater gebruik nie). Druk die wond versigtig droog met 'n skoon handdoek. Geen verdere skoonmaak van die wond sal nodig wees wanneer Trifectiv® Plus Wound & Burn Care gebruik word nie. Suiet die aangetaste area deeglik met Trifectiv® Plus en laat dit natuurlik droog word. Moenie die oplossing in die vel invryf nie. Gaan voort om die wond 3 tot 4 keer per dag te spuiet. As dit nodig is, kan die wond bedek word met 'n crepe verband of pleister.

Chirurgiese wonde en steke

Verwyder enige chirurgiese verband die dag na jou operasie of so gou as moontlik daarna. Wend 'n enkele laag nie-gemedieerde paraffien gaas oor die steke aan. Maak 3-5 lae skoon nie-gesteriliseerde geweefde gaas nat met 5 mL* Trifectiv® Plus Wound & Burn Care en plaas dit oor die paraffien gaas. Hou in plek met 'n lugdeurlaatbare verband. Verander alle verbande daaglik. Sodra die steke verwyder is spuiet Trifectiv® Plus Wound & Burn Care 2 x per dag oor die area en laat dit natuurlik droog word. Bedek indien nodig met 'n lugdeurlaatbare verband.

As jy nie steke het nie, volg die aanwysings hieronder vir oop wonde.

Oop en chroniese wonde en drukere

Suiet dit op die aangetaste gebied totdat die wond nat is. Suiet 5 mL* van Trifectiv® Plus Wound & Burn Care op 3-5 lae skoon nie-gesteriliseerde geweefde gaas totdat die gaas nat maar nie deurweek is nie. Plaas die nat gaas direk op die wond en sorg dat die hele aangetaste gebied bedek is. Vir dieper wonde, maak seker dat die gaas in die wond ingepronk word sodat die nat gaas direk kontak maak met alle oppervlaktes van die wond. Bedek die nat gaas met 'n crepe verband of lugdeurlaatbare verband. Indien moontlik, verander die verband elke dag of ten minste op alternatiewe dae. Maak die wond minstens twee keer per week skoon onder lopende water vir 2-3 minute voordat 'n nuwe verband opgesit word. As die area oopgelos kan word, spuiet Trifectiv® Plus Wound & Burn Care elke 2-3 uur op die wond en laat dit natuurlik droog word. Pasiënte moet gereeld oefen, in die mate wat hul toestand dit toelaat.

Brandwonde

Verwyder enige los vel en vreemde voorwerpe. Wend Trifectiv® Plus Wound & Burn Care aan deur dit op die gebrande area te spuiet. Maak 3-5 lae skoon nie-gesteriliseerde geweefde gaas nat met 5 mL* van Trifectiv® Plus Wound & Burn Care en wend dit direk op die wond aan, maak seker dat die hele area bedek is. Verbind met 'n crepe verband of lugdeurlaatbare verband. Vervang die verband daaglik.

'n Spesiale opmerking oor paraffien gaas

As die wond bloei na die verwydering van die gaasverband, kan 'n enkele laag nie-gemedieerde paraffien gaas toegedien word voordat die gaasverband aangesit word, MAAR SLEGS as AL die nekrotiese materiaal (doeie weefsel, doeie biofilm, vreemde voorwerpe) reeds deur die daaglikse aanwending van Trifectiv® Plus Wound & Burn Care gaasverbande verwyder is. In pediatriese brandwonde kan 'n enkele laag nie-gemedieerde paraffien gaas op die wond gesit word voordat die gaas lae wat met Trifectiv® Plus Wound & Burn Care nat gemaak is, toegedien word. Dit sal ongemaak verminder wanneer die verband vervang word.

Nuwe-effekte en spesiale voorsorgmaatreëls

Die eerste dag van gebruik kan effens branderig voel.

Moet dit nie saam met waterdigte verbande gebruik nie.

Moenie Trifectiv® Plus Wound & Burn Care saam met silwer-bevattende verbande gebruik nie.

Moenie Trifectiv® Plus meng of gebruik met of na sout, jodium, chloorheksidien of enige ander handelsmerk-ontsmettingsmiddel nie.

Vir optimale genesing word aanbeveel dat enige sigbare nekrotiese weefsel, en vreemde materiaal verwyder word voordat behandeling met Trifectiv® Plus Wound & Burn Care begin word. Raadpleeg asseblief 'n dokter indien nodig.

Die bottel is GLAS.. Wees asb. versigtig!

Moenie binne die bereik van babas en kleuters los wanneer dit sonder toesig is nie. Vervang die doppie na gebruik om die spuitstuk te beskerm en breek te voorkom.

Simptome van oordosering

Geen

Voorkoms van produk

Deursigtige, helder skoon vloeistof

Houer

450 mL (15.22 FL. OZ) oplossing in 'n wit GLAS bottel met spuitpomp.

Berging

Bêre bottel by kamer temperatuur.

Hou bottel uit direkte sonlig.

Gooi enige ongebruikte produk weg 12 maande na opening.

Naam en adres van vervaardiger

Thoclor Labs (Pty) Ltd, Unit E1 Stellenbosch Agri-Park, Baden Powell Drive, Lynedoch, Stellenbosch 7600, ZA
Strepieskode No. 6009900474472

Nappi 1102811-001

SAHPRA 733MD Mediese Toestel Klas C (ZA)

ISO 13485:2016

Besoek www.trifectiv.com/usage vir meer inligting of gebruik die QR-kode



*Elke verband van 3-5 lae geweefde gaas benodig 5 mL produk – dit is gelyk aan 10 pompe van die 450 mL bottel per verband. Dit verseker optimale benutting van die gaas vir genesing = ongeveer 90 verbande per bottel.