



REGISTRATION

In which category is WOUND registered?

The category is Medical Device class IIb.

Have you performed any toxicologic tests?

Yes, it has been demonstrated that there is no evidence of skin irritation, sensitivity or cell toxicity.

APPLICATION

What are the key benefits of WOUND?

Simple, natural and effective. The product is an all-in-one spray for the woundbed, woundedge and the periwound skin.

Where should be WOUND used?

WOUND can be used for all acute and chronic wounds, as well as minor skin wounds and burns. Regardless of a dry, moist or wet wound environment.

Can WOUND be used on stitches (sutures)?

Yes. But WOUND should only be used on non-absorbable stitches. Absorbable stitches might be resolved too fast, as WOUND brings additional moisture to the wound situation.

May I use WOUND in post-surgical wounds?

Yes, as far as the seam material is not resorbable. Otherwise it might trigger that the stiches are resorbed too fast.

In which wounds is WOUND not recommended?

We have not observed any contraindications in any wounds.

How much oil should be sprayed on the wound?

Minimum: We advise to spray until an oil layer is visible (minimally 2 puffs/layers on the same area).

As a general rule: rather use too much than too little oil, in order to minimize the risk that the secondary dressing adheres to the wound (observed in situation where too little oil was applied, or no oil was re-applied for >48 hours).



Which gauze is recommended for the secondary dressing?

- Because of its fine texture the ideal secondary dressing is a simple non woven gauze (e.g. Cutisoft from BSN)
Appr. 90% of cases
- In case of an exudating wound an absorbent dressings (i.e. foam) is recommended.
Appr. 5-10% of cases
- In case of strong exudation, a superabsorbent secondary dressing is recommended (e.g. Sorbion Sachet).
Appr. 1-3% of cases

Can WOUND be combined with all secondary dressings?

Yes, provided the dressing material is made for a daily change. Modern wound care products are often too expensive for a daily change. Therefore, we recommend a simple non woven gauze (see Herzig 174 consecutive patients).

Can WOUND be used in (strong) exudating wounds?

Yes, but the secondary dressing has to adjusted to the wound exudate

Should the wound to be covered after application of WOUND?

This is to be decided by the treating health care professional. In general, in human medicine, wounds are covered with a secondary dressing, which is adjusted to the wound exudate. In most cases, a simple non-woven dressing is sufficient.

Does WOUND occlude the wound?

No, the oil film is semi-occlusive (which is specific to natural oils if compared to synthetic oils/fats due to the shorter chains of the molecules of natural oils).

Consequently, important gases like oxygen can come into the wound, but exudate and bacteria can get out of the wound into the secondary dressing.

Do oil residues have to be removed when changing the dressing?

No. This is not necessary.

Is there a risk for nearby structures such as bones and tendons?

No, clinically there is no risk if the oil comes in contact with exposed structures (see e.g. the Lächli cases, where the product is sprayed directly on exposed bone).



Do I have to let the product first penetrate the wound before I close the wound with a secondary dressing?

Yes. Ideally, let the oil penetrate the wound for approx. 1 to 2 minutes, before covering with the secondary dressing.

Is there an active ingredient in WOUND?

No, the combination of the oils has pure physical effects.

MODE OF ACTION

What are the exact effects of WOUND?

- Creation of a moist wound environment.
- The secondary dressing does not adhere to the wound. This reduces pain and skin trauma.
- Anti-microbial effect without cytotoxic side effect
- Protection of a healthy skin function, protection of the wound edges and periwound skin from maceration.

Why have you chosen the combination of neem and hypericum oil?

Both oils have traditionally been used in wound healing. The mix of Neem and Hypericum shows an ideal profile of fatty acids, which acts synergistically. A corresponding patent has been filed and granted to the WOUND spray in 2006. In addition, both oils have a good skin care effect.

Why the secondary dressing does not stick on to the wound?

The wound surface and secondary dressing are separated through a water rejecting (hydrophobic) oil layer. But please use sufficient oil (2 layers).

Why does WOUND keep the wound environment moist?

The oil layer is rejecting water (hydrophobic), therefore the moisture stays in the wound and prevents/prolongs the evaporation of the water molecules that are in the wound (see e.g. internal vapor water evaporation rate study).

Is the product antibacterial?

The fatty acids have a bacteriolytic effect. WOUND is even anti-microbial, meaning besides the anti-bacterial effect there is also an anti-mycotic effect (thanks to Neem oil).



How does the process of bacteriolysis work with WOUND?

The free fatty acids cover the bacterium cell wall, which can no longer uptake nutrients and oxygen. Hence, the bacteria's slowly die with a lysis of their cell walls, but in gentle way without releasing endotoxins.

Antimicrobial effect: against which germs does WOUND work?

"WOUND" was tested in vitro (conservation stress test - USP 51 test) against:

- Pseudomonas aeruginosa (log5 in 2 days)
- Staphylococcus aureus (log5 in 7 days)
- Candida albicans (log5 in 2 days)
- Aspergillus niger (log5 in 2 days)

Log 5 reduction means the time needed to reduce the amount of bacteria from 100'000 to 1. (Logarithm of 5 = $10 \cdot 10 \cdot 10 \cdot 10 \cdot 10$).

What happens with the absorbed oil in the body?

The oil is being absorbed by the body. The uptaken oil is like food for the newly formed cells and extracellular matrix.

Does WOUND protect the wound edge?

Yes, through lipid synthesis. The fatty acids build the skin barrier in the intercellular and surrounding area of the wound. Maceration is also prevented.

Can I use WOUND also in children?

Yes, since March 2018, the product can be used also in children as of 1 months of age (see details on package insert).

Which is your main competitor, which product can be replaced?

The main advantage of the product is, that it is part of a simple treatment concept (together with a simple non-woven gauze), that endorses self-treatment. In addition, it is possible to address all the important prerequisites of modern wound care and all locations (wound bed, edge and peri-wound skin) with one product. There is no 1-1 competitor with the same properties.

Does WOUND have an effect on the revascularization?

WOUND creates a wound environment which helps the system to accelerate the physiological wound healing process. Various cases have shown a positive effect on angiogenesis.



Does WOUND improve granulation?

WOUND creates a wound environment in which physiological wound healing gets activated. Clinical experience often shows an increase of granulated tissue.

INGREDIENTS

What is the active ingredient in the product?

The mode of action of the product is based on the physical properties of the oil film and its fatty acids.

Can the product cause an irritation or allergic reaction?

For the CE registration, the product was tested for irritation and sensitization (delayed-type hypersensitivity test). All results were negative. During the Post Marketing Surveillance, an allergic reaction to the product was reported in 5 of 280 cases. All the patients reporting an allergic reaction suffered from multiple allergies.

St. John's Wort is known as an antidepressant drug. Is the mode of action of WOUND similar?

Antidepressant drugs using St. John's Wort are taken orally, and used systemically based on concentrated alcoholic extracts of Hypericin.

WOUND is topically applied and does not show a pharmacological relevant concentration of hypericin.

Does the Hypericin in WOUND have an antidepressant effect after being absorbed by the body?

No, the concentration of hypericin in WOUND is far too low to have this effect. Note: Anti-depressants made out of St. John's Wort oil are taken orally, and are based on concentrated alcoholic extract of Hypericin in factors higher concentration than present in WOUND.

What is the active ingredient in neem oil and St. John's Wort oil?

WOUND does not have pharmacologically active ingredients. The effects of WOUND are based on a physical mode of action.

Is WOUND organic?

WOUND is not a certified as an organic product. However, no pesticides are used and no pesticides can be detected in residue analyses.



CONTRA-INDICATIONS

Can I use WOUND to treat radiation dermatitis?

Yes, but after radiation treatment is finalized, in order to treat the radiation related wound situation. The product should not be used during radiation treatment, as the oil film on the wound could lead to a situation where even more heat is conserved by the body.

Is there a danger of photosensitization?

No, not if the wound is covered by a secondary dressing.

SHELF LIFE / STORAGE

For how long can I use WOUND? (Or What is the shelf life of WOUND?)

Do not use after the expiry date marked on the spray and carton (the shelf life is 42 months, 36 months in Zone IV countries).

Is the propellant gas dangerous?

The used propellants propane/butane are natural and nontoxic gases which catabolize into CO₂.

Should I be concerned that the content of the spray is contaminated after the first treatment?

No. Due to the fact that the spray contains propellants, air cannot penetrate into the spray. Furthermore, WOUND has anti-microbial properties and is self-preserving.

How long is the shelf life after the first application?

Even after first use, WOUND is still stable and can be used until the expiry date indicated on the packaging.

Do propellants remain on the wound after the spray application?

Only for a very short moment, as they evaporate quickly.

Is the product sterile?

All the purity regulations of the European Pharmacopoeia are met. The product did not go through sterilization, but is self-preserving. No increase of bugs seen during stability testing throughout the shelf life.