

LeiProtect – Cutaneous Leishmaniasis Protection is in your alcohol disinfected hands on the tip of your finger – Information for Users

1. Preliminary Remark:

Leishmaniasis parasites are transmitted through sand fly bites and induce a delayed hypersensitivity reaction in the human host skin leading within weeks to the formation of a papule, which finally breaks open. After its application to this skin lesion, LeiProtect forms a thin cellulose film, which supplements the loss of the skin integrity, our mechanical barrier against all sorts of pathogens. Under the protective shield of LeiProtect, which contains propylene glycol as preservative, physiological wound healing remains undisturbed till final epithelisation and wound closure with optimum cosmetic results. The majority of leishmaniasis skin lesions are in the face, often at sites, which are most difficult to cover with conventional dressings, such as the conches, eyelids, nose, lips.

2. Indications:

For the protection of skin lesions, caused by the transmittance of leishmania parasites in the early papular as well as in the late ulcer stage.

3. Instruction of Use:

Once the papules have opened, the resulting skin defects should be cleansed leaving a gauze soaked with 0.1 % polyhexanide for at app. 5 minutes on the lesion. A thin layer of LeiProtect dressing is then applied after careful dabbing with a dry gauze. No other antiseptics (Iodine, gentiane/violet etc.) should be used with LeiProtect. As LeiProtect was developed not only for the point of care but also for the patient's own use, it should be noted here, that the patient has to disinfect his hands before applying LeiProtect to his skin lesions. WHO has developed tips and instructions as well as cheap alcohol based hand rub (ABHR) formulas for this (<http://www.who.int/gpsc/5may/en/>). We call the instructions to treat CL lesions with clean hands "LeiClean".

Depending on the lesion size 0.1 to 0.3 ml of LeiProtect should be deposited on the previously disinfected finger tip without the dispensing container of the semi-solid dressing then touching the skin. This semi-solid droplet is then dispersed on the lesion to form a regular thin cellulose layer on the lesion and up to 3 mm of the surrounding intact skin. After 30 minutes this layer has dried to a thin transparent cellulose film.

The LeiProtect film stays intact for 24 hours. After 24 hours a second layer is dispersed on the old cellulose sheet. The patient or his relative repeats this same procedure at home daily for 6 days. In case the hydro soluble cellulose has been inadvertently exposed to water or mechanical frictions, another LeiProtect sheet is added outside the normal treatment cycle, which is 24 hours.

As long as the skin defect is not completely closed, all weekly LeiProtect applications have to be carried out by qualified medical staff. In doing so the hydro soluble cellulose sheets have to be dissolved by applying a gauze soaked with a solution of 0.1% undecylenamidopropyl-betaine surfactant and 0.1% polyhexanide for 20 minutes to the old dressings and by carefully dabbing the eventually remaining cellulose rests off without disturbing the granulation and epithelisation. Before applying LeiProtect for the first time and after removing old layers the medical staff has to photo document the state of the skin defect and the final healing result.

The weekly LeiClean / LeiProtect treatment cycles are repeated as long as the photo documentation does not prove a complete closure of the skin defect.

5. Compatibility of LeiProtect:

LeiProtect has no toxic cellular effects, is neither irritative, nor sensitizing and is well tolerated by the skin. LeiProtect application is a painless procedure.

6. Undesirable effects:

No side effects of LeiProtect are known.

7. Safety recommendations:

LeiProtect is to be used externally on the skin. It should not be ingested. The LeiProtect container should not be exposed to UV light nor to room temperatures >30°C.

8. Composition: Aqua purificata, elastic cellulose ether, 1,2-Propylen-glycol, *Natrii chlorotis solutio* (Sodium chlorite produced without chlorate).

9. Technical Details / Shelf life: colourless, virtually inodore viscous jelly / 1 year below 24°C.