

Unofficial translation of the German package leaflet

Instructions for use - Please read carefully.

Medice[®] Burn and Wound Gel



Composition:

Purified water, glycerine 85%, urea, monosodium phosphate dihydrate, disodium phosphate dodecahydrate, sodium alginate, laureth-9, benzethonium chloride, potassium sorbate

Form of administration and contents of the pack

1 pack contains 25/50 g gel

Mode of action

Protective and cooling gel for burns and wounds; does not prevent natural fluid exchange between the skin and the wound.

Manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhloweg 37, 58638 Iserlohn, Germany
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Intended purpose

For the treatment of 1st and 2nd degree burns (blistering), sunburn, grazes and insect bites. For thin application to damaged skin. Medice[®] Burn and Wound Gel dries slowly. It forms an air-permeable film which protects the affected areas of skin, without affecting the drainage of wound secretions. The gel creates a pleasant cooling effect following application.

It is therefore indicated for the treatment of 1st and 2nd degree burns (blistering), sunburn, grazes and insect bites.

Contraindications

Do not use Medice[®] Burn and Wound Gel:

- If you are allergic to any of the ingredients

Warning and precautions for use

What precautions should be taken?

Do not apply to the eyes.

In the event of large burns and/or burns that appear to be deep, a doctor must be consulted before treatment with Medice[®] Burn and Wound Gel.

A doctor should also be consulted if a burn or wound becomes red, swells, or does not start to heal after a few days of treatment with Medice[®] Burn and Wound Gel.

Interactions

What other medical devices or medicines affect the action of Medice[®] Burn and Wound Gel or can be affected by simultaneous use?

Please note that this information may also apply to medicines or other medical devices that have been used recently.

The release of active substances from other skin products and their absorption by the skin may be increased by Medice[®] Burn and Wound Gel. Therefore, Medice[®] Burn and Wound Gel should not be used together with other skin products on the same area of skin.

Dosage instructions, method and duration of administration

Please follow the instructions for use, otherwise Medice[®] Burn and Wound Gel may not work properly. The tube should be tightly closed after dispensing of the gel. Only use the original lid to close the tube. When using Medice[®] Burn and Wound Gel, please avoid bending and breaking the tube, which can be caused by rolling up the tube from the fold.

How much Medice[®] Burn and Wound Gel should you use and how often?

Apply a thin layer of Medice[®] Burn and Wound Gel using clean and dry fingers, a plaster, or a clean cotton swab. The tube opening must not come into contact with the wound.

Once the cooling and protective effect subsides, application can immediately be repeated in the same way.

How and when should you use Medice[®] Burn and Wound Gel?

Medice[®] Burn and Wound Gel should not be used over large areas for an extended period. The slow drying time of the gel is an intentional feature of this product, as it ensures longer protection for the affected skin areas. Where possible, wound dressings should be avoided for exposed parts of the body; however, if needed, such dressings can be applied over the dry gel film. Clean wound conditions rapidly develop beneath the smooth dried gel, which promotes good healing. The gel film is permeable to air and moisture. The ability to inspect the wound is not impaired, meaning that subsequent treatment providers are free to use any further treatment measures that may be necessary. Wounds that are weeping heavily are first to be cleaned with sterile swabs, and only then should Medice[®] Burn and Wound Gel be applied.

How long should Medice[®] Burn and Wound Gel be used?

The duration of use depends on the course of the healing process.

Improper use and overdose

What should you do if Medice[®] Burn and Wound Gel is applied in excessive quantity (intentional or accidental overdose)?

The gel can be washed off with lukewarm water.

Side effects

What side effects can occur with the use of Medice[®] Burn and Wound Gel?

If you get any side effects, contact your pharmacist or the manufacturer. This also includes any side effects not listed in these instructions for use.

Medice[®] Burn and Wound Gel is generally well tolerated. In rare cases, the ingredient laureth-9 can cause a skin reaction, probably due to an allergy.

In predisposed patients, the hypersensitivity develops within a period of approx. 1-2 weeks. The ingredient urea can cause short-term irritation on inflamed areas of skin or weeping wounds.

What action should be taken in the event of side effects?

Discontinuation of the product. Please consult your doctor.

Notes and information on shelf life of the medical device

The expiry date of this pack is printed on the tube and the outer carton. Do not use Medice[®] Burn and Wound Gel after this expiry date.

Medice[®] Burn and Wound Gel can only be used for 12 months after opening of the tube.

Under what circumstances can Medice[®] Burn and Wound Gel no longer be used, even if the expiry date has not passed?

If the tube is damaged, decomposition of the ingredients may take place. Therefore, please do not use if the tube is damaged.

How to store Medice[®] Burn and Wound Gel?

Do not store above 25°C.

Last revised in:

January 2016

Explanation of the packaging symbol



Please follow the instructions for use



Do not use if the tube is damaged.



Upper temperature limit



Expiry date



Batch code



This medical device should be kept out of the reach and sight of children.