

Bepanthen® Plus

Cream

Active ingredients:

Each gram contains:

Dexpanthenol 50 mg

Chlorhexidine dihydrochloride 5 mg

For a list of the inactive ingredients and allergens, see section 6 'Additional information' and section 2 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet.

Consult your pharmacist if you need further information. Consult a doctor if your symptoms of illness get worse or do not improve within 10-14 days.

1. What is this medicine intended for?

Antiseptic healing treatment of wounds with an infection risk such as slight skin irritations, wounds, cuts, mild burns and skin inflammation.

Therapeutic group:

Dexpanthenol - provitamin B5

Chlorhexidine dihydrochloride - antiseptic

Bepanthen® Plus contains chlorhexidine which fights the bacteria on the skin or which get into the wound with dirt, and by doing so prevents or moderates bacterial infection in wounds. The medicine also contains dexpanthenol, which is converted in the skin into the vitamin pantothenic acid which supports the accelerated regeneration of skin cells from within, causing the wound to heal more quickly. Furthermore, the newly formed skin is more elastic. The cream is easy to apply and wash off and is not greasy or sticky.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to dexpanthenol, chlorhexidine dihydrochloride or to any of the other ingredients in this medicine.
- Do not apply this preparation to a perforated eardrum.
- Do not use Bepanthen® Plus on deep, serious or infected wounds. Such wounds will be treated by a doctor.

Special warnings about using this medicine

- **Before using Bepanthen® Plus, tell your doctor if:**
 - You suffer from any illness.
 - You have any allergies, are sensitive to any substance or medicine.
 - You are taking other medicines (including over-the-counter medicines) or using other creams.
- Avoid contact with the eyes, ears or mucous membranes.
- Repeated use in the same area of skin can lead to skin irritation.
- Bepanthen® Plus is suitable for use on small areas of skin only. Avoid using on large areas of skin.
- Large, deep, serious or very dirty wounds as well as stings/bites and stab wounds require referral to a doctor/medical attention due to risk of tetanus infection.

- A doctor should be consulted if the size of the wound does not decrease after some time or if the wound does not heal within 10-14 days. The same applies if the edges of the wound are very red, the wound swells rapidly or is very painful and if the wound is accompanied by fever (risk of blood poisoning).
- Do not use the preparation to treat irritations with a low risk of infection (for example: sunburns, pressure points, inflamed skin areas). In such a case, it is advisable to use a preparation that does not contain an antiseptic.
- In rare cases, serious allergic reactions, including anaphylactic shock, may occur when using medicines that contain chlorhexidine, such as Bepanthen® Plus. If you experience symptoms of a serious allergic reaction such as wheezing or breathing problems, swelling of the face, itching, nettle rash (urticaria, which can lead to serious symptoms), severe skin rash or shock, immediately stop the treatment with Bepanthen® Plus and consult a doctor without delay.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medications, medicines applied to the skin and dietary supplements, tell your doctor or pharmacist.

Bepanthen® Plus should not be applied to the affected area concomitantly with soaps, detergents and other antiseptics. Use of other antiseptics at the same time may weaken the effect of this medicine.

Pregnancy and breastfeeding:

Pregnancy:

If you are pregnant, consult your doctor or pharmacist before treatment with Bepanthen® Plus. Use over large areas of skin should be avoided.

Breastfeeding:

Bepanthen® Plus may be used while breastfeeding, but you should avoid applying it over large areas of skin. If you are breastfeeding, remove residues of the medicine before breastfeeding to ensure that the baby does not swallow the medicine.

Driving and using machines

There is no known negative effect on the ability to drive or use machines.

Important information about some of this medicine's ingredients:

This medicine contains cetyl alcohol, stearyl alcohol and lanolin, which may cause a local skin reaction (such as contact dermatitis).

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Directions for use and standard dosage, if not otherwise instructed by your doctor: Apply a thin layer to the affected area up to 4 times a day.

Wounds may be covered using a dressing or left open.

Do not exceed the recommended dose.

Length of treatment:

Consult your doctor if the symptoms of the disease worsen or do not improve within 10-14 days.

If you feel that the effect of the preparation is too strong or too weak, consult a doctor or pharmacist.

Mode of administration:

Do not swallow! This medicine is intended for external use only. If you accidentally swallow a large quantity of the preparation, consult a doctor.

In case of contact with the eyes, wash thoroughly with water and consult your doctor.

If you have accidentally taken a higher dose, an increase in liver enzymes (aminotransferase) may occur.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, ask a doctor or pharmacist.

4. Side effects

Like with all medicines, using Bepanthen® Plus may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and contact a doctor immediately if:

- Allergic skin reactions may occur, such as contact dermatitis, itching, redness, eczema, nettle rash (urticaria), skin irritation, burning sensation or blisters.
- Hypersensitivity reaction, anaphylactic reaction, anaphylactic shock with accompanying clinical manifestations such as asthma, shortness of breath, wheezing, other impairments of the airways, swelling of the face, skin reactions such as itching, rash or nettle rash (urticaria), problems of the gastrointestinal tract and cardiovascular system have been observed.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult a doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/tube. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Bepanthen® Plus can be used for up to 12 months after the tube is opened. It is recommended to write the date of opening on the package.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Liquid paraffin, white soft paraffin, cetyl alcohol, wool fat (lanolin), macrogol stearate, stearyl alcohol, DL-pantolactone, purified water.

What the medicine looks like and contents of the pack:

Off-white coloured cream.

Pack sizes: 3.5, 30, 100 grams. Not all pack sizes may be marketed.

Registration holder and importer's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Revised in December 2021 according to MoH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
127 48 26501 01