

PACKAGE LEAFLET: INFORMATION FOR THE USER

BEPANTHEN

50 mg / g Ointment

DEXPANTHENOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What BEPANTHEN is and what it is used for
2. Before you take BEPANTHEN
3. How to take BEPANTHEN
4. Possible side effects
5. How to store BEPANTHEN
6. Further information

1. WHAT BEPANTHEN IS AND WHAT IS IT USED FOR

BEPANTHEN contains the active ingredient dexpanthenol (precursor of vitamin B5) in an oil-rich ointment base. Dexpanthenol is rapidly converted in skin cells to pantothenic acid (precursor of vitamin B5). Pantothenic acid plays a part in both the formation and the regeneration of the skin.

BEPANTHEN ointment contains dexpanthenol in an oil-rich ointment base, thus prevents contact of the treated surface with water (or urine). It is recommended for skin areas that are not covered with hair, because unlike BEPANTHEN ointment, ointment is stickier (has higher viscosity) and therefore is more difficult to spread.

BEPANTHEN Ointment is used

- for the prevention and treatment of chafed, cracked or split skin;
- for dry skin;
- by nursing mothers for regular breast care and the treatment of sore nipples;
- in infant care as a protective barrier against nappy (diaper) wetness and for the prevention and treatment of chafing, redness and diaper rash
- for stimulation of healing and epithelialization of the minor injuries (e.g., burns and scratches), skin irritation (for example, from radiation therapy, phototherapy, or exposure to UV light), chronic wounds and decubital ulcers, anal fissures (small split in the skin of the anal canal), skin grafts and erosion of the cervix (cervical)

- Skin care during interruption of therapy with corticosteroids and after that.

2. BEFORE YOU TAKE BEPANTHEN

Do not use BEPANTHEN

- If you are allergic (hypersensitive) to Dexpanthenol or any of the other ingredients of BEPANTHEN

Take special care with BEPANTHEN

Special warnings and precautions are not necessary.

In the case of infected wounds, use BEPANTHEN plus ointment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no known interactions with other medicines.

Pregnancy and breastfeeding

You can use medicine BEPANTHEN ointment during pregnancy and breastfeeding.

Before taking any medicine, consult your doctor or pharmacist.

Driving and using machines

BEPANTHEN does not affect your ability to drive or use machines.

Other warnings

Cetyl alcohol, stearyl alcohol, lanolin, may cause local skin reactions (e.g., contact dermatitis).

3. HOW TO USE BEPANTHEN

- Damaged skin: apply BEPANTHEN Ointment one or more times daily, as needed.
- Nursing mothers: apply BEPANTHEN Ointment to the nipples after each breastfeeding.
- Infant care: at each nappy (diaper) change spread BEPANTHEN Ointment over your baby's bottom and groin, after cleaning these areas thoroughly with water.
- Stimulation of healing and epithelialization with minor injuries: medicine BEPANTHEN ointment is applied once or more times a day or as recommended by a doctor.
- Treatment of cervical erosion: BEPANTHEN ointment is applied once or more times a day or as recommended by a doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **BEPANTHEN** can cause side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

These side effects are based on spontaneous reports, thus the frequency cannot be estimated from the available data.

There have been allergic reactions and allergic skin reactions such as contact dermatitis, allergic dermatitis, itching, redness, eczema, rash, hives, skin irritation and blisters.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE BEPANTHEN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **BEPANTHEN** after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

Shelf life: 3 years.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BEPANTHEN contains

Active ingredient: 1 g of ointment contains 50 mg of dexpanthenol.

Other ingredients are: glycerol monooleate, lanolin alcohols, liquid paraffin, yellow soft paraffin, ozokerite, cetyl alcohol, stearyl alcohol, white wax (E901), lanolin (E 913), white soft paraffin, almond oil, purified water.

What BEPANTHEN looks like and contents of the pack

BEPANTHEN ointment is homogenous, smooth emulsion, yellowish in color with a specific smell of lanolin.

BEPANTHEN ointment is available in a box with aluminum tube with PP cap containing 30 g and 100 g fat.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Bayer Schering Pharma AG, 13342 Berlin, Germany

Manufacturer of the medicinal product

GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, 79639 Grenzach-Wyhlen, Germany