PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 The medicine is dispensed without a doctor's prescription

Bepanthen® 5%

Ointment

Composition:

Each gram contains: Dexpanthenol 50 mg

For a list of the inactive ingredients - please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

For prevention and treatment of diaper rash in infants. For prevention and treatment of cracked or sore nipples in nursing women. For prevention and treatment of chafed, cracked or split skin. For treatment of light skin wounds and dry skin.

Therapeutic group: Provitamin B5

2. REFORE USING THE MEDICINE

Do not use the medicine if:

ou are sensitive (allergic) to dexpanthenol or to any of the other ingredients contained in the medicine.

Special warnings regarding use of this medicine:

Before treatment with Bepanthen®, tell the doctor if: you are sensitive to any agent or medicine

- Avoid contact of the preparation with the eyes.
- If Bepanthen® is being used around the genitals, the effectiveness of latex condomtype contraceptives may be impaired.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

HPregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult the doctor or pharmacist before treatment with Bepanthen[®].

Important information about some of the ingredients of Bepanthen®:

This medicine contains cetyl alcohol, stearyl alcohol and lanoline, which may cause a local skin reaction (e.g., atopic dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are unsure how to use Bepanthen®.

The usual dosage is generally:

Diaper rash - Apply a thin layer on the baby's bottom at every diaper change. Nipples - Apply a thin layer on the nipples after each nursing session. Wash the nipples thoroughly before the next nursing session.

Dry/cracked skin or **light wounds and chafed skin** - Apply to the dry areas and/or to the wound up to 3 times a day.

Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, ask the doctor or pharmacist

4. SIDE EFFECTS

As with any medicine, use of Bepanthen® may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor immediately in the event of:

Allergic reaction and/or allergic skin reaction such as: atopic dermatitis, all dermatitis, pruritus, redness, rash, eczema, urticaria, local irritation or blistering. allergic If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. <u>Do not induce</u> vomiting without explicit instruction from a doctor.

The expiry date refers to the last day of the indicated month. Storage conditions: store at a temperature below 25°C

Store in the original package.

Bepanthen® Bepanthen® can be used for up to 3 months after first opening the package. Do not use Bepanthen® after this period. It is recommended to record the date of opening on the package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Wool fat (lanoline), Purified water, Paraffin liquid, White soft paraffin, Refined almond oil, Protegin X, White beeswax, Cetyl alcohol, Stearyl alcohol.

What the medicine looks like and the contents of the package: Cream to white-colored ointment.

Authorized pack sizes: 3.5, 30, 50, 100 gram. Not all package sizes may be marketed. Registration holder: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Manufacturer: GP Grenzach Produktions, Emil-Barell 7, D-79639 Grenzach-wyhlen, Germany

This leaflet was checked and approved by the Ministry of Health in April 2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 127 76 22663 01

