PROFESSIONAL INFORMATION

Bepanthen

NAPPY CARE OINTMENT



COMPOSITION

Bepanthen® contains as active substance dexpanthenol, the alcohol corresponding to pantothenic acid. The ointment contains 50 mg/g dexpanthenol.

Other ingredients: Purified water, Lanolin, Liquid Paraffin, White soft Paraffin, Protegin X, Almond Oil, Beeswax, Cetyl alcohol and stearyl alcohol.

CATEGORY AND CLASS

Category: Nutritional substances that purport to have to have therapeutic or medicinal effects.

PHARMACOLOGICAL ACTION

Promotes the formation and functioning of epithelial tissues. Dexpanthenol exerts the same action as pantothenic acid, to which it is converted in the body. The alcohol nevertheless has advantage of better absorption, a particularly useful property in the case of local application. A factor of vitamin B complex, pantothenic acid is required by the body for the synthesis of co-enzyme A. This co-enzyme plays an important part in the intermediary metabolism, and above all in synthetic processes. It activates the otherwise torpid acetic acid and this contributes to the formation of fatty acids, cholesterol, citric acid and acetylcholine. It further promotes the acetylation of exogenous substances and thus the process of detoxification.

INDICATIONS

PROFESSIONAL INFORMATION

Retains the integrity of chafed, dry, cracked or split skin.

Regular breast care in nursing mothers and soothing of sore or cracked nipples.

<u>Infant care</u>: Soothes, protects and repair nappy (diaper) rash.

Promotion of regeneration of skin in minor injuries (e.g. minor burns and scrapes), skin irritations, chronic

decubitus (bedsores) ulcers, anal fissures, skin grafts and cervical erosions.

Off-day and follow-up usage for patients treated with corticosteroids.

CONTRA-INDICATIONS

Bepanthen Ointment must not be used by persons known to be hypersensitive to any of its ingredients.

DOSAGE AND DIRECTIONS FOR USE

Repair of skin in superficial wounds of any kind and the prevention of chafed or split skin: apply one or

more times daily, as needed.

Breast care: In nursing mothers: apply ointment to nipples after each breast feeding.

Infant care: Apply at each nappy (diaper) change.

Apply one or more times daily as directed by a physician, for cervical erosions.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Allergic reactions may occur in very rare cases.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Accidental poisoning and over-dosage has not been reported.

<u>IDENTIFICATION</u>

Ointment: Homogenous, opaque, slightly yellowish ointment.

PRESENTATION

Ointment 50 mg/g Dexpanthenol – 3,5 g, 30 g and 100 g

Page 2 of 3

PROFESSIONAL INFORMATION

The ointment is packed in laminate tubes (plastic and aluminium layers).

STORAGE INSTRUCTION

Store at or below 25 °C.

Keep out of reach of children.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd.,

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