

HALICOS-NF

Ointment

150 mg/gm

Zinc
Oxide

Read this entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you need further information or advice, ask your pharmacist.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

1. WHAT HALICOS-NF IS AND WHAT IT IS USED FOR

HALICOS-NF is a medicine belonging to the pharmacotherapeutic group: Medicines used for skin conditions – Wound healing aids.

Each gram of ointment contains 150 mg of zinc oxide.

Due to the nature of its formulation, HALICOS-NF is a medicine with remarkable tissue-regenerating action, as well as significant protective, soothing, astringent, and antiseptic properties, thanks to the presence of zinc oxide.

Due to its soothing, healing, and tissue-regenerating action, HALICOS-NF is indicated for diaper dermatitis (diaper rash), first-degree burns, and the healing of superficial wounds.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HALICOS-NF

Do not use HALICOS-NF

- if you are allergic to zinc oxide or any of the other ingredients of this medicine (listed in section 6).

Take special care with HALICOS-NF

- When applied repeatedly over a large surface area, under an occlusive dressing, or in a thick layer; on sensitized or burned skin; or on mucous membranes.
- On the skin of newborns or small children, due to the surface-area-to-weight ratio and the effect of spontaneous occlusion in skin folds and creases in the buttock area.

Other medicines and HALICOS-NF

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. No incompatibilities with other medicines are known.

Do not use concomitantly with antiseptics possessing oxidizing properties.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking any medicine.

HALICOS-NF contains vitamin A; therefore, it should be used with caution during pregnancy.

Driving and operating machinery

HALICOS-NF has no effect on the ability to drive or operate machinery.

Important information about some components of HALICOS-NF

HALICOS-NF contains butylhydroxyanisole (E320) and butylhydroxytoluene (E321). These may cause local skin reactions (e.g., contact dermatitis) or irritation of the eyes and mucous membranes.

HALICOS-NF contains parabens (methyl parahydroxybenzoate and propyl parahydroxybenzoate). May cause allergic reactions (possibly delayed).

3. HOW TO USE HALICOS-NF

Talk to your doctor or pharmacist if you have any questions.

For skin irritations where the skin is intact:

Apply an amount of ointment sufficient to cover the affected area and spread by rubbing gently. This includes cases such as diaper rash and irritation caused by prolonged sun exposure. Applications should be made several times a day.

For superficial wounds, you may cover them with a dressing or gauze previously coated with the ointment. Change the dressing daily.

If you use more HALICOS-NF than you should

Given the route of administration, intoxication is practically impossible.

If you forget to use HALICOS-NF

Do not use a double amount to make up for a missed application.

If you stop using HALICOS-NF

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

HALICOS-NF is a very well-tolerated medicine. However, local reactions may occur, such as:

- Contact dermatitis
- Irritation of the eyes and mucous membranes
- Allergic reactions (possibly delayed).

Reporting of side effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to INFARMED, I.P., using the contact details below. By reporting side effects, you help provide more information on the safety of this medicine.

5. HOW TO STORE HALICOS-NF

Store below 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the packaging, after EXP. The expiry date refers to the last day of the month indicated.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What HALICOS-NF contains

The active substance is zinc oxide.

Each gram contains:

- Zinc Oxide BP 150 mg

Ingredients: Zinc Oxide BP, Vitamin A Palmitate BP, Vitamin D3 BP, Petrolatum, Butylated Hydroxyanisole, Butylated Hydroxytoluene, Acrisol K-140, Magnesium Sulfate Heptahydrate, Methylparaben, Propylparaben, Talc, Propylene Glycol, Sorbitol (70%) (Non-crystallizing), Beeswax, Microcrystalline Wax, Sunflower Oil, Cod Liver Oil, Castor Oil.

What HALICOS-NF looks like and contents of the pack

HALICOS-NF is a white, creamy ointment supplied in white polyfoil tubes of 20, 30, 50, and 100 g.

Alternatively, the 20 g and 30 g presentations are packaged in aluminum tubes.

A hospital pack containing 50 aluminum tubes of 30 g is available. Not all pack sizes may be marketed.

METHODS OF APPLICATION

On the Baby's Bottom

- At every nappy change, apply a thick layer of HALICOS-NF to create a protective barrier between the baby's skin and urine or faeces.
- If nappy rash is already present, change the nappy as frequently as possible and apply a layer of HALICOS-NF at each change.

For Healing Skin Lesions

- In the case of a wound, place HALICOS-NF on gauze or a dressing before applying it to the skin.
- For other skin injuries, such as first-degree burns, apply a layer of HALICOS-NF directly onto the skin.

Manufactured by:



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