

PACKAGE LEAFLET: Information for the user

BABY CREAM

Cream – (4000 IU / 2000 IU / 2 mg / 50 mg) / g

(Vitamin A, Vitamin D3, Vitamin E, Zinc oxide)

Read all of this 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 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. See section 4.

What is in this leaflet:

1. What Baby Cream is and what it is used for
2. What you need to know before you use Baby Cream
3. How to use Baby Cream
4. Possible side effects
5. How to store Baby Cream
6. Further information

1. WHAT BABY CREAM IS AND WHAT IT IS USED FOR

Baby Cream contains vitamins A, D3 and E, and zinc oxide. It is used in cases of dehydration of the outermost layer of skin (the epidermis), especially in neonates and premature children, in skin redness and irritation (i.e. from diapers), and to protect and keep sensitive and delicate skin safe in this age group.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BABY CREAM

Do not use Baby Cream on your baby if they are hypersensitive to any of the ingredients of this cream.

Warnings and precautions

Talk to your doctor or pharmacist before using Baby Cream. This product is for external use only. This cream should not be allowed to come into contact with the eyes or other mucous areas of your baby, because it may cause burns and irritation. Therefore, application of the cream around these areas should be done with caution.

Other medicines and Baby Cream

There are no known interactions with any other products.

Using Baby Cream concomitantly with food and drinks

Use of Baby Cream is not affected by food or drinks.

Pregnancy and breastfeeding

Baby Cream is safe to use during pregnancy and breastfeeding.

Driving and using machines

Use of Baby Cream does not affect driving or using machines.

Important information about some of the ingredients of Baby Cream

Baby Cream contains:

- methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed);
- hydrogenated wool fat, which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE BABY CREAM

Apply an amount of Baby Cream several times a day to your baby's body areas that you want to protect.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Baby Cream can cause side effects, although not everybody gets them.

The side effects that this product may cause are very rare. Skin allergic reactions, hypersensitivity reactions or irritation may occur.

Inform your doctor or pharmacist if these side effects or any other side effects not mentioned in this package leaflet occurs to your baby.

5. HOW TO STORE BABY CREAM

Keep out from the sight and reach of children.

Do not store above 25°C.

Store in the original packaging.

6. FURTHER INFORMATION

What Baby Cream contains

The active substances are vitamin A, vitamin D3, vitamin E and zinc oxide.

One gram of the cream contains 4000 IU retinol (vitamin A palmitate), 2000 IU cholecalciferol (vitamin D3), 2 mg alpha-tocopherol acetate (vitamin E) and 50 mg zinc oxide.

The other ingredients are: ethyl oleate, light liquid paraffin, white beeswax, hydrogenated wool fat, macrogol glyceryloleate, PEG-6 stearate glycol stearate PEG-32 stearate, boric acid, methyl hydroxybenzoate, propyl hydroxybenzoate, glycerol, baby essence, purified water.

Content of the pack

Plastic jars of 50 ml and 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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