

Package leaflet: Information for the patient

# Betasono Cream

Betamethasone valerate

**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. (See section 4.)

## What is in this leaflet

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

## 6. Contents of the pack and other information

**1. What Betasono is and what it is used for**  
Betasono contains a medicine called betamethasone. It belongs to a group of medicines called steroids that reduce swelling and irritation. Betasono is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

## 2. What you need to know before you use Betasono

### Do not use Betasono:

- if you are allergic (hypersensitive) to Betamethasone or any of the other ingredients of this medicine (listed in section 6)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:

- Acne
- severe flushing of skin on and around your nose (rosacea)
- spotty red rash around your mouth (perioral dermatitis)
- itching around your anus or genitals (penis or vagina)
- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)

- itchy skin which is not inflamed

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Betasono.

## Warnings and precautions

Talk to your doctor or pharmacist before using Betasono if:

- you have previously had an allergic reaction with another steroid
- you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much.
- you have psoriasis, your doctor will want to see you more often.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- you are applying to a large surface area
- you are applying the cream on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye
- you have an infection of the skin as this will need to be treated
- you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts.

Dressing or bandages should not be used on children or on the face where the cream is applied. Use on children or on the face should be limited to 5 days.

Contact your doctor if you experience blurred vision or other visual disturbances.  
Do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

## Other medicines and Betasono

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

## Pregnancy, breast-feeding and fertility

If you are pregnant or are breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## Driving and using machines

Betasono cream is a medicinal product for topical application. Does not affect the ability to drive and use machines.

## Betasono contains Propylene glycol.

Betasono contains Propylene glycol. Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

## Betasono contains Methyl paraben and Propyl paraben.

Methyl paraben and Propyl paraben may cause allergic reactions (possibly delayed).

## Betasono contains Ethanol

Betasono contains Ethanol. Ethanol may cause burning sensation on damaged skin.

## 3. How to use Betasono

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

## Using this medicine

- You usually apply Betasono once or twice a day. This may be reduced as your skin begins to get better.
- This cream is for use on your skin only.
- Do not use more than the amount prescribed for you.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- The germs that cause infections like warm, moist conditions under bandages or dressings so always clean the skin before a fresh dressing is put on.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

## Guidance on how to apply the cream

1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Betasono to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.

3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.



## For an adult

Face and neck:  
**2 1/2 fingertip units.**

Back: **7 fingertip units.**  
Front: **7 fingertip units.**

One arm (not including the hand):  
**3 fingertip units**

Both sides of one hand:  
**1 fingertip unit.**

One leg (not including the foot):  
**6 fingertip units.**

One foot:  
**2 fingertip units.**

Do not worry if you find you need a little more or less than this. It is only a rough guide.

## For a child aged 1 - 10

Child's age	Number of fingertip units needed				
	Face and neck	Arm and hand	Leg and foot	Front	Back including Buttocks
1-2 years	1 1/2	1 1/2	2	2	3
3-5 years	1 1/2	2	3	3	3 1/2
6-10 years	2	2 1/2	4 1/2	3 1/2	5

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer.

## If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

## If you apply Betasono to your face

You should only apply the cream to your face if your doctor tells you to. It should not be used for more than 5 days, as the skin on your face thins easily. **Do not let the cream get into your eyes.**

## If you use more Betasono than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

## If you forget to use Betasono

If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

## If you stop using Betasono

If you use Betasono regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly. 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.

## Stop using Betasono and tell your doctor immediately if:

- you find that your skin condition gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to Betasono, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

## Other side effects you may notice when using Betasono include:

### Common (may affect up to 1 in 10 people)

- a feeling of burning, pain, irritation or itching where the cream is applied.

## Very Rare (may affect up to 1 in 10,000 people)

- an increased risk of infection
- an allergic skin reaction where the cream is applied
- rash, itchy bumpy skin or redness of the skin
- thinning and dryness of your skin and it may also damage or wrinkle more easily
- stretch marks may develop
- blood vessels under the surface of your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- weight gain, rounding of the face.
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- a decrease in the level of the hormone cortisol in your blood
- increased blood sugar levels or sugar in the urine
- high blood pressure

## Not Known: frequency cannot be estimated from the available data

- blurred vision

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Betasono

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer box and tube. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information What Betasono contains

The active ingredient is Betamethasone valerate. Each 1 g contains 1.21 mg of Betamethasone valerate equivalent to 1 mg of Betamethasone (0.1%).

The other ingredients are Emulsifying wax, Paraffin, Propylene glycol, Methyl paraben, Propyl paraben, Ethanol, Imidazolidinyl urea, Water.

## What Betasono looks like and contents of the pack

Betasono comes in a tube containing 15 g of white cream, packed in a carton.

## Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon  
P.O. Box 90201 Jdeidet-El-Metn, Lebanon  
Contact us: pharmaline@maliagroup.com  
Website: www.pharmaline.com.lb

Betasono Reg. N° Lebanon 26556/88

## This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists

**The leaflet was last revised in March 2022.**