Betesil®

2.250 mg medicated plaster

Betamethasone valerate

FI/155 (UK) 500000318 2 Rev. 05 10.24

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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 symptoms 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.

What is in this leaflet

1. What BETESIL is and what it is used for

BETESIL is a medicated plaster to be applied on the skin. It contains betamethasone valerate, which is a potent corticosteroid. When applied to the skin, it reduces redness, swelling and itching.

BETESIL is used to treat inflamed skin conditions that do not respond to less potent corticosteroids such as eczema and psoriasis although your doctor can prescribe it for the treatment of other localized skin diseases.

BETESIL is suitable for the treatment of mild to moderate psoriasis (patchy red skin with white scales) located in difficult to treat areas such as elbows and knees.
Overall, the surface area treated with BETESIL should not exceed 5 times the palm of your hand.

2. What you need to know before you use BETESIL

Do not use BETESIL:
- If you are allergic to betamethasone valerate or any of the other ingredients of this medicine (listed in section 6).
- If your skin disease is caused by a viral (e.g. herpes zoster, herpes simplex or vaccinia pustules), fungal or bacterial infection (e.g. syphilitic skin lesions).
- If the skin area to be treated is affected by acne, acne rosacea, perioral dermatitis (around the mouth), skin ulcers, burns, or frostbite, or injured, with or without exuding liquid (serum).
- If your disease is located on the face.
- If you are under 18 years old.

Warning and precautions
Talk to your doctor before using BETESIL.
- If you need to use it for prolonged periods and on large areas of your body, it may cause an increase in the absorption of corticosteroid into your blood. The use of occlusive bandages, especially with plastic material, may increase this effect. The symptoms of this are:
facial redness, weight changes (fat increase in your body and face and loss in your legs and arms), reddish streaks on your stomach, headache, menstrual alterations, or an increase in unwanted face and body hair.
In these situations, get in touch with your doctor immediately and do not interrupt the treatment without first consulting him/her.

- If you decide to discontinue the treatment, you should be aware that a sudden stopping of treatment in psoriasis may cause worsening of symptoms. Stopping should take place gradually and under the strict control of a doctor.

- If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using BETESIL without consulting your prescriber. If your condition has resolved but on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

- If you are affected by widespread psoriasis or diffuse eczema or if your lesions are located in skin folds (e.g. inside of the elbow or knee, armpits, groin, genital area). In these cases, the use of BETESIL for long periods is not advisable (except if treating isolated patches), since these conditions may give rise to an increase in absorption of the corticosteroid into your blood.

- BETESIL acts by reducing inflammation, but if used for long periods it may irritate the skin or cause sensitization reactions. It could also damage and make skin thinner by inhibiting its natural repair process.

- If you need to do a test known as the nitroblue tetrazolium test (NBT) to check for bacterial infections, the corticosteroid contained in the medicated plaster may alter the results of this test.

- If your body is not able to cope with infections as it should, or if you are using drugs which lower your body's ability to fight off diseases (immunosuppressants). These drugs are used to prevent rejection after transplants and may also be prescribed to heal skin diseases likely to be treated with BETESIL.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children
BETESIL is indicated for use in adults only.

Other medicines and BETESIL
Tell your doctor if you are using, have recently used or might use any other medicines.
Since only a minimum quantity of corticosteroid is absorbed by your body, BETESIL is unlikely to interact with other medicines.

BETESIL with food and drink
Since only a minimum quantity of corticosteroid is absorbed by your body, BETESIL is unlikely to interact with food or drink.

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

Driving and using machines
BETESIL does not alter your ability to drive vehicles or use machines.

BETESIL contains
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These substances may cause allergic reactions (possibly delayed).

3. How to use BETESIL

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is: Apply BETESIL to the skin area to be treated once a day.
Do not use more than 6 medicated plasters at the same time.
A new medicated plaster must be applied every 24 hours. It is advisable to wait at least 30 minutes between one application and the next.
Do not use BETESIL for more than 30 days.

Use in children and adolescents
Since no clinical data concerning use in children and adolescents is available, do not use BETESIL if you are less than 18 years old.

Method of administration
Carefully clean and dry the skin area where the medicated plaster will be applied before using BETESIL.
Open the sachet and cut the medicated plaster, if necessary, so that it fits the area to be treated. Peel off the protective film and apply the medicated adhesive part to the area concerned. Any unused part of the plaster should be put back into the sachet so that it can be preserved and used at the next application (see section 5).
Once removed, the medicated plaster must not be reused.
Do not get the medicated plaster wet: it is advisable to take a bath or have a shower between applications. If the edges of medicated plasters applied to particularly mobile parts (e.g. elbow or knee) lift up, apply the adhesive strips for securing dressings included in the medicinal product pack. Never cover the medicated plaster completely with plastic material or occlusive dressings.

If you use more BETESIL than you should
Always use BETESIL exactly as your doctor has told you. If you should accidentally apply more medicated plasters than your doctor prescribed on one day, do not worry, but avoid doing it again.

If you forget to use BETESIL
If you forget to apply the medicated plaster for one day, apply as normal the next.
Do not apply two plasters to the same area on the same day to try to make up for the oversight.

If you stop using BETESIL
If you are following the treatment correctly without seeing improvements, consult your doctor before deciding to discontinue BETESIL treatment.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Side effects which may occur when using BETESIL are local effects on the skin in the plaster application area. These include: redness, itching, boils, skin eruptions with or without pus, skin thinning, the appearance of small red spots of various shapes caused by widening of the surface blood vessels and skin erosion. These side effects are common.

Side effects which have not been observed with BETESIL, but which have occurred with other topical corticosteroids include: swelling, allergic reactions, skin irritation, dry skin and skin flaking, a feeling of skin stretching, stretch marks caused by skin thinning, increase in hair growth, skin redness around the mouth and hair follicles, burning sensation and skin decolouration.

Blurred vision may occur with a not known frequency.

Stopping long term treatment at high doses may cause a worsening of the psoriasis including serious skin reactions with pus. In these situations, get in touch with your doctor immediately and do not interrupt the treatment without first consulting him/her.

Long-term treatment at high doses may increase drug absorption which may lead to an increase in side effects. These effects disappear quickly and completely once the treatment is discontinued.

Steroid withdrawal reaction
If BETESIL is used continuously for prolonged periods, a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning and/or stinging sensation, intense itching, peeling of the skin, oozing open sores (see section 2). The steroid withdrawal reaction may occur with an unknown frequency.

If your conditions get worse during treatment, you may be allergic to BETESIL or require a different treatment. In this case, consult your doctor immediately.

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. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BETESIL

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 carton. If the expiry date is reported as month/year, the expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not use this medicine if you notice visible sign of deterioration.

Store the medicated plaster in its original sachet in order to preserve its integrity (write the date of opening in the space provided on the inside sachet).

Once the sachet is opened, the medicated plaster must be used within 1 month.

Do not throw away any medicines via wastewater or household waste. 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 BETESIL contains:
Each 7.5 cm x 10 cm medicated plaster contains the active substance: 2.250 mg of betamethasone valerate (corresponding to 1.845 mg of betamethasone).

The other ingredients are:
Plaster: unwoven cloth (polypropylene/polyethylene and rayon fibres) laminated with an ethylene-methyl methacrylate copolymer film.
Adhesive layer: sodium hyaluronate, 1,3-butylene glycol, glycerol, disodium edetate, tartaric acid, aluminium glycinate, polyacrylic acid, sodium polyacrylate, hydroxypropylcellulose, carmellose sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water.
Protective film: polyethylene terephthalate film.

What BETESIL looks like and contents of the pack
This medicinal product is a medicated plaster consisting of a colourless plaster. Each medicated plaster is covered with a removable protective film.

Each medicated plaster is individually packed in a sachet in boxes containing 4, 8 or 16 plasters.

Each box includes adhesive strips for securing dressings (medical device).

Not all pack sizes may be marketed

Marketing Authorisation Holder-
IBSA Farmaceutici Italia S.r.l.
Via Martiri di Cefalonia, 2
26900 Lodi

Manufacturer
Altergon Italia S.r.l., Zona Industriale,
83040, Morra de Sanctis, Avellino (Italia)

Distributed by
Derma UK Ltd., Toffee Factory, Ouseburn, Newcastle upon Tyne, NE1 2DF, UK.

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