

Package Leaflet: Information for the user

Betnovate[®]-C Cream

(betamethasone valerate/cloquinoxol)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The name of this medicine is Betnovate-C Cream but it will be referred to as Betnovate-C throughout the remainder of this leaflet.

In this leaflet:

1. What Betnovate-C is and what it is used for
2. Before you use Betnovate-C
3. How to use Betnovate-C
4. Possible side effects
5. How to store Betnovate-C
6. Further information

1. What Betnovate-C is and what it is used for

Betnovate-C contains two different medicines called betamethasone valerate and cloquinoxol.

- Betamethasone valerate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.
- Cloquinoxol is a type of anti-infective medicine. It fights bacterial and fungal infections of the skin.

Betnovate-C is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis, dermatitis or insect bites, where an infection may be a problem.

2. Before you use Betnovate-C

Do not use Betnovate-C:

- if you are allergic (hypersensitive) to betamethasone valerate, cloquinoxol or any of the other ingredients (listed in Section 6)
- if you are allergic (hypersensitive) to iodine
- on a child under 1 year
- 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)
 - viral infections, such as cold sores, herpes or chicken pox
 - blisters or sores on your face and hands (impetigo), or other bacterial infections
 - fungal infections, such as ringworm, athlete's foot, or thrush
 - itching around your back passage (anus) or private parts (genitals) – unless your doctor has told you to do so.

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

Take special care with Betnovate-C

- Check with your doctor or pharmacist before using your medicine if:
- 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.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding.

3. How to use Betnovate-C

Always use cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Guidance on how to apply the cream

1 Wash your hands.

2 Gently rub the correct amount of cream into the skin until it has all disappeared. You can measure how much cream to use with your fingertip. This picture shows one fingertip unit.



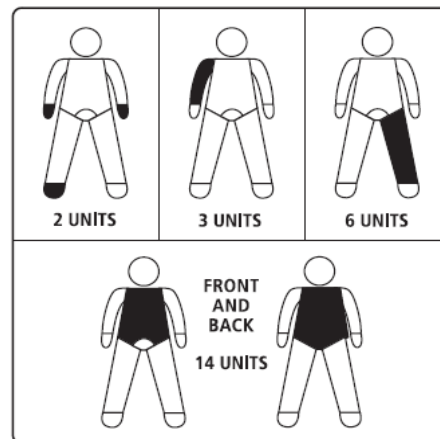
3 Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult

You should find that:

- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.

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



For a child

- Do not use it on children under 1 year of age.
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult amount.
- A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer.

Using this medicine

- You usually apply the cream 2 or 3 times 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 after 7 days talk to your doctor.**
- Do not mix with any other creams or ointments.

If you apply Betnovate-C 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 Betnovate-C than you should

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is 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 Betnovate-C

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 Betnovate-C

If you use this medicine regularly make sure you talk to your doctor before you stop using it.

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

4. Possible side effects

Like all medicines, Betnovate-C can cause side effects, although not everybody gets them.

STOP using this medicine and tell your doctor as soon as possible if:

- you find your condition gets worse or becomes swollen during treatment. You may be allergic to the cream or need other treatment.

Other side effects you may notice when using Betnovate-C include:

- a feeling of burning, irritation or itching where the cream is applied
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Side effects if you use Betnovate-C for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:

- stretch marks may develop
- veins under the surface of your skin may become more noticeable
- increased hair growth and changes in skin colour
- thinning of your skin and it damages more easily
- weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.

Staining of your hair, skin and clothes can occur. You can protect clothes by covering the treated area with a cotton bandage or piece of clean cloth.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betnovate-C

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date on the tube end or carton (Exp). The expiry date refers to the last day of that month.
- Do not store above 30°C.
- If your cream becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Betnovate-C Cream contains

- Each 1g of cream contains 1mg betamethasone (0.1% w/w) as valerate and 30mg clioquinol (3% w/w).
- Also contains chlorocresol, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium dihydrogen phosphate dihydrate, phosphoric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and purified water.

What Betnovate-C Cream looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains 30g of cream. A pale yellow, homogenous, aqueous based cream.

Manufacturer

Glaxo Operations UK Ltd., Harmire Road, Barnard Castle, County Durham, DL12 8DT, UK

Procured from within the EU by the product licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER

Repackaged by MPT Pharma Ltd.

PL 33532/0515 Betnovate®-C Cream

Leaflet dated 05 September 2014
Leaflet coded xxxxxxxx

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Betamethasone valerate 1mg/g and Clioquinol 30mg/g Cream

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- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The name of this medicine is Betamethasone valerate 1mg/g and Clioquinol 30 mg/g Cream but it will be referred to as Betamethasone/Clioquinol Cream throughout the remainder of this leaflet.

In this leaflet:

1. What Betamethasone/Clioquinol Cream is and what it is used for
2. Before you use Betamethasone/Clioquinol Cream
3. How to use Betamethasone/Clioquinol Cream
4. Possible side effects
5. How to store Betamethasone/Clioquinol Cream
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1. What Betamethasone/Clioquinol Cream is and what it is used for

Betamethasone/Clioquinol Cream contains two different medicines called betamethasone valerate and clioquinol.

- Betamethasone valerate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.
- Clioquinol is a type of anti-infective medicine. It fights bacterial and fungal infections of the skin.

Betamethasone/Clioquinol Cream is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis, dermatitis or insect bites, where an infection may be a problem.

2. Before you use Betamethasone/Clioquinol Cream

Do not use Betamethasone/Clioquinol Cream:

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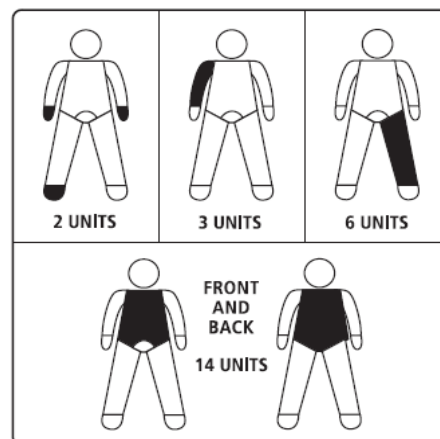
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