

BETNOVATE® cream and ointment

betamethasone valerate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BETNOVATE. It does not contain all the available information about this medicine.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BETNOVATE against the benefits this medicine is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about using this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What is BETNOVATE used for

BETNOVATE contains the active ingredient betamethasone valerate (a type of cortisone) and belongs to the group of medicines called corticosteroids.

BETNOVATE is available as a cream and an ointment.

It is a topical corticosteroid, which is applied to the body surface (skin).

It is used to help relieve the redness, swelling, itching and discomfort of various skin problems such as:

- eczema
- other types of dermatitis.

Ask your doctor or pharmacist if you have any questions about why BETNOVATE has been prescribed for you.

Your doctor knows which skin conditions BETNOVATE is helpful for.

The cream and ointment are only available with a doctor's prescription.

Before you use it

When you must not use it

Do not use BETNOVATE if you have ever had an allergic reaction to:

- betamethasone valerate or any other corticosteroid
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to BETNOVATE may include red, itchy skin rashes or a lumpy rash ("hives").

It may also include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever or fainting.

Do not use this medicine if you are pregnant or intend to become pregnant or breast feed.

Your doctor will discuss the risks and benefits of using BETNOVATE during pregnancy and breast feeding

Do not use BETNOVATE if you suffer from the following medical conditions:

- acne rosacea or vulgaris
- inflammation around the mouth
- a viral skin infection (e.g. chickenpox, cold sores, shingles, warts)
- a bacterial skin infection (e.g. impetigo, boils, cellulitis)

- a fungal skin infection (e.g. tinea, ringworm, thrush)
- skin conditions with ulcers e.g. leg ulcers
- tuberculosis of the skin
- anal or genital itching.

If you are not sure whether you suffer from any of the above medical conditions, ask your doctor before you start using this medicine.

BETNOVATE should not be used if you suffer from poor circulation of blood in the skin region, as it may result in skin ulcers.

Occlusive dressings should not be used if you have a skin infection.

BETNOVATE should not be used in children under the age of 1 year, unless advised by your doctor.

Do not use this medicine after the expiry date (EXP.) printed on the pack.

Do not use your medicine if the packaging shows signs of tampering or if the seal on the tube is broken, or if the product does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

You must tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives
- you have any other health problems, especially if you have an infection
- you are pregnant or intend to become pregnant
- you are breast-feeding or intend to breastfeed.

If you have not told your doctor about any of the above, tell them before you start to use BETNOVATE.

Use in children

BETNOVATE is not recommended for use in children, unless your doctor tells you to do so.

Using other medicines

Tell your doctor or pharmacist if you are using any other creams, ointments or lotions or if you are taking any medicine.

This includes medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with BETNOVATE if they are used excessively or for prolonged periods.

Your doctor or pharmacist has a list of medicines that may interfere with BETNOVATE.

If you have not told your doctor about any of the above, tell them before you start using BETNOVATE.

How to use it

Follow your doctor's instructions carefully, as they may differ from the information contained in this leaflet.

How to use it

Before you start using BETNOVATE, wash and dry your hands thoroughly.

Gently rub a small amount of cream or ointment on the affected area as directed by your doctor.

After applying the ointment or cream, wash and dry your hands thoroughly, unless it is being used for treating your hands.

Occlusive dressings are NOT recommended, unless advised by your doctor.

It is important to use BETNOVATE exactly as your doctor or pharmacist has told you to.

Do not use it just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of BETNOVATE.

Do not apply BETNOVATE to your face unless specifically advised by your doctor.

If your doctor has told you to use it on your face, do not let the cream or ointment get into your eyes.

If you accidentally get some in your eyes, wash them thoroughly with running water for at least ten minutes.

If you use BETNOVATE less than you should, it may not work as well and your skin problem may not improve.

However, if you use BETNOVATE more often than you should, it may not improve your skin problem any faster and may cause or increase side effects.

How long to use it

Your doctor will tell you how long to use BETNOVATE.

Your doctor may tell you to reduce the number of applications as the skin disorder subsides.

If you use BETNOVATE for a long time, the chance of side effects occurring is increased.

If you forget to use it

If you forget to use BETNOVATE, use it as soon as you remember and then go back to your normal times for applying BETNOVATE.

Do not try to make up for the amount that you missed by using more than you would normally use.

If you swallow it

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the accident and

emergency centre at your nearest hospital, if anyone swallows BETNOVATE. Do this even if there are no signs of discomfort or poisoning.

Urgent medical attention may be needed.

While you are using it

Things you must do

Immediately discontinue using BETNOVATE if an irritation or sensitisation occurs.

Tell any doctors and pharmacists who are treating you that you are using this medicine.

Tell your doctor if you become pregnant while using it.

Tell your doctor if you feel it is not helping your condition or if your skin condition worsens or seems infected.

Tell your doctor if, for any reason, you have not used BETNOVATE exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not use BETNOVATE under occlusive dressings (airtight covering) or on large areas of skin unless your doctor tells you to.

Do not use it in or near the eyes.

Do not stop using it or change the amount, area or method of application, without first checking with your doctor.

Do not give this medicine to anyone else even if his or her symptoms seem similar to yours.

Do not use plastic pants or tight-fitting nappies if BETNOVATE is to be used on the nappy area of young children.

Do not use it to treat any other conditions unless your doctor tells you to do so.

Your doctor has prescribed BETNOVATE especially for you

and your condition. If you use it for another condition, it may not work at all or make the condition worse.

Things to be careful of

Do not use large amounts of BETNOVATE for a long period of time.

If you use large amounts for a long time, the chance of systemic absorption through the skin and the chance of side effects may increase.

Only use the cream or ointment on skin areas that rub together such as under the arm or in the groin area if your doctor tells you to.

Only use it on the face if your doctor tells you to. If improvement does not occur within one week, tell your doctor immediately.

Children and adolescents should be followed closely by the doctor, since this medicine is absorbed through the skin and can affect growth or cause other unwanted side effects.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using BETNOVATE.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are using BETNOVATE.

It helps most people with skin problems but it may have some unwanted side effects in some people.

If side effects occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The most commonly reported side effect is local irritation which includes:

- itching
- burning
- dryness
- redness.

Tell your doctor or pharmacist immediately if you notice any of the following at the application site:

- thinning of the skin with easy bruising
- rash around the mouth area
- stretch marks or streaks on the skin
- infection of the hair roots
- change in skin colour
- increased hair growth
- heat rash
- acne.

Side effects are more frequent if BETNOVATE is used under dressings that are close-fitting and keep out the air.

Long periods of treatment under close-fitting dressings may cause thinning of the skin.

If large areas of the skin are treated, especially for a long time and under tight dressings, some steroid may be absorbed into the body. This may cause various effects including:

- stomach ulcers
- high blood pressure
- delayed wound healing
- increased chance of infection
- excessive growth of facial and body hair
- acne
- increased body fluid
- muscle weakness
- eye problems e.g. cataracts, glaucoma and blurred vision.

If you have any questions about any of these effects, you should speak to your doctor immediately.

If you think you are having an allergic reaction to your medicine, tell your doctor immediately or go to the accident and emergency centre at your nearest hospital.

Symptoms may include:

- wheezing

- swelling of the eyelids, face, lips and mouth
- lumpy rash (“hives”)
- tightness in the chest
- fainting.

This is not a complete list of all possible side effects. This medicine may cause other side effects.

Check with your doctor as soon as possible if you have any other problems while using BETNOVATE, even if you do not think the problems are connected with this medicine or are not listed in this leaflet.

After using it

Storage

Keep your BETNOVATE in its pack, until it is time to use it.

Keep your medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep BETNOVATE cream in a cool dry place, protected from light, where the temperature stays below 25°C.

Keep BETNOVATE ointment in a cool dry place, protected from light, where the temperature stays below 30°C.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using BETNOVATE or it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

BETNOVATE cream is a soft, white cream with a faint odour of chlorocresol. It is available in the following strengths:

- BETNOVATE cream (0.1%): 2 g (sample pack), 30 g & 100 g aluminium tube
- BETNOVATE 1/2 cream (0.05 %): 2 g (sample pack), 15 g and 30 g aluminium tube
- BETNOVATE 1/5 cream (0.02%): 2 g (sample pack) & 100 g aluminium tube.

BETNOVATE ointment is a greyish-white, smooth ointment. It is available in the following strengths:

- BETNOVATE ointment (0.1%): 2 g (sample pack) & 30 g aluminium tube
- BETNOVATE 1/2 ointment (0.05 %): 2 g (sample pack), 15 g & 30 g aluminium tube

Note: Not all pack sizes may be available.

Ingredients

Betamethasone valerate is the active ingredient in BETNOVATE cream and ointment.

Inactive ingredients

BETNOVATE cream

- white soft paraffin
- paraffin-liquid
- chlorocresol (preservative)
- cetostearyl alcohol
- cetomacrogol 1000
- monobasic sodium phosphate
- water-purified.

BETNOVATE cream contains a preservative.

BETNOVATE ointment

- white soft paraffin
- paraffin-liquid.

BETNOVATE ointment is preservative free.

BETNOVATE cream and ointment do not contain any colouring agents, lanolin or parabens.

Australian Product Registration numbers:

BETNOVATE cream: AUST R 12492

BETNOVATE ointment: AUST R 57335

BETNOVATE 1/2 ointment: AUST R 57336

BETNOVATE 1/2 cream: AUST R 12488

BETNOVATE 1/5 cream: AUST R 12491.

Sponsor details

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

This information was revised in August 2018.