BETNOVATE cream and ointment

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BETNOVATE?

BETNOVATE contains the active ingredient betamethasone (as betamethasone valerate). BETNOVATE is used to help relieve the redness, swelling, itching and discomfort of various skin problems.

For more information, see Section 1. Why am I using BETNOVATE? in the full CMI.

2. What should I know before I use BETNOVATE?

Do not use if you have ever had an allergic reaction to betamethasone, any other corticosteroid or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BETNOVATE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BETNOVATE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use BETNOVATE?

Gently rub a small amount on the affected area.

More instructions can be found in Section 4. How do I use BETNOVATE? in the full CMI.

5. What should I know while using BETNOVATE?

Things you should do	• Remind any doctor or pharmacist you visit that you are using BETNOVATE. • Tell your doctor if you feel it is not helping your condition or if your skin condition worsens or seems infected.
Things you should not do	• Do not apply to your face unless advised by your doctor. • Do not use it just before having a bath, shower or going swimming. • Do not use BETNOVATE under tight dressings or on large areas of skin unless advised by your doctor.
Looking after your medicine	• Keep in a cool dry place, protected from light where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using BETNOVATE? in the full CMI.

6. Are there any side effects?

The most common side effect is local skin irritation which includes itching, burning, dryness and redness.

If large areas of the skin are treated, especially for a long time and under tight dressings, this medicine may be absorbed into the body causing more serious side effects. This can include stomach ulcers, high blood pressure, delayed wound healing, muscle weakness, increased body fluid and eye problems.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

BETNOVATE cream and ointment

Active ingredient: *betamethasone (as betamethasone valerate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BETNOVATE.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BETNOVATE.

Where to find information in this leaflet:

1. Why am I using BETNOVATE?
2. What should I know before I use BETNOVATE?
3. What if I am taking other medicines?
4. How do I use BETNOVATE?
5. What should I know while using BETNOVATE?
6. Are there any side effects?
7. Product details

1. Why am I using BETNOVATE?

BETNOVATE contains the active ingredient betamethasone (as betamethasone valerate). BETNOVATE is a type of topical cortisone you can apply to the skin and belongs to the group of medicines called corticosteroids. It is available as both a cream (in three different strengths) and an ointment.

BETNOVATE is used to help relieve the redness, swelling, itching and discomfort of various skin problems such as eczema and other types of dermatitis.

Ask your doctor or pharmacist if you have any questions about why BETNOVATE has been prescribed for you.
Your doctor may have prescribed this medicine for another purpose.

2. What should I know before I use BETNOVATE?

Warnings

Do not use BETNOVATE if:

- **you are allergic to betamethasone, any other corticosteroid, or any of the ingredients listed at the end of this leaflet.**
- **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
  - you suffer from poor circulation of blood in the skin region, as it may result in skin ulcers.
  - tuberculosis of the skin
  - anal or genital itching.
- **the packaging shows signs of tampering**
- **the expiry date printed on the pack has passed.**

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- have any other medical conditions, especially if you have an infection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with BETNOVATE and affect how it works.

4. How do I use BETNOVATE?

How to use BETNOVATE

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

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

Gently rub a small amount of cream or ointment on the affected area.

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

Airtight dressings should not be used with BETNOVATE unless advised by your doctor.

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 BETNOVATE

BETNOVATE should be used regularly at the same time each day. If you miss your dose at the usual time, 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 use too much

If you think that you have used too much BETNOVATE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BETNOVATE?

Things you should 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 should not do

- **Do not use BETNOVATE under airtight dressings 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.

Do not use the cream or ointment on skin areas that rub together such as under the arm or in the groin area unless your doctor tells you to.

Do not use it on the face unless 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.

Looking after your medicine

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

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Local skin irritation which includes itching, burning, dryness or redness. These side effects are common.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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.	**Tell your doctor or pharmacist immediately if you notice any of these side effects at the application site.**
If large areas of the skin are treated, especially for a long time and under airtight 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.	**Speak to your doctor immediately if you have any of these effects.**
If you think you are having an allergic reaction to your medicine, with symptoms including: • wheezing • swelling of the eyelids, face, lips and mouth • lumpy rash (“hives”) • tightness in the chest • fainting.	**Tell your doctor immediately or go to the accident and emergency centre at your nearest hospital.**

Side effects are more frequent if BETNOVATE is used under airtight dressings.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BETNOVATE cream contains

Active ingredient (main ingredient)	• betamethasone (as betamethasone valerate) *(refer to below description for strength)*
Other ingredients (inactive ingredients)	• white soft paraffin • liquid paraffin • chlorocresol • cetostearyl alcohol • cetomacrogol 1000 • monobasic sodium phosphate • purified water. BETNOVATE cream contains chlorocresol as a preservative.

What BETNOVATE ointment contains

Active ingredient (main ingredient)	• betamethasone (as betamethasone valerate) 1 mg/g
Other ingredients (inactive ingredients)	• white soft paraffin • liquid paraffin. BETNOVATE ointment is preservative free.

Do not take this medicine if you are allergic to any of these ingredients.

What BETNOVATE looks like

BETNOVATE is available as both a cream (in three different strengths) and an ointment.

- BETNOVATE cream is a soft, white topical cream with a faint odour of chlorocresol, a preservative. It is available in the following strengths and pack sizes:
  - BETNOVATE cream contains betamethasone (as valerate) 1 mg/g. Available in a 30 g aluminium tube.
  - BETNOVATE 1/2 cream contains betamethasone (as valerate) 0.5 mg/g. Available in a 15 g aluminium tube.
  - BETNOVATE 1/5 cream contains betamethasone (as valerate) 0.2 mg/g. Available in a 100 g aluminium tube.
- BETNOVATE ointment is a greyish-white, smooth ointment. It is available in a 30 g aluminium tube.

Australian Product Registration numbers:

BETNOVATE cream: AUST R 12492
BETNOVATE 1/2 cream: AUST R 12488
BETNOVATE 1/5 cream: AUST R 12491

BETNOVATE ointment: AUST R 57335

Who distributes BETNOVATE

Aspen Pharmacare Australia Pty Ltd
Sydney NSW
Australia

www.aspenpharma.com.au

This leaflet was revised in September 2026.