

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.
- In this leaflet, Betamethasone 0.1% w/w Eye Ointment will be called Betamethasone Ointment

In this leaflet:

1. What Betamethasone Ointment is for
2. Before you use Betamethasone Ointment
3. How to use Betamethasone Ointment
4. Possible side effects
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1. What Betamethasone Ointment is for

Betamethasone Ointment belongs to a group of medicines called topical corticosteroids ('steroids' for short).

Betamethasone Ointment work by reducing inflammation (redness, itching and soreness). Topical means that they are used on the outside of the body and not taken by mouth or injection. Betamethasone Ointment is used to treat inflammation of the eye where there is no infection present.

It is important to use this medicine to prevent any damage to the delicate tissues of your eyes and to prevent any infection developing.

2. Before you use Betamethasone Ointment

Important: Never use this medicine in your eye without first checking with your doctor. If it is used for the wrong condition, it could lead to blindness.

Do not use Betamethasone Ointment if:

- You are allergic to betamethasone
- You are allergic to any of the other ingredients of Betamethasone Ointment (listed in section 6)
- You have not checked your eye condition with your doctor first. If this medicine is used in your eye, for the wrong condition, it could lead to blindness.
- You have an infection in the eye, or it is producing pus and is sticky
- You have ulcers in your eye (shingles)
- You have glaucoma (increased pressure

in the eye)

- You have Tuberculosis (TB)

If any of the above applies to you talk to your doctor or pharmacist.

Check with your doctor before using Betamethasone Ointment if:

- You have been treated with Betamethasone or similar corticosteroid medicine recently. You should not use corticosteroids for a long time without regular medical check-ups from your doctor
 - You have redness in your eyes for which you do not know the cause. Steroid treatment must not be given unless the cause of the redness is known.
 - You have thinning of the cornea or sclera (the tissues which cover the outer surface of the eye). Using this ointment could lead to a hole in the eyeball.
 - You are giving this medicine to a baby. Using this medicine for a long time in babies may cause the adrenal gland to stop working properly.
- If any of the above applies to you talk to your doctor or pharmacist.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Betamethasone Ointment and your doctor may wish to monitor you carefully if you are taking these medicines (including some

medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Betamethasone Ointment. If you use Betamethasone Ointment while pregnant there may be small risk of damage to the ear, cleft palate or retarded growth in the foetus.

Driving and using machines

Betamethasone Ointment may cause temporary blurred vision and light headedness. If this happens to you, do not drive or use machinery until you return to normal.

Warnings about visual problems when using Betamethasone Ointment

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

3. How to use Betamethasone Ointment

Important: Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Things to remember about your dose:

- Always use Betamethasone Ointment exactly as your doctor has told you
- Treatment should be with as little ointment as possible for the shortest time. Once you notice an improvement in your condition, the number of times you use the ointment should be reduced.

Getting ready to use your medicine

Check that the seal on the tube is not broken before using Betamethasone Ointment for the first time. Wash and dry your hands.

Using your medicine

To open tube:

Unscrew and remove the upper screw cap to reveal a pointed nozzle. Unscrew the main cap and use the nozzle to pierce the metal seal on the tube. Replace the main cap onto the tube and squeeze out the ointment as required. Replace the small screw cap after use.

If you do not notice any improvement after 7 days, then, you should stop the treatment and tell your doctor.

Adults, the elderly and children

1. Tilt your head backwards.
2. Look up and squeeze approximately 1/4 inch of the ointment below the lower lid, 2 or 3 times daily and/or at night.
3. Close your eyes
4. After use, always replace the cap on the tube

Medical check-ups

If you are using this medicine for your eyes and you use it for a number of weeks, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for:

- An increase in pressure
- Cataracts
- Infection.

If you use more Betamethasone Ointment

than you should

If you accidentally use too much Betamethasone Ointment it is unlikely to lead to any serious side effects. However, if you are concerned, contact the nearest hospital casualty department or your doctor. Accidental swallowing of the contents of one tube (up to 3g) is unlikely to lead to any serious adverse events.

If you forget to use Betamethasone Ointment

Do not use a double dose to make up for a missed dose. Simply use the next dose as planned.

How to stop using Betamethasone Ointment

Do not stop using Betamethasone Ointment without first talking to your doctor.

If you have been using Betamethasone Ointment for a long period of time (around 6 to 8 weeks), then you should stop using it gradually, to avoid the inflammation coming back.

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

4. Possible side effects

Like all medicines Betamethasone Ointment can cause side effects, although not everybody gets them. These may include:

- Sensitivity reactions, which may not appear until some time after you have started to use the ointment, include irritation, burning, stinging and itching, and inflammation.
- Increased pressure in your eye (glaucoma), which may lead to problems with your sight. This medicine

may cause ulceration of the front part of the eye (the cornea). Tell your doctor if your eye becomes painful and/or you have blurred vision which does not get better after a few minutes.

- Using the ointment in the eye very often or for a long time may cause cataracts (clouding of the lens of the eye). Enlarged pupils, drooping of the eyelids or inflammation of the outer surface of the eye may also occur.
- Some diseases cause thinning of parts of the eye, corticosteroid treatment of these diseases can lead to perforation.
- 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. You can also report side effects directly via Yellow Card Scheme on the MHRA website (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 Betamethasone Ointment

Keep out of the sight and reach of children. Do not use Betamethasone Ointment after the expiry date on the label. The expiry date refers to the last day of that month. The tube should be disposed of 28 days after first opening, even if there is medicine remaining. Store Betamethasone Ointment below 30°C.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Betamethasone Ointment contains

The active substance is betamethasone sodium phosphate at a concentration of 0.1%w/w.

The other ingredients are white soft paraffin and liquid paraffin.

What Betamethasone Ointment looks like

Betamethasone Ointment comes in a collapsible tube with an application nozzle and a plastic cap. It contains 3g of ointment.

Marketing Authorisation Holder

RPH Pharmaceuticals AB, Lagervägen 7, 136 50 Jordbro, Sweden.

Manufacturer

BePharBel Manufacturing SA, Rue des Cultivateurs, 25, Bruxelles 1040, Belgium. This leaflet was last updated October 2017.

If this leaflet is difficult to see or read or you would like it in a different format, please contact RPH Pharmaceuticals AB, Lagervägen 7, 136 50 Jordbro, Sweden.