XOBET®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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Xobet Ointment?

Xobet Ointment contains the active ingredient clobetasol propionate. Xobet is used only for short-term treatment of resistant or severe skin conditions in adults. The resistant skin conditions include psoriasis, persistent lesions on the skin, a condition called lichen sclerosus/planus which is an inflammatory condition that can cause bumps on your skin and/or sores in moist areas like your mouth and vagina and around your vulva and a condition called discoid lupus erythematosus (a persistent skin condition of sores with inflammation and scarring mostly on the face, ears, and scalp).

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

2. What should I know before I use Xobet Ointment?

Do not use if you have ever had an allergic reaction to Xobet Ointment or any of the ingredients listed at the end of the CMI. Do not use Xobet Ointment on skin infections, including bacterial, mycobacterial, viral, fungal or parasitic infections, wound ulcers, rosacea, acne, itching without a rash. Do not use Xobet cream on the face, groin or under arms.

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 Xobet Ointment? in the full CMI.

3. What if I am taking other medicines?

Some antivirals and antifungals may lead to increased systemic exposure when used on conjunction with Xobet Ointment.

4. How do I use Xobet Ointment?

Your doctor will tell you when and how much of Xobet Ointment to used. Generally, it can be used twice a day for not more than 2 weeks continuously. More instructions can be found in Section 4. How do I use Xobet Ointment? in the full CMI.

5. What should I know while using Xobet Ointment?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Xobet Ointment.	
Things you should not do	 Do not stop using this medicine suddenly. Do not use for more than 2 weeks continuously Do not use more than 14 g/week 	
Driving or using machines	The effect of Xobet Ointment on driving or operating machinery is not known.	
Drinking alcohol	Effect of alcohol on the activity of Xobet Ointment is not known.	
Looking after your medicine	 Store it in a cool dry place away from sunlight. Keep it where young children cannot reach it. 	

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

6. Are there any side effects?

Extreme fatigue; lightheadedness, dizziness or fainting; muscle or joint pain; skin thinning, wrinkling, dryness or discolouration; itch, rash, redness, burning or pain; increased hair growth, acne, weblike veins or red spots, infections due to reduced immune system. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

XOBET® OINTMENT?

Active ingredient: clobetasol propionate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Xobet Ointment. 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 Xobet Ointment.

Where to find information in this leaflet:

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

1. Why am I using Xobet Ointment?

Xobet Ointment contains the active ingredient clobetasol propionate. Xobet is a very potent topical corticosteroid.

Xobet is used only for short-term treatment of resistant or severe skin conditions in adults. The resistant skin conditions include psoriasis (excluding widespread plaque psoriasis); persistent lesions on the skin; a condition called lichen sclerosus/planus which is an inflammatory condition that can cause bumps on your skin and/or sores in moist areas like your mouth, vagina and around your vulva; and a condition called discoid lupus erythematosus which is a persistent skin condition of sores with inflammation and scarring mostly on the face, ears, and scalp.

2. What should I know before I use Xobet Ointment?

Warnings

Do not use Xobet Ointment:

use this medicine.

- If you are allergic to clobetasol propionate, or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can
- For treatment of skin conditions in children under one year of age, including dermatitis and nappy rash.
- To treat following conditions:
 - Untreated skin infections

- Ulcerous wounds
- Rosacea which is a common skin condition that causes blushing or flushing and visible blood vessels in your face
- Acne
- Severe itching of the skin without any inflammation
- Itching or burning sensations in the genital area
- Rash around the mouth.

Check with your doctor if you:

- Take any medicines for any other condition.
- Have a condition which may affect your immune system or have had genital warts.
- You have been advised to use the medicine in a child younger than 18 years of age.

You have not been instructed on the amount, or duration of time to apply the medicine. 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 <u>6. Are there any side effects?</u>

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.

There are no adequate studies in pregnant women to show if Xobet could or could not be used when pregnant or when breastfeeding. Xobet Ointment should only be used if the potential benefit to the mother is higher than the potential risk to the fetus of the baby. The steroid in Xobet has been shown to cause damage to the fetuses in studies in pregnant animals. Xobet ointment should be avoided during pregnancy, unless clearly necessary.

If appropriate a mild to moderate topical corticosteroid should be used.

Skin Changes

Xobet can cause skin burning, stretch marks, thinning of the skin, pigmentation changes, excessive hair growth and can make symptoms worse.

Treatment of psoriasis with corticosteroids such as Xobet (or its withdrawal) may make psoriasis more severe. Xobet may also cause rosacea and steroid acne to appear.

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 antivirals and antifungals may lead to increased systemic exposure when used in conjunction with Xobet Ointment.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Xobet Ointment.

4. How do I use Xobet Ointment?

How much to use?

- Your doctor will tell you how much Xobet Ointment to used
- Apply thinly and gently rub to cover the entire affected area once or twice a day until improvement occurs.
- After application of Xobet Ointment, moisturising creams or ointments should not be applied to the skin for at least one to two hours.
- Your doctor will tell you if the skin area should be covered with polythene film after application of Xobet Ointment.
- Your doctor will tell you when and how to stop using the Ointment. It has to be stopped gradually.

When to use Xobet Ointment?

 Your doctor will tell you when and how much of Xobet Ointment to used. Generally, it can be used twice a day for not more than 2 weeks continuously.

If you forget to use Xobet Ointment

Xobet Ointment should be used regularly once or twice daily for not more than 2 weeks. If you forget to apply the ointment at the usual time, do not apply twice the amount to make up for the dose that was missed.

If you use too much Xobet Ointment

As the Xobet Ointment is applied on the skin, severe overdosage is not likely. However, in cases of overdose, application of the ointment must be stopped gradually.

You should:

- 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 Xobet Ointment?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Xobet Ointment.

Things you should not do

- Unless instructed by your doctor, you should not apply the ointment or ointment for more than 2 weeks.
- Unless instructed by your doctor, you should not apply more than 14 grams of ointment or ointment each week.
- Unless instructed by your doctor, you should not apply the ointment to the face or genital area.
- Do not stop using this medicine suddenly.

Driving or using machines

There have been no studies to investigate the effect of clobetasol on driving performance or the ability to operate machinery. A negative effect on such activities is not expected.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 25°C in a cool dry place away from sunlight. Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

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	
Infections: Infection caused by bacteria, fungi, parasites or viruses due to a reduced immune system Inflamed hair follicles		Speak to your doctor if you have any of these side effects.	
Ch	anges to your skin Apart from improvement in your		
	skin condition, you may notice the following changes to your		
	skin during the application of the ointment.		

•	Itch, rash, redness, burning or	
	pain.	
•	Skin thinning, wrinkling, dryness	
	or discolouration.	
•	Increased hair growth, acne, fine	
	or weblike veins or red spots.	

Serious side effects

Tell your doctor right away if any of the following side effects occur: unusual/extreme tiredness, weight loss, headache, swelling in the ankles/feet, increased thirst/urination, vision problems. These symptoms may be due to too much Xobet being absorbed into your body.

A very serious allergic reaction to Xobet is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Serious side effects	What to do
 Extreme fatigue Lightheadedness, dizziness or fainting Muscle or joint pain Itching or swelling of the face, tongue or throat Trouble breathing 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 Xobet Ointment contains

Active ingredient	Clobetasol propionate
-------------------	-----------------------

Other ingredients	Sorbitan Sesquioleate Propylene Glycol White Petrolatum

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

What Xobet Ointment looks like

Xobet Ointment is a white to off-white translucent ointment.

(AUST R 386560).

Who distributes Xobet Ointment?

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121 AUSTRALIA

www.arrotex.com.au

This leaflet was prepared in February 2025.