

PACKAGE LEAFLET

Package leaflet: Information for the user

Wynzora 50 micrograms/g + 0.5 mg/g cream calcipotriol/betamethasone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Wynzora is and what it is used for
2. What you need to know before you use Wynzora
3. How to use Wynzora
4. Possible side effects
5. How to store Wynzora
6. Contents of the pack and other information

1. What Wynzora is and what it is used for

Wynzora is used on the skin to treat mild to moderate psoriasis vulgaris, including scalp psoriasis in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

Wynzora contains calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. Be aware the percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betamethasone is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use Wynzora

Do not use Wynzora:

- if you are allergic to calcipotriol, betamethasone or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with calcium levels in your body (ask your doctor)
- if you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor).

As Wyzora contains a bethamethasone, a strong steroid, do NOT use it on skin affected by:

- skin infections caused by viruses (e.g. cold sores or chicken pox)
- skin infections caused by a fungus (e.g. athlete's foot or ringworm)
- skin infections caused by bacteria
- skin infections caused by parasites (e.g. scabies)
- tuberculosis (TB)
- perioral dermatitis (red rash around the mouth)
- thin skin, easily damaged veins, stretch marks
- ichthyosis (dry skin with fish-like scales)
- acne (pimples)
- rosacea (severe flushing or redness of the skin on the face)
- ulcers or broken skin.

Warnings and precautions

Talk to your doctor, pharmacist or nurse **before using** Wyzora if:

- you have diabetes mellitus (diabetes) as your blood sugar/glucose level may be affected by the steroid
- you are using other medicines that contain steroids as you may get side effects
- you have a certain type of psoriasis called guttate psoriasis.

Talk to your doctor, pharmacist or nurse **during treatment** if:

- you have used this medicine for a long time and plan to stop (as there is a risk your psoriasis will get worse or 'flare up' when steroids are stopped suddenly)
- your skin becomes infected as you may need to stop your treatment
- the calcium level in your blood changes (see section 4 for further information)
- you experience blurred vision or other visual disturbances.

Special precautions

- Avoid use on more than 30% of your body or using more than 15 grams per day;
- Avoid using under a bathing cap, bandages or dressings as it increases the absorption of the steroid;
- Avoid use on large areas of damaged skin, on mucous membranes, or in skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid;
- Avoid use on your face or genitals (sex organs) as they are very sensitive to steroids;
- Avoid excessive sunbathing, excessive use of solarium and other forms of light treatment.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children

Wyzora is not recommended for the use in children below the age of 18 years.

Other medicines and Wyzora

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Pregnancy

Use of Wynnzora during pregnancy should only take place as directed by a doctor.

Breast-feeding

Use of Wynnzora during breast-feeding should only take place as directed by a doctor.

Do not apply Wynnzora to the breast if you are breast-feeding.

Driving and using machines

This medicine has no or negligible effect on your ability to drive or use machines.

Wynnzora contains butylhydroxyanisole (E320) and macroglycerol hydroxystearate

Butylhydroxyanisole (E320) may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes. Macroglycerol hydroxystearate may cause local skin reactions.

3. How to use Wynnzora

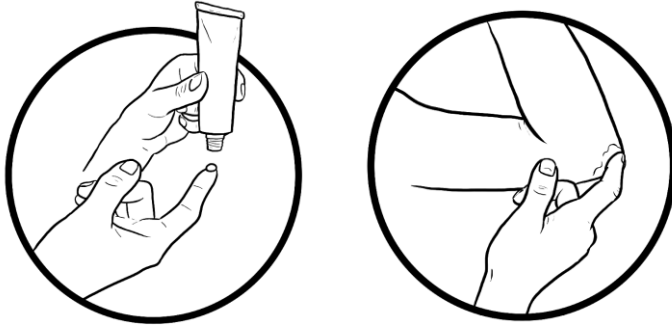
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Wynnzora is for cutaneous use (on the skin).

Instructions for proper use

When used on the body

- Use only on your psoriasis and do not use on skin which does not have psoriasis.
- Squeeze the cream onto a clean finger or directly onto the area affected by psoriasis.
- Apply the cream to the affected area with your fingertips, and rub in the cream thoroughly in a thin layer.
- Do not bandage, tightly cover or wrap the treated skin area.
- Wash your hands well after using Wynnzora. This will avoid accidentally spreading the cream to other parts of your body (especially the face, mouth and eyes).
- Do not worry if some cream accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far.
- In order to achieve optimal effect, it is recommended not to take a shower or bath immediately after application of Wynnzora Cream. It is recommended to allow 8 hours between the application and showering to avoid washing it off.
- After applying the cream, avoid contact with textiles which are easily stained by grease (e.g. silk).



When used on the scalp

- Before applying Wynzora to the scalp, comb the hair to remove any loose scales.
- It may help to part your hair before you use Wynzora.
- Washing your hair before application of Wynzora is not necessary.
- Apply Wynzora Cream to fingertip, and then apply directly to the areas where you can feel the raised plaques. Rub in the cream thoroughly in a thin layer.



- In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of Wynzora.
- It is recommended to allow 8 hours between the application and showering to avoid washing it off.

Duration of treatment

- Use the cream once a day. It may be more convenient to use the cream in the evening.
- The normal initial treatment period is 8 weeks.
- Your doctor may decide on a different treatment period.
- Your doctor may decide on repeated treatment.
- Do not use more than 15 grams in one day.

If you use other calcipotriol containing medicines, the total amount of calcipotriol medicines must not exceed 15 grams per day, and the area treated should not exceed 30% of the total body surface.

What should I expect when I use Wynzora?

Most patients see obvious results after 1 week, even if the psoriasis is not yet cleared at that point.

If you use more Wyzora than you should

Contact your doctor if you have used more than 15 grams in one day.

Excessive use of Wyzora may also cause a problem with calcium in your blood, which usually normalises when discontinuing treatment. Your doctor may need to carry out blood tests to check that using too much cream has not caused a problem with calcium in your blood.

Excessive prolonged use can also cause your adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).

If you forget to use Wyzora

Do not take a double dose to make up for a forgotten dose.

If you stop using Wyzora

The use of Wyzora should be stopped as indicated by your doctor. It may be necessary for you to stop this medicine gradually, especially if you have used it for a long time.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects that have been observed with Wyzora:

Uncommon (may affect up to 1 in 100 people):

- Inflammation or swelling of the hair root at application site (folliculitis)
- Sleeplessness (Insomnia)
- Itchiness (Pruritus)
- Rash
- Hives (Urticaria)
- Skin irritation at application site
- Pain at application site
- Eczema at application site
- Peeling at application site (exfoliation)
- Application site spider veins (telangiectasia)

Frequency not known (frequency cannot be estimated from the available data):

- Blurred vision.

Wyzora contains betamethasone and calcipotriol. You may therefore experience the following side effects. These side effects are more likely to happen if Wyzora is used for a long time, if used under dressings or in skin folds (e.g. groin, armpits or under breasts), or if used on large skin areas:

- allergic reactions with swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may also occur

- calcium levels in your blood or urine may increase so much that you get symptoms. Signs are frequent urination, constipation, muscle weakness, and confusion. When the treatment is stopped, the calcium levels return to normal
- your adrenal glands may stop working properly. Signs are tiredness, depression, anxiety
- cloudy vision, difficulty seeing at night, sensitivity to light (this could be a sign of cataracts)
- eye pain, red eye, decreased or cloudy vision (this could be a sign of increased pressure inside the eye)
- infections (because your immune system is weakened)
- pustular psoriasis (a red area of psoriasis with yellowish pustules (pimples))
- you may experience fluctuations in blood sugar levels.

If you experience any of the above side effects you should **contact your doctor immediately**.

Less serious side effects known to be caused by calcipotriol or betamethasone include the following:

- thinning of the skin
- stretch marks
- blood vessels under your skin may become more noticeable
- changes in hair growth
- red rash around the mouth (perioral dermatitis)
- worsening of your psoriasis
- sensitivity of the skin to light resulting in a rash
- itchy skin rash (eczema)
- white or grey hair can transiently change to a yellowish colour at the application site when used on the scalp.

Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Wyzora

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not freeze.

Discard the tube with any remaining cream 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Wyzora contains

- The active substances are: calcipotriol and betamethasone.
One gram of cream contains 50 micrograms of calcipotriol and betamethasone dipropionate equivalent to 0.5 mg betamethasone.
- The other ingredients are: isopropyl myristate, paraffin liquid, medium-chain triglycerides, isopropyl alcohol, macrogol lauryl ether , poloxamer, macrogolglycerol hydroxystearate, carbomer interpolymers, butylhydroxyanisole, trolamine, sodium phosphate dibasic heptahydrate, sodium dihydrogen phosphate monohydrate, all-rac- α -tocopherol and purified water.

What Wyzora looks like and contents of the pack

Wyzora is a white cream filled in aluminium tubes coated with epoxyphenol and with polyethylene screw cap.

Pack size: 1 tube of 60 g, 2 x tube of 60 g

Marketing Authorisation Holder

Almirall, S.A.
Ronda General Mitre 151
08022 Barcelona
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Manufacturer

Laboratoires Chemineau
93 route de Monnaie
Vouvray, 37210
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