

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

WYNZORA®

Calcipotriol and betamethasone dipropionate cream

This Patient Medication Information is written for the person who will be taking **WYNZORA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **WYNZORA®** talk to a healthcare professional.

What WYNZORA® is used for:

WYNZORA® is used on the skin in adults to treat psoriasis vulgaris for up to 8 weeks. Based on studies done in adults, WYNZORA® can also be used in adolescents aged 12 to 17 years.

How WYNZORA® works:

WYNZORA® contains two medicines, calcipotriol and betamethasone, that work together to control psoriasis.

Calcipotriol helps slow down the fast growth of skin cells with psoriasis. Betamethasone is a type of medicine called a corticosteroid that helps reduce redness, swelling, and itching.

You may start to see improvement in your skin within a few weeks. Signs that WYNZORA® is working include less scaling, redness, and itching.

The ingredients in WYNZORA® are:

Medicinal ingredients: calcipotriol and betamethasone (as betamethasone dipropionate).

Non-medicinal ingredients: alpha-tocopherol, butylated hydroxyanisole, carbomer interpolymers (type A), dibasic sodium phosphate heptahydrate, isopropyl alcohol, isopropyl myristate, medium-chain triglycerides, mineral oil, poloxamer (407), sodium dihydrogen phosphate monohydrate, polyoxyl 40 hydrogenated castor oil, polyoxyl lauryl ether, purified water and triethylamine.

WYNZORA® comes in the following dosage forms:

Cream: 0.05 mg/g of calcipotriol and 0.5 mg/g of betamethasone (as betamethasone dipropionate)

Do not use WYNZORA® if:

- You are allergic to any of the ingredients in WYNZORA®.
- You are allergic to any part of the container, for example, to aluminium.
- You have a condition that affects your calcium levels.
- You have a skin infection caused by a virus, fungus, bacteria or parasite.
- You have a skin condition related to tuberculosis.
- You have a rash around the mouth called perioral dermatitis. You must not use WYNZORA® on this skin area.
- You have areas on your body with thin skin, stretch marks or fragile veins. You must not use WYNZORA® on these areas.

- You have a condition called ichthyosis which causes dry, thickened and scaly skin. You must not use WYNZORA® on these areas.
- You have acne, a condition called rosacea which causes red flushed facial skin, ulcers or wounds. You must not use WYNZORA® on these areas.
- You have a type of psoriasis with severe inflammation called erythrodermic psoriasis.
- You have a type of psoriasis with pus-filled blisters called pustular psoriasis.
- You have a type of psoriasis that causes widespread skin peeling.

WYNZORA® is not approved for use in children under 12 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take WYNZORA®. Talk about any health conditions or problems you may have, including if you:

- have diabetes
- have a skin infection or if skin areas with psoriasis become infected
- have a skin condition called guttate psoriasis
- use other medicines that contain corticosteroids or calcipotriol
- have liver problems
- have kidney problems

Other warnings you should know about:

Applying WYNZORA®

Do not use WYNZORA® in or around your eyes, on your face, under the arms, in the groin area, in skin folds/creases or on areas of broken skin.

Do not bandage, cover or wrap the treated skin area after applying WYNZORA®.

Avoid using other steroid medicines on the same area of skin at the same time. Always wash your hands after each application to prevent the medicine from spreading to other areas or being absorbed through your hands. Using WYNZORA® for a long time may increase the risk of side effects. Talk to your healthcare professional. It is recommended to take breaks from treatment from time to time. Stopping treatment may cause your psoriasis to suddenly get worse or may cause a serious skin reaction with blisters and bumps called generalized pustular psoriasis

Pregnancy

Before you take WYNZORA®, tell your healthcare professional if you are pregnant, think you may be pregnant or are planning to become pregnant. It is not known if it is safe to use WYNZORA® while pregnant. Since it may harm an unborn baby, you should use WYNZORA® for the shortest amount of time and in the smallest amount possible. Talk to your healthcare professional if you have questions about what this means for you.

Breastfeeding

Before you take WYNZORA®, tell your healthcare provider if you are breastfeeding or are planning to breastfeed. It is not known if WYNZORA® is safe to use while breastfeeding. This is because one of the ingredients may pass into breast milk and could harm a baby. Do not apply WYNZORA® on your breasts if you are breastfeeding. Talk to your healthcare professional if you have questions about what this means for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to use WYNZORA®:

- Use WYNZORA® exactly as your healthcare professional tells you to and follow all their instructions.
- Apply WYNZORA® only to your skin areas with psoriasis and do not use on skin which does not have psoriasis.
- Squeeze the cream onto a clean finger or directly onto the area with psoriasis.
- Apply the cream with your fingertips, and rub in the cream thoroughly and gently in a thin layer. Make sure that the psoriasis plaques are saturated with the cream.
- Do not bandage, tightly cover or wrap the treated skin area.
- Wash your hands well after using WYNZORA®. This will avoid accidentally spreading the cream to other parts of your body such as the face, mouth or eyes.
- If some cream accidentally gets on normal skin near your psoriasis areas you can leave it, but wipe it off if it spreads too far.
- So that WYNZORA® works properly, it is recommended not to take a shower or bath after application of WYNZORA®. You should wait 8 hours between applying WYNZORA® and showering to avoid washing it off.

When used on the scalp:

- Before applying WYNZORA® to the scalp, comb your hair to remove any loose scales.
- It may help to part your hair before you apply WYNZORA®.
- Washing your hair before applying WYNZORA® is not necessary.

Usual dose:

Apply WYNZORA® once a day to the affected skin. Keep using it until your skin is fully clear for up to 8 weeks. You must talk to your healthcare professional to keep using WYNZORA for longer than 8 weeks or to start using it again.

You must not use more than 15 grams of WYNZORA in a day or more than 100 g in a week. If you are using other medicines that contain calcipotriol in addition to WYNZORA®, the total amount of calcipotriol from all products you use should not be more than 15 grams per day and 100 grams per week. You should not apply WYNZORA to more than 30% of your body, including your scalp. Adolescents may be more likely to get certain side effects because of their skin surface area is large compared to their body weight.

Overdose:

If you think you, or a person you are caring for, have taken too much WYNZORA®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a dose, apply it as soon as you remember. Then, go back to your usual dosing schedule. Never apply WYNZORA® twice in one day to make up for a missed dose.

Possible side effects from using WYNZORA®:

These are not all the possible side effects you may have when taking WYNZORA®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Itchiness
- Rash
- Hives
- Irritation
- Application site pain
- Eczema
- Skin peeling
- Red and swollen hair follicles
- Insomnia
- Burning or stinging sensation
- Dry skin, redness
- Sensitivity to sunlight
- Thinning skin, stretch marks or surface veins
- Changes in hair growth
- Rash around the mouth
- Temporary lightening of skin color
- Small white bumps on the skin

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Worsening of psoriasis: red, scaly, thick patches of skin		√	
Rare			
Pustular psoriasis: chills, feeling unwell, fever, headache, joint pain, loss of appetite, nausea, red area with yellow fluid-filled bumps or blisters, skin pain or itchiness			√
Adrenal effects (when your adrenal glands don't make enough hormones): fatigue, increased urination/thirst, problems controlling blood sugar levels, weakness, weight loss		√	
Vision problems: blurry vision, cloudy vision, eye pressure or pain, trouble seeing clearly, seeing halos around lights, faded or yellowed colours.		√	
Very rare			
Allergic reaction: dizziness, itching, hives or rash, swelling of the face,			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
tongue or throat, difficulty breathing or swallowing, swelling of the face or lips			
Hypercalcaemia (high calcium levels in the blood): constipation, depression, fatigue, increased urination/thirst, loss of appetite, mental confusion, nausea, vomiting, muscle weakness and pain, heart palpitations			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store WYNZORA® between 15°C-25°C.
- Do not freeze.
- Protect from light and excessive heat.
- Throw away any unused product 6 months after opening the tube.
- Keep out of reach and sight of children.

If you want more information about WYNZORA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](https://www.hc-sc.gc.ca/drugs-drugs/banque-produits/index-eng.php)); the manufacturer's website (<https://knighttx.com>), by emailing medinfo@knighttx.com or by calling 1-844-483-5636.

This leaflet was prepared by Knight Therapeutics Inc.

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