
SCHEDULING STATUS: [S4]

PSOZEROL (Topical suspension)

Calcipotriene hydrate 0,005 % and betamethasone dipropionate 0,064 %

Read all of this leaflet carefully before you start taking

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **PSOZEROL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What PSOZEROL is and what it is used for

PSOZEROL is used as topical treatment of scalp and body psoriasis in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

2. What you need to know before you use PSOZEROL

Do not use PSOZEROL:

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- If you are hypersensitive (allergic) to calcipotriene or betamethasone or any of the other ingredients of **PSOZEROL** (see *section 6*)
 - If you have erythrodermic (intense and widespread psoriasis) or pustular (small bumps on the skin that contain fluid or pus) psoriasis
 - If you have bacterial, viral, fungal or parasitic skin infections
 - If you have severe liver problems or kidney problems
 - If you are pregnant or breastfeeding

Warnings and precautions

Special care should be taken with PSOZEROL

- Before using this medicine, tell your doctor/ nurse/ pharmacist if you have diabetes mellitus (diabetes) as your blood sugar/ glucose level may be affected by the steroid
- 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 or skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid
- Avoid use on your face, mouth or eyes
- If you develop problems with your vision (eyesight) such as blurred vision
- Wash your hands thoroughly after each application
- If you develop hypercalcaemia (too much calcium in your blood)
- If you develop a skin infection on the affected area
- Do not use for long periods of time

Other medicines and PSOZEROL

Always tell your healthcare provider if you are using, have recently used or might use any other medicines. (This includes all complementary or traditional medicines.)

Always tell your healthcare provider if you are taking any other medicine.

Pregnancy, breastfeeding and fertility

Pregnancy:

Do not use **PSOZEROL** if you are pregnant, think that you may be pregnant or want to become pregnant, as it may harm your unborn baby.

If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you receive any treatment. If you get pregnant during your treatment, you must immediately inform your doctor.

Breastfeeding:

You must not breastfeed your baby while you are treated with **PSOZEROL** because it passes into breast milk and could affect the baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you take **PSOZEROL**.

Driving and using machines

PSOZEROL has no or negligible influence on the ability to drive and to use machines.

3. How to use PSOZEROL

Do not share medicines prescribed for you with any other person.

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

- Use only on your psoriasis on the scalp and body and do not use on skin which does not have psoriasis
- Washing your hair before application of **PSOZEROL** is not necessary
- Shake the bottle before use

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- Before applying **PSOZEROL** to the scalp, comb the hair to remove any loose scales
 - Apply **PSOZEROL** to the affected area with your fingertips, and rub it in gently
 - Usually, an amount between 1 g and 4 g per day is sufficient for treatment of the scalp
 - Do not bandage, tightly cover or wrap the treated skin area
 - Wash your hands well after using **PSOZEROL**. This will avoid accidentally spreading the gel to other parts of your body (especially the face, mouth and eyes).
 - In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of **PSOZEROL**. Let **PSOZEROL** remain on the scalp during the night or during the day.

If you use more PSOZEROL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, consult the nearest hospital or poison centre.

4. Possible side effects

PSOZEROL can have side effects.

Not all side effects reported for **PSOZEROL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **PSOZEROL**, please consult your healthcare provider for advice.

If any of the following happens, stop using **PSOZEROL** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A severe, potentially life-threatening allergic reaction (anaphylaxis) which can present as swelling of the face and throat area, skin rash, nausea, vomiting, difficulty breathing and shock

These are all very serious side effects. If you have them, you may have had a serious reaction to **PSOZEROL**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- Worsening of your psoriasis. If your psoriasis gets worse, tell your doctor as soon as possible

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pruritus (an uncomfortable, irritating sensation that creates an urge to scratch that can involve any part of the body)

Less frequent side effects:

- Skin reactions such as burning, pain, irritation, folliculitis (inflammation of a hair follicle), dermatitis (skin inflammation), erythema (redness of the skin), acne (pimples), dry skin, rash (widespread eruptions or skin lesions)
- Pustular rash (multiple pustular lesions) and pustular psoriasis
- Hypopigmentation (patches of skin that are lighter than your overall skin tone)
- Rebound effect (return of your symptoms once you discontinue the product)
- Skin atrophy (abnormal/ unhealthy looking skin)
- Telangiectasia (dilated small blood vessels on the skin or mucous membranes)
- Striae (stretch marks)
- Hypertrichosis (excessive hair growth)
- Perioral dermatitis (inflammation of the skin around the mouth)
- Allergic contact dermatitis (a red, itchy rash caused by direct contact with a substance)
- Colloid milia (rare, degenerative, cutaneous deposition disorders)

Side effects with unknown frequency:

- Hypercalcaemia (high calcium levels in the blood)

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- Blurred vision
 - Hair colour changes
 - Suppression of the adrenal gland
 - Cataract (a clouding of the normally clear lens of the eye)
 - Infections
 - Poor blood sugar level control in diabetes mellitus
 - Increased pressure inside of the eye
 - Inhibition of the adrenal cortex
 - Application site reactions
 - Stinging sensation of the skin
 - Photosensitivity (sensitivity to light) and hypersensitivity reactions
 - Angioedema (swelling under the skin)
 - Facial swelling
 - Hypercalciuria (high levels of calcium in the blood)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **PSOZEROL**.

5. How to store PSOZEROL

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not refrigerate.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PSOZEROL contains

The active ingredients are calcipotriene hydrate and betamethasone dipropionate.

Each gram of suspension contains calcipotriene hydrate 52,18 mcg equivalent to calcipotriene 50,0 mcg and betamethasone dipropionate USP 0,643 mg equivalent to betamethasone 0,5 mg.

The other ingredients are butylated hydroxytoluene, hydrogenated castor oil, mineral oil, polyoxypropylene stearyl ether, vitamin E.

What PSOZEROL looks like and contents of the pack

Viscous, nearly odourless, almost clear, colourless to slightly off-white suspension.

Carton containing 60 g topical suspension in an opaque white HDPE bottle with white nozzle and 20 mm red ribbed screw cap along with leaflet.

Holder of Certificate of Registration

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