

AXTRIOI-B GEL

Calcipotriol (as Monohydrate) 50 mcg/g & Betamethasone (as Dipropionate) 0.5 mg/g

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What Axtriol-B Gel is used for

Axtriol-B Gel is used as a topical treatment of scalp and non - scalp plaque psoriasis vulgaris in adults.

How Axtriol-B Gel works

Axtriol-B Gel contains two active ingredients which are Calcipotriol Monohydrate and Betamethasone Dipropionate.

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

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Axtriol-B Gel

-When you must not use it

Do not take Axtriol-B Gel

- if you have are allergic to any of the ingredients listed at the end of this leaflet.
- If you have problems with your calcium levels in your body (ask your doctor)
- If you have certain type of psoriasis: these are guttate, erythrodermic, exfoliative and pustular (ask your doctor)
- If you have serious liver or kidney disease.

As *Axtriol-B Gel* contains a strong steroid do NOT use on skin affected by

- infections caused by viruses (e.g. cold sores or chicken pox)
- infections caused by a fungus (e.g. athlete's foot and ringworm)
- infections caused by bacteria
- infections caused by parasites (e.g. scabies)
- tuberculosis (an infectious bacterial disease that mainly affects the lungs) or syphilis (a bacterial infection usually spread by sexual contact)
- 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
- itching of the anus (back passage) or genitals (sex organs).

-Pregnancy

There are no data from the use of Calcipotriol and Betamethasone Dipropionate in pregnant women. In general, the use of topical preparations containing glucocorticoids should be avoided during the first trimester of pregnancy. In particular, treating large areas, prolonged use or occlusive dressing should be avoided during pregnancy. Thus, the clinical indication for treatment with Axtriol-B Gel must be carefully reviewed and the benefits weighed against the risks in pregnant women.

-Lactation

Betamethasone passes into breast milk, but risk of an adverse effect on the infant seems unlikely with therapeutic doses. There are no data on the excretion of Calcipotriol in breast milk.

Caution should be exercised when prescribing Axtriol-B Gel to women who breast-feed. The patient should be instructed not to use Axtriol-B Gel on the breast when breastfeeding.

Tell your doctor if you are pregnant, may be pregnant, or plan to become pregnant.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy.

How to use Axtriol-B Gel



*Use a needle to poke open the head after removing the cap

-How much to use

Always use Axtriol-B Gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

-When to use it

Axtriol-B Gel should be applied to affected areas once daily. Usually amount of 1g to 4g is sufficient for treatment of the scalp (4g corresponds to 1 teaspoon)

-How long to use it

The recommended treatment period is 4 weeks for scalp areas and 8 weeks for "non-scalp" areas. If it necessary to continue or restart the treatment after this period, treatment should be continued after medical review and under regular medical supervision.

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-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Use above the recommended dose may cause elevate serum calcium which subsides when treatment is discontinued. The symptoms of hypercalcemia include polyuria, constipation, muscle weakness, confusion and coma.

Excessive prolonged use of topical corticosteroids may suppress the pituitary-adrenal functions, resulting in secondary adrenal insufficiency which is usually reversible. In such cases, symptomatic treatment is indicated.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Axtriol-B Gel

-Things you must do

Take your medicine exactly your doctor has told you.

If you are about to start taking any new medicine, tell your pharmacist or doctor that you are taking Axtriol-B Gel.

-Things you must not do

Do not stop apply the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Axtriol-B Gel to anyone else, even if they have the

same symptoms or condition as you.

-Things to be careful of

Axtriol-B Gel contains butylated hydroxytoluene (E321) as an excipient, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. The following adverse reactions are considered to be related to the pharmacological classes of Calcipotriol and Betamethasone, respectively:

Side effects

Like all medicines, Axtriol-B Gel can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor/nurse immediately or as soon as possible if any of the following happens. You may have to stop your treatment. Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Axtriol-B Gel. You should tell your doctor as soon as possible if any of the serious side effects occur. These side effects are more likely to happen after long-term use or use under occlusion.

The side effects include the following:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.
- Cataracts (signs are cloudy and foggy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside your eye (signs are eye pain, red eye, decreased or cloudy vision)
- Infections (because your immune system, which fights infections, may be suppressed or weakened)
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop taking

Axtriol-B Gel and tell your doctor as soon as possible

- Impact on the metabolic control of diabetes mellitus (if you have diabetes, you may experience fluctuations in the blood glucose levels).

Serious side effects known to be caused by calcipotriol

- Allergic reactions with deep 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 occur. If you have an allergic reaction, stop taking Axtriol-B Gel, tell your doctor immediately or go to the casualty department at your nearest hospital
- Treatment with this gel may cause the level of calcium in your blood or urine to increase (usually when too much gel has been used). Signs of increased calcium in blood are bone pain, constipation, poor appetite, nausea and vomiting. This can be serious, and you should contact your doctor immediately. However, when the treatment is stopped, the levels return to normal.

If you notice the above or any other changes in your health while taking this medicine, tell your doctor.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Axtriol-B Gel

-Storage

Store below 30°C.

Do not refrigerate.

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Keep container well closed.
Keep the outer carton in order to protect from light.
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date. Consult your pharmacist on how to safely dispose of any medicines no longer required.

Product Description

-What it looks like

Axtriol-B Gel is a translucent off-white viscous gel with characteristic odour, available in 15g & 30g HPDE bottle.

-Ingredients

-Active ingredient(s):

Calcipotriol Monohydrate
0.00522% w/w (equivalent to
Calcipotriol 0.005% w/w) and
Betamethasone Dipropionate
0.0643% w/w (equivalent to
Betamethasone 0.05% w/w).

-Inactive ingredient(s):

*Liquid Paraffin, Polyoxy
Propylene Stearyl Ether,
Hydrogenated Castor Oil, Alpha
Tocopherol and Butylated
Hydroxytoluene*

MAL number

XXXXX

Manufacturer and Product Registration Holder

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