aZematop 0.1%

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 aZematop 0.1%?

aZematop 0.1% contains the active ingredient tacrolimus. aZematop 0.1% is used for the treatment of moderate to severe atopic dermatitis in adults and adolescents 16 years of age and above who cannot use or did not respond to other simple treatments.

For more information, see Section 1. Why am I using aZematop 0.1%? in the full CMI.

2. What should I know before I use aZematop 0.1%?

Do not use if you have ever had an allergic reaction to tacrolimus or any of the ingredients listed at the end of the CMI.

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 [medicine name]? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with aZematop 0.1% and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use aZematop 0.1%?

- aZematop 0.1% should be applied as a thin layer to affected areas of the skin.
- aZematop 0.1% treatment will be started by your doctor. Follow all directions given to you by your doctor carefully.

More instructions can be found in Section 4. How do I use aZematop 0.1%? in the full CMI.

5. What should I know while using aZematop 0.1%?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using aZematop 0.1%. • Make sure that you wash your hands thoroughly after application of aZematop 0.1% if the hands are not the site for treatment. • Protect your skin when you are in the sun, especially between 10 am and 3 pm. If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen
Things you should not do	• Other creams and ointments should not be used in the same area for 2 hours before and 2 hours following aZematop 0.1% use. • Avoid contact with eyes and mucous membranes (i.e. inside of nose and mouth) • Do not use aZematop 0.1% under dressings (i.e. bandages, wraps, plasters)
Driving or using machines	• aZematop 0.1% should not affect your ability to drive or use machines.
Drinking alcohol	• Tacrolimus tablets and capsules can affect how you react to alcohol. The effect of the ointment has not been studied. • It is recommended that alcohol be limited or not used at all while using aZematop 0.1%.
Looking after your medicine	• Store below 25°C • Store it in a cool dry place away from moisture, heat or sunlight

For more information, see Section 5. What should I know while using aZematop 0.1%? in the full CMI.

6. Are there any side effects?

The most common side effects include burning and itching, skin infections and skin irritation where it is used.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicinal product is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side affects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

aZematop 0.1

Active ingredient(s): *Tacrolimus monohydrate* (tak-ROW-ly-MUS)

0.1% w/w ointment

Consumer Medicine Information (CMI)

This leaflet provides important information about using aZematop 0.1%. **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 aZematop 0.1%.**

Where to find information in this leaflet:

1. Why am I using aZematop 0.1%?

aZematop 0.1% contains the active tacrolimus monohydrate. aZematop 0.1% belongs to a group of medicines called macrolides. The active ingredient, tacrolimus monohydrate, affects your immune response.

aZematop 0.1% is used for the treatment of moderate to severe atopic dermatitis in adults and adolescents who cannot use or did not respond to other simple treatments.

2. What should I know before I use aZematop 0.1%?

Warnings

Do not use aZematop 0.1% if:

- you are allergic to tacrolimus, or a class of medicines called macrolides (e.g. azithromycin, clarithromycin, erythromycin).
- you are allergic to any of the ingredients listed at the end of this leaflet.
- If you are under 16 years of age.
- always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as:
  - suspected or confirmed skin cancer,
  - swollen lymph nodes.
  - inherited skin diseases (such as Netherton's syndrome).
  - lamellar ichthyosis (extensive scaling of the skin due to a thickening of the outer layer of the skin).
  - generalized erythroderma (inflammatory reddening and scaling of the entire skin).
  - cutaneous graft versus host disease (an immune reaction of the skin may happen in patients who have had a bone marrow transplant).
  - any other breakdown in the skin that may increase how much tacrolimus is absorbed by the skin.
  - liver failure.
  - any other disease affecting your immune system.
  - any skin infections
- you are being treated with a medicine or other treatment that affects your immune system. You may be at an increased risk of developing certain forms of cancer if you are also using aZematop 0.1%.
- take any medicines for any other condition.

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 6. Are there any side effects?

Pregnancy and breastfeeding

aZematop 0.1% should not be used during pregnancy unless your doctor recommends you do so. If you become pregnant while using this medicine, discontinue use and tell your doctor immediately.

Talk to your doctor about using aZematop 0.1% if you are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Malignancies

A very small number of people using tacrolimus ointment have developed a cancer (for example lymphoma or other skin cancer). So far it has not been shown that this is because of using tacrolimus ointment.
Keep all of your doctor's appointments so that you can be monitored.

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.

It is not known whether tacrolimus ointment interacts with other medications used on the skin.

Some medicines may interfere with aZematop 0.1% and affect how it works.

It is possible that some medicines (described as CYP3A4 inhibitors) may interfere with absorption of tacrolimus ointment. These inhibitors include, but are not limited to:
- erythromycin
- itraconazole
- ketoconazole
- diltiazem

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect aZematop 0.1%.

4. How do I use aZematop 0.1%?

How much to use

aZematop 0.1% should be applied as a thin layer to affected areas of the skin.

aZematop 0.1% treatment will be started by your doctor. Follow all directions given to you by your doctor carefully.

If you do not understand the instructions given to you, Ask your doctor or pharmacist for help.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you use the wrong dose, aZematop 0.1% may not work as well and your problem may not improve.

When to use aZematop 0.1%

aZematop 0.1% may be used on any part of the body, except on mucous membranes (for example, on the inside of your nose or mouth) or in your eyes.

aZematop 0.1% should not be applied under dressings (i.e. bandages, wraps, plasters).

Use aZematop 0.1% at about the same time each day.

aZematop 0.1% should be used for short periods of time every now and then.

aZematop 0.1% should not be used continuously on a long-term basis.

When your dermatitis is bad:
Usually, aZematop 0.1% will be used twice daily until the affected area looks and feels better.

Generally, your skin will get better within one week of starting treatment. If this does not happen talk to your doctor about different treatment choices.

After your dermatitis gets better:
Some people may need to use aZematop 0.1% more often to stop flares. Usually this will be once a day, twice weekly (such as Monday and Thursday).

There should be 2-3 days without aZematop 0.1% treatment between each application.

Your doctor will review your condition after 12 months and discuss whether you need to continue using aZematop 0.1%.

If you forget to use aZematop 0.1%

aZematop 0.1% should be used regularly at the same time each day. If you miss your application at the usual time, do it as soon as you remember and then continue as before.

If you have any further questions about the use of aZematop 0.1%, ask your doctor or pharmacist.

If you use too much aZematop 0.1%

It is unlikely that using too much ointment on your skin will cause a problem.

If you accidentally swallow aZematop 0.1% do not try and cause vomiting.

You should immediately:

- 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 aZematop 0.1%?

Things you should do

Make sure that you wash your hands thoroughly after application of aZematop 0.1% if the hands are not the site for treatment.

If you are about to be started on any medicine tell your doctor and pharmacist that you are using aZematop 0.1%.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen. This medicine may cause your skin to be much more sensitive to sunlight that normal. Use of ultraviolet (UV) light from a solarium, therapy with UVB or UVA in combination with psolarens (PUVA) should be avoided while using aZematop 0.1%.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine

If you become pregnant while using this medicine, stop use and tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Remind any doctor, dentist or pharmacist you visit that you are using aZematop 0.1%.

Things you should not do

- Do not give aZematop 0.1% to anyone else, even if they have the same condition as you.
- Other creams and ointments should not be used in the same area for 2 hours before and 2 hours following aZematop 0.1% use.
- Avoid contact with eyes and mucous membranes (for example, the inside of your nose or mouth) unless your doctor has recommended this. If contact occurs, the affected area should be thoroughly wiped to remove aZematop 0.1% and/or area rinsed with water.
- Do not use aZematop 0.1% under dressings (i.e. bandages, wraps, plasters).

Driving or using machines

aZematop 0.1% should not affect your ability to drive or use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Tacrolimus tablets and capsules have affected the response to alcohol in some people. The effect of the ointment is unknown. Limit your alcohol use while using aZematop 0.1%.

Looking after your medicine

- Store below 25^{o}C

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Medicines should not be kept indefinitely. Get rid of medicines that are past their expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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
• Acne • Folliculitis • Cold sores • Conjunctivitis • Itchy skin • Increased skin sensitivity • "Pins and needles" sensation • Burning sensation • Discolouration of the skin • Irritation at the application site	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing • Swelling at the application site • Hives • Fainting. • Swelling or pain at the application site • Warmth at the application site • Rash at the application site • Any other changes to your skin at the application site.	**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 aZematop 0.1% contains

Active ingredient (main ingredient)	Tacrolimus (as tacrolimus monohydrate)
Other ingredients (inactive ingredients)	white soft paraffin, paraffin (liquid), propylene carbonate, beeswax (white), paraffin (hard)
Potential allergens	N/A

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

What aZematop 0.1% looks like

aZematop 0.1% is a white to slightly yellowish ointment containing 0.1% w/w tacrolimus in a 10 g, 30 g or 60 g laminated aluminium tube.

Not all pack sizes may be available.

AUST R 388172

Who sponsors and distributes aZematop 0.1%

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
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AUSTRALIA

www.arrotex.com.au

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