Zatamil*

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.

1. Why am I using Zatamil?

Zatamil contains the active ingredient mometasone furoate. Zatamil is used on the skin to relive the redness, swelling, itching and discomfort of many skin problems such as psoriasis, eczema and other types of dermatitis.

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

2. What should I know before I use Zatamil?

Do not use if you have ever had an allergic reaction to mometasone furoate or any of the ingredients listed in Section <u>7. Product details</u>.

Do not use if you have a viral skin condition, a fungal skin condition, on acne, inflammation around the mouth, a skin condition with ulcers, or your have tuberculosis of the skin.

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 Zatamil? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zatamil and affect how it works.

Refer to Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Zatamil?

 Apply a light film of Zatamil Hydrogel or Ointment or a few drops of Zatamil Lotion to the affected area once a day and rub in lightly.

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

5. What should I know while using Zatamil?

Things you should do	 If your condition does not improved after one week of using Zatamil daily, tell your pharmacist or doctor. Tell your doctor if your skin condition worsens or becomes infected.
Things you should not do	 Do not use Zatamil under dressings or on large areas of skin, particularly in infants and children, unless your doctor tells you. Do not use Zatamil under a nappy or under plastic pants, in the case of infants or young children, unless the doctor tells you. Do not use Zatamil in or around the eyes. Do not use Zatamil if the packaging is torn or shows signs of tampering.
Looking after your medicine	 Store below 25C. Do not refrigerate Zatamil Lotion.

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

6. Are there any side effects?

Most side effects are likely to be minor and temporary. Consult your doctor immediately if you have blurred vision, or other vision disturbances.

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.

Zatamil

Active ingredient(s): mometasone furoate 0.1% w/w

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zatamil. 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 Zatamil.

Where to find information in this leaflet:

- 1. Why am I using Zatamil?
- 2. What should I know before I use Zatamil?
- 3. What if I am taking other medicines?
- 4. How do I use Zatamil?
- 5. What should I know while using Zatamil?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Zatamil?

Zatamil contains the active ingredient mometasone furoate. Zatamil is a cortisone and belongs to the group of medicines called corticosteroids.

There are three dosage forms of Zatamil: gel, ointment and lotion.

Zatamil Lotion is formulated for easier application to the scalp and hairy parts of the body.

Zatamil is used on the skin to relieve redness, swelling, itching and discomfort of many skin problems such as:

- Psoriasis a stubborn skin disorder with raised, rough, reddened areas covered with dry, fine silvery scales.
- Eczema an often itchy skin condition with redness, swelling, oozing of fluid, crusting which may lead to scaling.
- Other types of dermatitis.

Your doctor, however, may have prescribed Zatamil for another purpose. Ask your doctor if you have any questions about why Zatamil has been prescribed for you.

A doctor's prescription is required for the 45g tube of Zatamil Hydrogel and Ointment, as well as Zatamil Lotion.

The 15g tube of Zatamil Hydrogel and Ointment can be purchased without a doctor's prescription.

Zatamil is not addictive.

2. What should I know before I use Zatamil?

Warnings

Do not use Zatamil if:

- You are allergic to mometasone furoate, any other corticosteroids, or any of the ingredients listed in Section 7. Product details
- Always check the ingredients to make sure you can use this medicine.
- 3. You have a viral skin infection (such as cold sores, shingles or chicken pox)
- You have a fungal skin infection (such as thrush, tinea or ringworm)
- You have acne

- 6. You have inflammation around the mouth
- You have a skin condition with ulcers
- 8. You have tuberculosis of the skin

Check with your doctor if you:

- Have any other medical conditions, particularly the skin conditions listed above.
- Have allergies to any other medicines.
- If you have allergies to any other substances, such as foods, preservatives or dyes.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not apply Zatamil to the breasts before breastfeeding.

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.

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

4. How do I use Zatamil?

How much to use

- Apply a light film of Zatamil Hydrogel or Ointment or a few drops of Zatamil Lotion
- Follow the instructions provided and use Zatamil until your doctor tells you to stop.
- If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

When to use Zatamil

 Zatamil should be used once a day, as prescribed by your doctor.

If you forget to use Zatamil

If you forget to apply Zatamil, use it as soon as you remember, and then continue using it at the usual time each day.

If it is almost time for your next application, skip the one you missed and continue with your regular schedule at the usual time.

Apply the same amount of Zatamil as usual. Do not apply more Zatamil to make up for the amount you missed.

If you swallow Zatamil

Zatamil must not be swallowed or taken internally. It is for use on the skin only.

If anyone accidentally swallows Zatamil **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 Zatamil?

Things you should do

- Tell all doctors and pharmacists who are treating you that you are using Zatamil.
- If your condition does not improve after one week of using Zatamil daily, tell your pharmacist or doctor.
- Tell your pharmacist or doctor if, for any reason, you have not used the medicine exactly as prescribed.
 Otherwise, your pharmacist or doctor may think that Zatamil was not effective and change your medicine unnecessarily.
- If your skin condition worsens or becomes infected, tell your doctor.

Things you should not do

- Do not use Zatamil under dressings or on large areas of skin, particularly in infants and children, unless your doctor tells you.
- Do not use Zatamil under a nappy or under plastic pants, in the case of infants or young children, unless the doctor tells you.
- Do not use Zatamil in or around the eyes.
- Do not use Zatamil on anyone else, even if they appear to have the same symptoms as yours.
- Do not use Zatamil to treat other complaints, unless your doctor tells you to.
- Do not use Zatamil just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of Zatamil.
- Do not use Zatamil if the packaging is torn or shows signs of tampering.
- Do not use Zatamil if the expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.

Things to be careful of

- Do not use large amounts of Zatamil for a long time.
 If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increase. Ask your doctor or pharmacist if you are concerned about the length of time you have been using Zatamil.
- Do not use Zatamil on skin areas that rub together, such as under the arm or in the groin area, unless your doctor has told you to apply it there.
- Do not use Zatamil on your face unless your doctor has told you to.

Looking after your medicine

- Keep Zatamil Hydrogel in a dry place where the temperature stays below 25C
- Keep Zatamil Ointment in a dry place where the temperature stays below 25C
- Keep Zatamil Lotion in a cool dry place where the temperature stays below 25C. Do not refrigerate.

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

Do not store Zatamil in the car or on window sills, where it can get very hot, as this may destroy the medicine.

Keep Zatamil where young children cannot reach it. Keep the medicine away from pets. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

Discard Zatamil if your doctor tells you to stop using it, or the product has passed its 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.

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
Skin: Itching Burning Tingling/stinging Appearance of small blood vessels on the surface of the skin Stretch marks or streaks on the skin Acne/pimples/lumps on the skin/ blisters containing pus Redness Boils/abscesses Dermatitis Increased size of affected area / worsening of disease Numbness Dry skin Inflamed hair roots	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
Ocular: Blurred vision or other vision disturbances	Call your doctor straight away, I if you notice this

Serious side effects	What to do
•	serious side effect.

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 Zatamil Hydrogel contains

Active ingredient	Mometasone furoate
(main ingredient)	
Other ingredients (inactive ingredients)	Hexylene glycol, purified water, hypromellose, citric acid

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

What Zatamil Lotion contains

Active ingredient (main ingredient)	Mometasone furoate
Other ingredients	Ethanol, propylene glycol,
(inactive ingredients)	purified water, hypromellose, citric acid

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

What Zatamil Ointment contains

Active ingredient (main ingredient)	Mometasone furoate
Other ingredients (inactive ingredients)	Soft white paraffin, light liquid paraffin, hexylene glycol, polyethylene, cetostearyl alcohol, purified water, colloidal anhydrous silica, citric acid

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

What Zatamil looks like

Zatamil Hydrogel (AUST R 195415) is a clear colourless soft gel packed in a tube.

Zatamil Lotion (AUST R 329568) is a light clear lotion packed in a dropper bottle.

Zatamil Ointment (AUST R 195416) is a white to off-white ointment packed in a tube.

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Who distributes Zatamil

Manufactured and distributed in Australia by: Ego Pharmaceuticals Pty Ltd 13-31 Malcolm Road, Braeside 3195

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