

ACZONE™ gel

(dapsone 7.5% w/w)

Consumer Medicines 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 ACZONE™ gel?

ACZONE™ gel contains the active ingredient dapsone. ACZONE™ gel is used to treat acne.

For more information, see Section [1. Why am I using ACZONE™ gel?](#) in the full CMI.

2. What should I know before I use ACZONE™ gel?

Check the list of ingredients at the end of the CMI. Do not use ACZONE™ gel if you have ever had an allergic reaction to any of them.

Talk to your doctor before you take this medicine if he/she is not aware that 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 ACZONE™ gel?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACZONE™ gel and affect how it works, or ACZONE™ gel may interfere with other medicines and affect how they work.

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 ACZONE™ gel?

- Use ACZONE™ gel once every day.
- Your doctor will tell you how much to use and where and how to apply it.
- Continue to use ACZONE™ gel for as long as your doctor tells you.

More instructions can be found in Section [4. How do I use ACZONE™ gel?](#) in the full CMI.

5. What should I know while using ACZONE™ gel?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you are about to start a new medicine, if you are taking oral dapsone and/or antimalarial medications, have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.• Carefully follow your doctor's instructions. Keep ACZONE™ gel away from your eyes, eyelids and mouth.• Remind any doctor, dentist, or pharmacist you visit that you are using ACZONE™ gel.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without checking with your doctor.• Do not use ACZONE™ gel if the pump/packaging shows signs of tampering and if the product does not look quite right.• Do not give ACZONE™ gel to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions on the bottle or carton on how to take care of your medicine properly.• Keep ACZONE™ gel in a cool place below 25°C. Do not refrigerate or freeze ACZONE™ gel.

For more information, see Section [5. What should I know while using ACZONE™ gel?](#) in the full CMI.

6. Are there any side effects?

Dryness, itching, pain, redness, stinging/burning, scaling of treated skin, methaemoglobinemia (shortness of breath, bluish colouring of the skin, headache, tiredness/lack of energy, dizziness).

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.

ACZONE™ gel

Active ingredient: *dapsone*

Consumer Medicines Information (CMI)

This leaflet provides important information about using ACZONE™ gel. **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 ACZONE™ gel.**

Where to find information in this leaflet:

- [1. Why am I using ACZONE™ gel?](#)
- [2. What should I know before I use ACZONE™ gel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ACZONE™ gel?](#)
- [5. What should I know while using ACZONE™ gel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ACZONE™ gel?

ACZONE™ gel 7.5% w/w (75 mg per gram) contains the active ingredient dapsone which has anti-inflammatory and antimicrobial properties. The exact mechanisms of action of dapsone gel for treating acne are not known. It is thought to act by helping to eliminate microbes as well as having an anti-inflammatory effect in acne.

ACZONE™ gel is used to treat acne. Acne is a characterised by inflamed pimples and non-inflamed pimples on the skin.

Your doctor may have prescribed ACZONE™ gel for another reason. Ask your doctor if you have any questions about why ACZONE™ gel has been prescribed for you.

2. What should I know before I use ACZONE™ gel?

Warnings

ACZONE™ gel is for topical use only.

Do not use ACZONE™ gel:

- if you are allergic to dapsone or any of the ingredients listed at the end of this leaflet.
- if you have a blood condition affecting red blood cells known as methaemoglobinæmia, which causes a reduction in the amount of oxygen being transported around the body by the blood.
- on broken skin.
- if the pump/packaging shows signs of tampering and if the product does not look quite right.
- If the expiry date on the tube has passed.

Tell your doctor if you:

- have been diagnosed with a shortage of the enzyme G6PD (glucose-6-phosphate dehydrogenase).
- have been diagnosed with a blood disease which causes the breakdown of red blood cells, such as haemolytic anaemia.
- using any other medicines applied to the skin, such as acne medicines with benzoyl peroxide.
- take any medicines for any other condition.
- are taking oral dapsone and/or antimalarial medications.

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

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed. It is not known if ACZONE™ gel may harm your unborn baby. The use of ACZONE™ gel is not recommended during pregnancy. You and your doctor will need to decide whether to discontinue nursing.

Children

ACZONE™ gel is for use in patients 12 years and over. It is not known whether ACZONE™ gel is safe and useful for children under 12 years for acne.

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.

Some medicines may interfere with ACZONE™ gel and affect how it works, while ACZONE™ gel may affect how other medicines work.

Medicines that may increase the effect of ACZONE™ gel include:

- dapsone when taken by mouth (i.e. orally)
- medicines to treat or prevent malaria
- trimethoprim and sulfamethoxazole (antibiotic)

If ACZONE™ gel is used with benzoyl peroxide, there may be a yellow or orange discolouring of the skin and/or hair of the treated area. This effect is temporary.

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

4. How do I use ACZONE™ gel?

How much to use

ACZONE™ gel is for topical use only. Your doctor will prescribe you how much to use and where to apply it.

When to use ACZONE™ gel

For acne: apply a thin film of ACZONE™ gel once a day to the entire face as well as other areas of the body affected by acne. Treatment with ACZONE™ gel is usually recommended for 12 weeks (3 months). Your doctor will decide whether treatment should be continued at the end of this time period.

How to apply ACZONE™ gel

1. Wash your face and gently pat dry. Ensure any make-up is completely removed.
2. Dispense a pea-sized amount of gel onto your hand.
3. Apply a thin layer of gel to the entire face.
4. Use ACZONE™ gel on other affected areas of the skin where the acne lesions appear once daily as well. Rub the gel in gently to ensure it is completely absorbed. All skin prone to acne should be treated.
5. Carefully avoid application of the gel to other areas that are not affected by acne.
6. If the gel is applied to areas that are not required to be treated, wash the gel off.
7. Wash your hands thoroughly after applying ACZONE™ gel.

If you forget to use ACZONE™ gel

It is important that you use ACZONE™ gel at the same time each day.

If you miss applying the gel, make sure you apply it at your next scheduled time.

Do not use double the amount to make up for the application you missed.

If you use too much ACZONE™ gel

- If you accidentally put ACZONE™ gel in your eye(s), immediately rinse your eye(s) with large amounts of cool water. If you have any concerns, contact your doctor for advice.

If ACZONE™ gel is accidentally swallowed, you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appears to be no signs of discomfort or poisoning.

5. What should I know while using ACZONE™ gel?

Things you should do

- Carefully follow your doctor's instructions.
- Keep ACZONE™ gel away from your eyes and mouth. If the gel gets in your eyes, wash them with large amounts of cool water. Contact your doctor if eye irritation continues. Do not use it on broken skin. Follow your doctor's directions for other routine skin care and the use of make-up. You should talk to your doctor about the use of sunscreens, moisturisers and cosmetics. Remind any doctor, dentist or pharmacist you visit that you are using ACZONE™ gel.
- Do not leave the top/lid off the container for any length of time to avoid contaminating the gel.
- If you become pregnant while using ACZONE™ gel, stop using it and tell your doctor immediately.
- Tell your doctor if your condition gets worse or does not get better while using ACZONE™ gel.

Things you should not do

Looking after your medicine

- Do not refrigerate or freeze ACZONE™ gel. Keep your ACZONE™ gel in a cool place where the temperature stays below 25°C. Keep the container where children cannot reach it. Do not leave the top/lid off the container for any length of time to avoid contaminating the gel.

Follow the instructions on the bottle or 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
- do not store it in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any remaining gel after 14 weeks from the date you opened it.

Getting rid of any unwanted medicine

If your doctor advises that 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 if the expiry date on the tube has passed. If you use this medicine after the expiry date has passed, it may not work effectively.

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.

Check with your doctor as soon as possible if you have any problems while using ACZONE™ gel even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

- When the active ingredient of ACZONE™ gel, dapsone, is taken orally as a tablet, it has been related to the abnormal breakdown of red blood cells (haemolytic anaemia, which may present as back pain, breathlessness, weakness with daily activities, dark-brown urine, high fever, and yellow or pale skin). If you have glucose-6phosphate dehydrogenase (G6PD) deficiency, you may have a greater risk for lowering your hemoglobin level. Please note that using ACZONE™ gel on the skin is not expected to put enough dapsone in the blood to cause clinical symptoms of haemolytic anaemia, however you should be aware of the signs and symptoms suggestive of this type of anaemia.

Serious side effects

Serious side effects	What to do
<p>Dapsone has been known to cause methaemoglobinæmia which is a blood disorder of red blood cells that carry oxygen to the body. Signs and symptoms suggestive of this blood disorder are</p> <ul style="list-style-type: none">shortness of breathbluish colouring of the skinheadachetiredness/lack of energydizziness.	<p>Discontinue ACZONE™ gel and 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.</p>

Less serious side effects

Less serious side effects	What to do
<p>Effects on the skin treated:</p> <ul style="list-style-type: none">dry skinitchingpainscaling of the skindrynessstinging/burning of the skinerythema (redness of the skin)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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 in Australia or to <https://nzphvc.otago.ac.nz/reporting/> in New Zealand. 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 ACZONE™ gel contains

Active ingredient (main ingredient)	Dapsone 7.5% w/w (Each gram contains 75mg of dapsone)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">diethylene glycol monoethyl ether (DGME)Acrylamide/sodium acryloyldimethyltaurate copolymerIsohexadecanePolysorbate 80Methyl hydroxybenzoatepurified water

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

What ACZONE™ gel looks like

ACZONE™ gel is an off-white to yellow gel supplied in an airless pump polypropylene bottle containing pack sizes 3g, 30 g, 60 g or 90 g of gel.

It is also supplied in a 3 g tube as a physician sample.

(Aust R 266267).

(Not all presentations may be available)

Who distributes ACZONE™ gel?

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

AUSTRALIA

Toll free: 1800 252 224 (AU)

ACZONE™ gel is distributed in New Zealand by:

AbbVie Limited

Wellington 6011

NEW ZEALAND

Freephone: 0800 659 912

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