

ACZONE® gel (dapsona 7.5% w/w)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ACZONE® gel. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you using ACZONE® gel against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ACZONE® gel is used for

ACZONE® 7.5% w/w (75 mg per gram) gel is used to treat acne in patients 12 years of age and older.

Acne is characterised by inflamed pimples and non-inflamed pimples on the skin.

ACZONE® gel contains dapsona as the active ingredient which has anti-inflammatory and anti-microbial properties. The exact mechanisms of action of dapsona 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 only available with a doctor's prescription from pharmacies.

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.

Before you use ACZONE® gel

When you must not use it

Do not use ACZONE® gel if:

- you have an allergy to dapsona or any of the ingredients listed at the end of this leaflet.
- you have been diagnosed with congenital or idiopathic methaemoglobinemia (decrease of oxygen in your blood caused by a certain type of abnormal red blood cell).
- the pump /packaging shows signs of tampering.
- the product does not look quite right.
- the expiry date on the tube has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

It is not known whether ACZONE® gel is safe and useful for children under 12 years in acne.

This gel is for topical use only. Avoid contact with eyes, eyelids and mouth.

Before you start to use it

Tell your doctor if:

- You have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
- You are pregnant or intend to become pregnant. It is not known if ACZONE® gel may harm your unborn baby. The use of ACZONE® gel is not recommended during pregnancy.

- You are breast feeding or intend to breast feed. You and your doctor will need to decide whether to discontinue nursing.
- You have glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- You have been diagnosed with a haemolytic disease such as haemolytic anaemia breakdown of red blood cells).
- You are taking oral dapsona and/or antimalarial medications.

Taking other medicines

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

Tell your doctor if you are taking medicines which include dapsona tablets, trimethoprim/sulfamethoxazole tablets or any antimalarial medications.

If you take these medicines while using ACZONE® gel, you may be more susceptible to certain side effects.

Tell your doctor if you are using any other medicines applied to the skin, such as acne medicines with benzoyl peroxide.

Your doctor will advise you of the same prior to starting to use ACZONE® gel.

Ask your doctor or pharmacist if you have any concerns about using ACZONE® gel as well as other medications.

How to use ACZONE® gel

How much to use

Your doctor will tell you how much gel you need to use each day. Use ACZONE® gel only as prescribed by your doctor.

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.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

Use ACZONE® gel every day, preferably at about the same time each day, unless your doctor tells you otherwise.

How to use it:

Remove makeup (if present) before applying ACZONE® gel. Wash your face prior to application and gently pat dry before applying ACZONE® gel.

Apply a pea-sized amount of ACZONE® gel as a thin layer to the entire face once a day.

In addition, apply a thin layer to other affected areas of the skin where the acne lesions appear once daily as well.

Rub in the gel gently and completely. All skin prone to acne should be treated.

Carefully avoid application of the gel to other areas that are not affected by acne. If the gel is applied to areas that are not required to be treated, wash the gel off.

Wash your hands after applying ACZONE® gel.

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.

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 on broken skin.

Ask your doctor or pharmacist any questions you may have.

How long to use it

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.

If you forget to use it

If you miss a dose, do not try to make it up. Continue your normal schedule.

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

If you use too much (overdose)

If you accidentally put ACZONE® gel in your eye(s), immediately rinse your eye(s) with large amounts of cool water. Contact your doctor if eye irritation continues.

If you think that you or anyone else may have swallowed ACZONE® gel, immediately telephone your doctor or **Poisons Information Centre (Australia: telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766)** for advice or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using ACZONE® gel

Things you must do

If you become pregnant while using ACZONE® gel, stop use and tell your doctor immediately.

Tell your doctor if your condition gets worse or does not get better while using ACZONE® gel.

If you are about to start any new medicine, tell your doctor and pharmacist that you are using ACZONE® gel.

Things you must not do

Do not give ACZONE® gel to anyone else, even if they have the same condition as you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ACZONE® gel.

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.

Ask your doctor or pharmacist any questions you may have.

Side effects in acne:

Tell your doctor if you notice any of the following at the application site and they worry you:

- dry skin
- itching
- pain

Less often the following effects have been seen:

- erythema (redness of the skin)
- scaling of the skin
- dryness
- stinging/burning of the skin

Use of benzoyl peroxide together with ACZONE® gel, at the same time may cause your skin to temporarily turn yellow or orange at the site of application.

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).

If you have glucose-6-phosphate dehydrogenase (G6PD) deficiency, you may have a greater risk for lowering your haemoglobin 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, listed below:

sudden onset of:

- back pain
- breathlessness
- weakness with daily activities
- dark-brown urine
- high fever and yellow or pale skin

If you experience these signs and symptoms, please discontinue ACZONE® gel and seek immediate medical attention

Dapsone has been known to cause methaemoglobinaemia which is a blood disorder of red blood cells that carry oxygen to the body. Signs and symptoms suggestive of this blood disorder are

- shortness of breath
- bluish colouring of the skin
- headache
- tiredness/lack of energy
- dizziness.

If you experience these signs and symptoms, please discontinue ACZONE® gel and seek immediate medical attention

After using ACZONE® gel

Storage

Keep your ACZONE® gel in a cool place where the temperature stays below 25°C. Do not put it in the refrigerator or freezer.

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

Disposal

Discard any remaining gel after 14 weeks from the date of opening.

If your doctor tells you to stop using the gel or it has passed the expiry date, ask your pharmacist what to do with any remaining gel.

Product description

What ACZONE® gel looks like:

Off-white to yellow gel supplied in 30g, 60g and 90g airless pump polypropylene bottles. Also supplied as a 3g physician sample in a tube.

Pack sizes:

3/30/60/90 g sizes

Ingredients

Active ingredient:

- Dapsone 7.5% w/w (Each gram contains 75mg of dapsone)

Preservative:

- Methyl hydroxybenzoate

Inactive ingredients:

- Diethylene glycol monoethyl ether (DGME);
- Acrylamide/sodium acryloyldimethyltaurate copolymer;
- Isohexadecane;
- Polysorbate 80
- Purified water

Manufactured by Allergan.

Supplier

Allergan Australia Pty. Ltd.

810 Pacific Highway,

Gordon NSW 2072

ABN 85 000 612 831

Toll free: 1800 252 224 (AU)

Allergan New Zealand Limited

Auckland

Free phone: 0800 659 912 (NZ)

ACZONE® gel can be identified by

registration numbers:

AUST R 266267

Date of preparation:

January 2017

® marks owned by respective owners.

© Allergan, 2017. All rights reserved.