

Duac[®]

Once Daily Gel

Active ingredients: clindamycin 1% w/w (as phosphate) and benzoyl peroxide 5% w/w

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This leaflet answers some common questions about Duac Once Daily 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 benefits and risks. Your doctor has weighed the benefits of you using Duac Once Daily Gel against the risks he expects it may have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What is Duac Once Daily Gel and what is it used for?

Duac Once Daily Gel contains clindamycin and benzoyl peroxide.

Clindamycin is an antibiotic, which prevents the growth of bacteria which are involved in acne. Benzoyl peroxide acts to reduce comedones (blackheads and whiteheads). It is also effective at killing the bacteria, which are involved in acne, and makes the skin less oily.

Duac Once Daily Gel is used on the skin to treat acne. It helps to:

- reduce the bacteria or germs, which are implicated in acne;

- reduce the number of acne spots;
- reduce the likelihood of new blackheads and whiteheads from forming; and
- make your skin less oily.

Your doctor may have prescribed Duac Once Daily Gel for another purpose. Ask your doctor if you have any questions about why Duac Once Daily Gel has been prescribed for you.

Duac Once Daily Gel is for use by adults and adolescents (aged 12 and above) with acne.

Duac Once Daily Gel is not addictive.

Duac Once Daily Gel is only available with a doctor's prescription.

Before you use Duac Once Daily Gel

When you must not use it

Do not use Duac Once Daily Gel:

- if you have an allergy to Duac Once Daily Gel or any of the ingredients in Duac Once Daily Gel listed at the end of this leaflet.
- if you have a known sensitivity to benzoyl peroxide, clindamycin or lincomycin.
- you have or have ever had:
 - regional enteritis (inflammation of the small intestine)
 - colitis (inflammation of the large intestine)

– ulcerative colitis (inflammation which may be due to the presence of ulcers)

- antibiotic associated colitis (inflammation which may be associated with the past use of antibiotics) if the packaging is torn or shows signs of tampering.
- for more than 2 months (kept in the refrigerator at 2°C to 8°C) after the date the pharmacist has dispensed it to you.

If you use this medicine for more than 2 months after the date the pharmacist has dispensed it to you, it may not work as well.

- 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.

- If you are not sure whether you should start taking Duac Once Daily Gel, contact your doctor.

Before you start to use it

Tell your doctor if:

- you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using Duac Once Daily Gel when pregnant.

- you are breast-feeding or intend to breast-feed.

Your doctor will discuss the risks and benefits of using Duac Once Daily Gel when breast-feeding.

Do not apply Duac Once Daily Gel to the breasts before breast-feeding.

Tell your doctor or pharmacist if you have used or taken any other clindamycin or erythromycin containing medicines recently.

If you have not told your doctor about any of the above, tell him before you use Duac Once Daily Gel.

Using other medicines

Tell your doctor if you are using other creams, ointments or lotions or taking any other medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

These include:

- medicated or abrasive soaps and cleansers;
- chemical peels; and
- cosmetic products that have a strong drying effect.

These also include products containing:

- erythromycin;
- clindamycin;
- lincomycin;
- benzoyl peroxide;
- tretinoin, isotretinoin or tazarotene;
- salicylic acid; and
- alcohol.

These medicines may have a cumulative irritant effect or affect how well Duac Once Daily Gel works. You may need to use different amounts of your medicine or you may need to use different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with, or avoid while using Duac Once Daily Gel.

How to use Duac Once Daily Gel

It is important to use Duac Once Daily Gel exactly as your doctor has told you.

Directions given to you by your doctor may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, tube or this leaflet, ask your doctor or pharmacist for help.

Wash the affected area thoroughly and rinse with warm water. Lightly pat dry the skin.

Remove make-up thoroughly before applying the gel. After it has dried, you can use a non-greasy make-up.

How to apply Duac Once Daily Gel

Duac Once Daily Gel is for application to the skin only.

A thin film of gel should be applied to all of the area of the skin which has acne, not just the individual spots. As a guide, one fingertip (the amount of gel squeezed from the tube which reaches from the tip of your finger to the first joint) is enough to cover the face, two and one-half fingertips of gel will cover your face and back. If the gel does not rub into your skin easily, you are using too much.

Wash your hands after applying the gel.

The usual dose for Duac Once Daily Gel is apply once daily in the evening.

How long should you use it for

It may take 4-6 weeks before you see the full effects of Duac Once Daily Gel on your acne.

Use Duac Once Daily Gel for as long as your doctor tells you to.

Do not use Duac Once Daily Gel for more than 11 weeks unless your doctor tells you to.

If you use Duac Once Daily Gel less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

If you are not sure of how long you need to use Duac Once Daily Gel, talk to your doctor.

If you forget to use it

If it is almost time for your next application of Duac Once Daily Gel, skip the application you missed and apply the gel when you are next meant to. Otherwise, use it as soon as you remember, and then go back to using your gel as you would normally.

Do not apply a double dose to make up for the dose that you missed.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you swallow it

Immediately telephone your doctor or Poisons Information Centre (In Australia 13 11 26; In New Zealand 0800 POISON or 0800 764 766), or go to casualty at your nearest hospital if you think that you or anyone else may have swallowed Duac Once Daily Gel. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep this telephone number handy.

While you are using Duac Once Daily Gel

Things you must do

Tell your doctor(s) who is treating you that you are using Duac Once Daily Gel.

If you feel that Duac Once Daily Gel is not helping your condition, tell your doctor.

Tell your doctor if for any reason, you have not used Duac Once Daily Gel exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using Duac Once Daily Gel, tell your doctor.

If you are breastfeeding while using Duac Once Daily Gel, tell your doctor.

Things you must not do

Do not give Duac Once Daily Gel to anyone else, even if they have the same symptoms as yours.

Things to be careful of

Keep Duac Once Daily Gel away from your lips, eyes, mouth and other mucous membranes. Do not apply to any irritated areas of your skin; for example if you have cuts, grazes, sunburn or eczema.

Be careful not to use too much on your neck or other sensitive areas of the skin.

Avoid excessive exposure to sunlight. Sunlamps should not be used. Avoid using at high altitudes or where the ground is snow-covered. When exposure to sunlight cannot be avoided, use a sunscreen product and wear protective clothing.

Duac Once Daily Gel may bleach hair and coloured fabrics, such as clothing, towels and bed linen. Be careful to avoid contact of Duac Once Daily Gel with hair and coloured fabrics.

Do not use occlusive (air or water tight) dressings on areas treated with Duac Once Daily Gel unless necessary. Using occlusive dressing may increase irritation.

Antibiotics may cause a condition that results in severe diarrhoea

and stomach cramps. Although this is unlikely to happen with antibiotics applied to the skin, if you develop stomach cramps or diarrhoea that does not improve or is severe, stop using Duac Once Daily Gel and contact your doctor immediately.

Side effects

Tell your doctor if you do not feel well while you are using Duac Once Daily Gel.

Duac Once Daily Gel helps most people with acne but it may have unwanted side effects in a few people.

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 these side effects.

Very common side effects:

At site of application:

- Dry skin
- Skin peeling
- Redness of your skin, especially during the first few weeks of use

These side effects are generally mild.

Common side effects:

- Headache
- At the site of application:
- Skin burning sensation
 - Itching
 - Skin pain
 - Sensitivity to sunlight

Uncommon side effects:

At the site of application:

- Tingling (paraesthesia)
- Red, itchy skin, rash (dermatitis, erythematous rash)
- Worsening of acne

Rare side effects:

- Allergic reactions

- nausea, vomiting, diarrhoea, including bloody diarrhoea, stomach pain

At the site of application:

- Skin reactions, discoloration of the skin
- Raised itchy rash (hives)

If you suffer severe burning, peeling or itching, or other effects not mentioned in this leaflet, you should stop using Duac Once Daily Gel and go back to your doctor for advice.

After using Duac Once Daily Gel

Storage

Duac Once Daily Gel should be stored in the refrigerator at 2°C to 8°C for up to 2 months. Do not freeze.

Do not leave it in the car, especially the glovebox, or on windowsills. Do not store Duac Once Daily Gel or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep Duac Once Daily Gel where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Duac Once Daily Gel or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

Duac Once Daily Gel is a white to slightly yellow gel that is available

in a 25 gram or 30 gram tube. A 5 gram sample tube is also available from your physician only.

Not all pack sizes may be available.

Duac® is a registered trade mark of Stiefel Laboratories, Inc.

Version 5.0

Ingredients

The active ingredients in Duac Once Daily Gel are clindamycin 1% w/w (as phosphate) and benzoyl peroxide 5% w/w.

Duac Once Daily Gel also contains the following inactive ingredients:

- carbomer 980
- dimeticone 100
- disodium lauryl sulfosuccinate
- disodium edetate
- glycerol
- silicon dioxide
- poloxamer
- purified water
- sodium hydroxide

Supplier

Duac Once Daily Gel is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford
Victoria 3067
Australia

Duac Once Daily Gel is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

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