DUAC ONCE DAILY GEL

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 DUAC ONCE DAILY GEL?

DUAC ONCE DAILY GEL contains the active ingredients clindamycin and benzoyl peroxide. DUAC ONCE DAILY GEL is used to treat acne.

For more information, see Section 1. Why am I using DUAC ONCE DAILY GEL? in the full CMI.

2. What should I know before I use DUAC ONCE DAILY GEL?

Do not use if you have ever had an allergic reaction to DUAC ONCE DAILY GEL 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 DUAC ONCE DAILY GEL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DUAC ONCE DAILY GEL 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 DUAC ONCE DAILY GEL?

DUAC ONCE DAILY GEL should be applied once daily in the evening

More instructions can be found in Section 4. How do I use DUAC ONCE DAILY GEL? in the full CMI.

5. What should I know while using DUAC ONCE DAILY GEL?

Things you should do	 Keep DUAC ONCE DAILY GEL away from your lips, eyes, mouth and other mucous membranes. Remind any doctor, dentist or pharmacist you visit that you are using DUAC ONCE DAILY GEL If you feel that DUAC ONCE DAILY GEL is not helping your condition, tell your doctor If you become pregnant or are breastfeeding while using DUAC ONCE DAILY GEL, tell your doctor
Things you should not do	 Do not give DUAC ONCE DAILY GEL to anyone else, even if they have the same symptoms as yours Do not apply to any irritated areas of your skin; for example, cuts, grazes, sunburn or eczema
Looking after your medicine	 Store in the refrigerator at 2°C to 8°C for up to 2 months Do not freeze

For more information, see Section 5. What should I know while using DUAC ONCE DAILY GEL? in the full CMI.

6. Are there any side effects?

Side effects which have been reported at the site of application include dry skin, discolouration of skin, skin peeling and pain, itching, burning sensation on skin, sensitivity to sunlight and redness of your skin, especially during the first few weeks of use. Other side effects which have been reported include headache, nausea, vomiting, diarrhoea including bloody diarrhoea and stomach pain.

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.

DUAC ONCE DAILY GEL

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using DUAC ONCE DAILY 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 DUAC ONCE DAILY GEL.

Where to find information in this leaflet:

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

1. Why am I using DUAC ONCE DAILY GEL?

DUAC ONCE DAILY GEL contains the active ingredients 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

DUAC ONCE DAILY GEL is for use by adults and adolescents (aged 12 and above) with acne.

DUAC ONCE DAILY GEL is not addictive.

2. What should I know before I use DUAC ONCE DAILY GEL?

Warnings

Do not use DUAC ONCE DAILY GEL if:

- you are allergic to clindamycin and benzoyl peroxide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a known sensitivity to benzoyl peroxide, clindamycin or lincomycin.
- you have or have ever had:

- regional enteritis (inflammation of the small intestine)
- o 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)

Check with your doctor if you:

- have any other medical conditions
- are using other creams, ointments or lotions or are taking any medicines for any other condition
- have used or taken any other clindamycin or erythromycin containing medicines recently

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with 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.

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

Some medicines may interfere with DUAC ONCE DAILY GEL and affect how it works.

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;
- 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.

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

4. How do I 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

- A thin film of gel should be applied to all of the area of the skin which has acne, not just the individual spot
- 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

When to use DUAC ONCE DAILY GEL

- DUAC ONCE DAILY GEL should be applied once daily in the evening
- 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
- it may take 4-6 weeks before you see the full effects of DUAC ONCE DAILY GEL on your acne
- do not use DUAC ONCE DAILY GEL for more than 11 weeks unless your doctor tells you to
- 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 DUAC ONCE DAILY GEL

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 DUAC ONCE DAILY GEL

If you think that you or anyone else has swallowed DUAC ONCE DAILY GEL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), 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 DUAC ONCE DAILY GEL?

Things you should do

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.

Keep DUAC ONCE DAILY GEL away from your lips, eyes, mouth and other mucous membranes.

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.

Call your doctor straight away if you:

- become pregnant while using DUAC ONCE DAILY GEL
- are breastfeeding while using DUAC ONCE DAILY GEL
- develop stomach cramps or diarrhoea that does not improve or is severe - stop using DUAC ONCE DAILY GEL and contact your doctor immediately 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

Remind any doctor, dentist or pharmacist you visit that you are using DUAC ONCE DAILY GEL.

Things you should not do

- do not give DUAC ONCE DAILY GEL to anyone else, even if they have the same symptoms as yours
- do not apply to any irritated areas of your skin; for example if you have cuts, grazes, sunburn or eczema
- do not use too much on your neck or other sensitive areas of the skin
- 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

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.

Looking after your medicine

- store in the refrigerator at 2°C to 8°C for up to 2 months
- do not freeze.

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.

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	
Skin and subcutaneous tissue disorders:	Speak to your doctor if you	
 dry skin skin peeling redness of your skin, especially during the first few weeks of use skin burning sensation itching skin pain sensitivity to sunlight red, itchy skin, rash (dermatitis, erythematous rash) worsening of acne discoloration of the skin 	have any of these less serious side effects and they worry you.	
Gastrointestinal disorders:		
 nausea vomiting diarrhoea, including bloody diarrhoea stomach pain 		
Nervous system disorders:		
headache		

Serious side effects

Serious side effects	What to do
Skin and subcutaneous tissue disorders:	Call your doctor straight away,
tingling (paraesthesia)raised itchy rash (hives)severe burning and peeling	or go straight to the Emergency Department at
Immune system disorders and allergic reactions: • allergic reactions	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 via https://pophealth.my.site.com/carmreportnz/s/

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 DUAC ONCE DAILY GEL contains

Active ingredient (main ingredient)	clindamycin 1% w/w (as phosphate) benzoyl peroxide 5% w/w.
Other ingredients	carbomer 980
(inactive ingredients)	dimeticone 100
	disodium lauryl sulfosuccinate
	disodium edetate
	glycerol
	silicon dioxide
	poloxamer
	purified water
	sodium hydroxide

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

What DUAC ONCE DAILY GEL looks like

DUAC ONCE DAILY GEL is a white to slightly yellow gel that is available in a 25 g or 30 g tube (TT50-7216).

A 5 g sample tube is also available from your physician only.

Not all pack sizes may be available.

Who distributes DUAC ONCE DAILY GEL

GlaxoSmithKline NZ Ltd Private Bag 106600

Downtown

Auckland 1143

New Zealand

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This leaflet was prepared in January 2025.

Version 7.0