

Package leaflet: information for the user

Duac Once Daily 10mg/g + 50mg/g Gel Clindamycin + anhydrous benzoyl peroxide

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What DUAC ONCE DAILY GEL is and what it is used for

DUAC ONCE DAILY GEL contains two medicines: clindamycin and benzoyl peroxide. DUAC ONCE DAILY GEL belongs to a group of medicines known as 'antiacne preparations'.

DUAC ONCE DAILY GEL is used for treating mild to moderate acne on your skin.

- Clindamycin is an antibiotic which kills the bacteria involved in acne.
- Benzoyl peroxide reduces blackheads and whiteheads. It also kills the bacteria involved in acne and makes the skin less oily.

Used together in DUAC ONCE DAILY GEL, these help to:

- reduce the bacteria which cause acne spots
- reduce the number of acne spots
- stop new blackheads, whiteheads and spots from forming
- make your skin less oily.

2. Before you use DUAC ONCE DAILY GEL

Do not use DUAC ONCE DAILY GEL if:

- you are allergic (hypersensitive) to clindamycin, benzoyl peroxide or any of the other ingredients of DUAC ONCE DAILY GEL (listed in Section 6)
- you are allergic (hypersensitive) to an antibiotic called 'lincomycin'.

Do not use DUAC ONCE DAILY GEL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you start using DUAC ONCE DAILY GEL.

Take special care with DUAC ONCE DAILY GEL

- Only use DUAC ONCE DAILY GEL on your skin. Keep it away from areas like your eyes, lips and mouth. If you accidentally get DUAC ONCE DAILY GEL in your eyes, rinse with plenty of water.
- Do not use the gel on any irritated areas of your skin. For example, if you have cuts, grazes, sunburn or eczema.
- Do not to use too much DUAC ONCE DAILY GEL on sensitive areas of skin.
- Try not to let DUAC ONCE DAILY GEL come into contact with coloured fabrics, including clothing, towels and bed linen. **DUAC ONCE DAILY GEL can bleach these materials.**
- DUAC ONCE DAILY GEL may bleach hair.

- DUAC ONCE DAILY GEL can make your skin more sensitive to the harmful effects of the sun. Avoid the use of sunbeds/lamps and minimise the time you spend in the sun.
- Do not exceed the stated dose.

Check with your doctor or pharmacist before using this medicine if:

- the patient is under 12 years old
- you have ever had any of the following gut problems: ‘regional enteritis’, ‘ulcerative colitis’ or ‘antibiotic-associated colitis’.

Using other medicines and soaps

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular, tell your doctor or pharmacist if you are using any of the following:

- any other acne treatments including antibiotics used on your skin
- medicated or ‘abrasive’ soaps and cleansers
- soaps or cosmetics that have a strong drying effect
- products which contain large amounts of alcohol or ‘astringents’.

This is because when used together with DUAC ONCE DAILY GEL, they may irritate your skin over time. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using them.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, trying to become pregnant, or breast-feeding.

3. How to use DUAC ONCE DAILY GEL

Always use DUAC ONCE DAILY GEL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Use DUAC ONCE DAILY GEL once a day in the evening.
- It may take 4 to 6 weeks before you see the full effect of DUAC ONCE DAILY GEL.
- Do not use for more than 12 weeks at one time. Your doctor will tell you how long your treatment will last.

How to apply DUAC ONCE DAILY GEL

1. Completely remove any make-up.
2. Wash the affected area of skin well. Then rinse with warm water and gently pat dry.
3. Put a thin film of gel on the affected skin, using your fingertips.
4. Apply to all of the areas of your skin which have acne, not just to the individual spots.
 - For your face only, use an amount of gel from the tube which reaches from the tip of your finger to the first joint (the first crease on your finger). This is a ‘finger tip’.
 - For your face and back, use two and a half ‘finger tips’ in total.

If the gel does not rub into your skin easily, you are using too much.
5. Wash your hands after using the gel.
6. After it has dried, you can use a non-greasy make-up.

If you use more DUAC ONCE DAILY GEL than you should

There has been no experience with overdose of DUAC ONCE DAILY GEL.

If you forget to use DUAC ONCE DAILY GEL

- Do not use a double dose to make up for forgotten individual doses.
- Apply the next dose at the usual time.

4. Possible side effects

Like all medicines, DUAC ONCE DAILY GEL can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop using DUAC ONCE DAILY GEL and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- signs of an allergic reaction (such as swelling of your face, eyes, lips or tongue, nettle rash or difficulty breathing)
- severe or prolonged diarrhoea, or abdominal cramps
- severe burning, peeling or itching.

Other possible side effects:

If you notice any of these side effects, try using DUAC ONCE DAILY GEL less often, or stop using it for one or two days and then start again.

Very common side effects

(at least 1 in 10 people are affected)

- Redness, peeling, dryness

Common side effects

(less than 1 in 10 people are affected)

- Burning, itching

Uncommon side effects

(less than 1 in 100 people affected)

- Tingling (paraesthesia), worsening acne.

Rash has also been reported.

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. How to store DUAC ONCE DAILY GEL

Keep out of the reach and sight of children.

Pharmacist: Store in a refrigerator (2°C-8°C). Do not freeze.

Patient: After you have received DUAC ONCE DAILY GEL from the pharmacist, do not store it above 25°C and discard after 2 months.

Do not use DUAC ONCE DAILY GEL after the expiry date which is stated on the tube and carton (after “Exp:”). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What DUAC ONCE DAILY GEL contains

- The active substances are: clindamycin phosphate, equivalent to clindamycin 1 % w/w (10 mg/g) and hydrous benzoyl peroxide, equivalent to anhydrous benzoyl peroxide 5 % w/w (50 mg/g).
- The other ingredients are: carbomer, dimeticone, disodium lauryl sulfosuccinate, disodium edetate, glycerol, silica, colloidal hydrated, poloxamer 182, purified water and sodium hydroxide.

What DUAC ONCE DAILY GEL looks like and the contents of the pack

- DUAC ONCE DAILY GEL comes in tubes containing 5, 6, 25, 30 or 50 grams.

- The gel is off-white yellow in colour.
- Each carton contains one tube of DUAC ONCE DAILY GEL.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline UK Limited

Trading as Stiefel, Stockley Park West

Uxbridge, Middlesex UB11 1BT, UK

GlaxoSmithKline (Ireland) Limited

Stonemasons Way, Rathfarnham

Dublin 16, Ireland. Trading as Stiefel

PL 19494/0075 PA 1077/120/1 MA 300/01401

Manufacturer:

Stiefel Laboratories (Ireland) Ltd.

Finisklin Business Park, Sligo , Ireland

Or

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