Package leaflet: Information for the patient

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What DUAC ONCE DAILY GEL is and what it is used for
2. What you need to know before you use DUAC ONCE DAILY GEL
3. How to use DUAC ONCE DAILY GEL
4. Possible side effects
5. How to store DUAC ONCE DAILY GEL
6. Contents of the pack and other information

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 'anti-acne preparations'.

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

- Clindamycin is an antibiotic which stops the bacteria involved in acne from reproducing.
- Benzoyl peroxide reduces blackheads and whiteheads. It also kills the bacteria involved in acne.

Used together in DUAC ONCE DAILY GEL, these work by:

- fighting the bacteria that can cause acne
- treating existing blackheads, whiteheads, and spots
- lowering the number of red, inflamed acne spots

DUAC ONCE DAILY GEL is for use by adults and adolescents aged twelve years or over.

2. What you need to know before you use DUAC ONCE DAILY GEL

Do not use DUAC ONCE DAILY GEL:

- if you are allergic to clindamycin, lincomycin, benzoyl peroxide or any of the other ingredients of DUAC ONCE DAILY GEL (listed in Section 6)

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.

Warnings and precautions

Talk to your doctor or pharmacist before using DUAC ONCE DAILY GEL.

- **Only use DUAC ONCE DAILY GEL on your skin**. Keep it away from areas like your eyes, lips, mouth, or inside your nose.

- **Do not use the gel on any irritated areas of your skin.** For example, if you have cuts, grazes, sunburn, or broken skin.

➔ If you accidently get DUAC ONCE DAILY GEL in your eyes, mouth, or inside your nose rinse with plenty of water.

- Do not use too much DUAC ONCE DAILY GEL on sensitive areas of skin.
- Most patients will experience some skin redness and peeling during the first few weeks of treatment. **If your skin becomes irritated,** you may need to use an oil-free moisturiser, use DUAC ONCE DAILY GEL less often, or stop using it for a short period to allow your skin to recover and then re-start treatment.
- Stop treatment and see your doctor if skin irritation is severe (severe redness, dryness, itching, stinging, or burning) or does not improve.
- Try not to let DUAC ONCE DAILY GEL come into contact with coloured fabrics, including clothing, towels, bed linen, furntiure or carpeting. **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. You should use a sunscreen and wear protective clothing while using DUAC ONCE DAILY GEL.

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

- you have ever had any of the following gut problems: 'regional enteritis', 'ulcerative colitis', or 'antibiotic-associated colitis'.
- I**f you 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.
- If you have recently used other clindamycin- or erythromycin-containing medicines, there is an increased chance that DUAC ONCE DAILY GEL will not work as well as it should.

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

Children

Do not give this medicine to children under twelve years. It is not known if it works or if it is safe for them.

Other medicines and DUAC ONCE DAILY GEL

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. 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.

DUAC ONCE DAILY GEL may make some acne medicines less effective when used at the same time. This includes:

- some acne medicines that are applied to the skin which contain **tretinoin**, **isotretinoin** or **tazarotene**

➔ **Tell your doctor or pharmacist** if you are also using one of these medicines. You may need to use the two products at different times of the day (e.g. one in the morning and the other in the

evening). Using other acne medicines at the same time as DUAC ONCE DAILY GEL can increase the risk of skin irritation.

➔ **Stop treatment and see your doctor** if skin irritation becomes severe (severe redness, dryness, itching, stinging, or burning).

- DUAC ONCE DAILY GEL should not be used at the same time as erythromycin-containing medicines.
- Applying DUAC ONCE DAILY GEL at the same time as medicines such as **dapsone** and **sulfacetamide** can cause a temporary colour-change of skin or facial hair (yellow/orange colour). This will not be permanent.
- One of the medicines in DUAC ONCE DAILY GEL can affect how certain general anaesthesia medicines work (called "neuromuscular blocking agents").

➔ **Tell your doctor or pharmacist** if you are going to have surgery.

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

Pregnancy, breast-feeding and fertility

There is only limited information about the safety of DUAC ONCE DAILY GEL in pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Your doctor will consider the benefit to you and the risk to your baby of using DUAC ONCE DAILY GEL while you're pregnant.

It is not known whether the ingredients of DUAC ONCE DAILY GEL can pass into breast milk. One of the medicines in DUAC ONCE DAILY GEL is clindamycin. When clindamycin is taken by mouth or injection, it may pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you use DUAC ONCE DAILY GEL.

Do not use DUAC ONCE DAILY GEL on your breast if you are breast-feeding.

3. How to use DUAC ONCE DAILY GEL

Always use this medicine exactly as your doctor or pharmacist has told you. 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 2 to 5 weeks before you see the 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 **entire** area of affected skin, using your fingertips.
4. Apply to all of the areas of your skin which have acne, not just to the individual spots. If the gel does not rub into your skin easily, you are using too much.
   - 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.

5. If you get a lot of dryness or skin peeling, you can use an oil-free moisturiser, use DUAC ONCE DAILY GEL less frequently or stop treatment for a short period, to allow your skin to adjust to the treatment. This medicine may not work properly if it is not applied every day.
6. **Wash your hands** after using the gel.
7. After it has dried, you can use a non-greasy make-up.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you use more DUAC ONCE DAILY GEL than you should

- **Take care not to apply too much.** Applying too much gel or applying it more frequently will not help your spots clear up more quickly, and may cause skin irritation. If this does happen, use the gel less often, or stop using it for a few days and then start again.

If you accidentally swallow DUAC ONCE DAILY GEL

- **If you do accidentally swallow the gel, seek medical advice.** You may get symptoms similar to when you take antibiotics by mouth (an upset stomach).

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.

Don't stop DUAC ONCE DAILY GEL without advice

Don't use the gel for more than 12 weeks at one time, without talking to your doctor. Use DUAC ONCE DAILY GEL for as long as your doctor recommends. Don't stop unless your doctor advises you to.

It is important to continue to use the gel as prescribed by your doctor. If you stop too soon, your acne may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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, collapse)
- 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*)

At site of application:

- Redness, peeling, dryness

These side effects are generally mild.

Common side effects

(*less than 1 in 10 people are affected*)

- Headache

At site of application:
- Burning, pain, sensitivity to sunlight

Uncommon side effects

(*less than 1 in 100 people affected*)
- Tingling (*paraesthesia*), worsening acne, red, itchy skin, rash (*dermatitis, erythematous rash*).

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is not known:

- Allergic reactions
- Inflammation of the intestine, diarrhoea, including bloody diarrhoea, stomach pain

At the site of application:

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

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DUAC ONCE DAILY GEL

Keep this medicine out of the sight and reach 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 this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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, 15, 25, 30, 50, 55, 60 and 70 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 (Ireland) Limited,
12 Riverwalk,
Citywest Business Campus,
Dublin 24,
Ireland

Manufacturer:

GlaxoSmithKline Trading Services Limited
12 Riverwalk,
Citywest Business Campus
Dublin 24,
Ireland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark: Clindoxyl Gel
Cyprus, Greece: Indoxyl Gel
Estonia, Iceland, Italy, Latvia, Portugal, Slovak Republic, Spain, Sweden: Duac Gel
Finland: Clindoxyl Geeli
Germany: Duac Akne Gel
The Netherlands: Duac Acne Gel
Czech Republic, Lithuania, Poland: Duac
Ireland, Malta, United Kingdom (Northern Ireland): Duac Once Daily Gel

This leaflet was last revised in 06/2022

Trade marks are owned by or licensed to the GSK group of companies

© 2022 GSK group of companies or its licensor.