

Package leaflet: information for the patient

Duac Acne Gel 10 mg/g + 50 mg/g, gel  
clindamycin + anhydrous benzoyl peroxide

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Duac Acne Gel and what is it used for?

This medicine contains two drugs: clindamycin and benzoyl peroxide. This medicine belongs to the group of drugs known as anti-acne agents. It is used for the treatment of mild to moderate acne on your skin.

Clindamycin is an antibiotic that prevents the bacteria involved in acne from multiplying. Benzoyl peroxide reduces blackheads (blackheads and whiteheads). It also kills the bacteria involved in acne.

When used together in this medicine, they work by:

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

Duac Acne Gel is intended for use by adults and adolescents aged twelve years or older.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

you are allergic to clindamycin, lincomycin, benzoyl peroxide or any of the other ingredients in this medicine. You can find these ingredients in section 6.

Do not use this medicine if the above applies to you. If you are not sure, contact your doctor or pharmacist before starting to use this medicine.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Use this medicine only on your skin. Do not use this medicine near your eyes, lips, mouth, or inside your nose.

Do not use this medicine on irritated skin surfaces. For example, if you have cuts, abrasions, sunburn, or damaged skin.

If this medicine accidentally gets into your eyes, mouth, or inside your nose, rinse with plenty of water.

Do not use too much of this medicine on sensitive skin surfaces.

Most patients will experience some redness and peeling of the skin during the first weeks of treatment. If your skin becomes irritated, you may need to use an oil-free moisturizer, use this medicine less often, or stop using it for a short time so your skin can recover and you can start the treatment again.

Stop the treatment and contact your doctor if the skin irritation is severe (severe redness, dryness, itching, stinging, or burning) or does not improve.

Try to prevent this product from coming into contact with colored textiles such as clothing, towels, bedding, furniture, or carpets. This product can bleach these materials.

This product can bleach hair.

This product can make your skin more sensitive to the harmful effects of the sun. Avoid using sunbeds/lamps and minimize the time you spend in the sun. Use sunscreen and wear protective clothing when using this product.

Contact your doctor or pharmacist before using this product in the following cases:

You have ever had any of the following bowel problems: localized inflammation of the intestinal lining (regional enteritis), inflammation of the colon with fever and ulceration (ulcerative colitis), or colon inflammation (colitis) caused by the use of antibiotics.

You experience abdominal cramps or diarrhea that do not improve or are severe. In that case, you should stop using this product immediately and contact your doctor. Antibiotics can cause a condition that results in severe diarrhea and abdominal cramps. However, it is unlikely to occur when antibiotics are applied to the skin.

You have recently used other medications containing clindamycin or erythromycin. There is then a greater chance that this product will not work as well as it should.

Tell your doctor or pharmacist if you have recently used other medications containing clindamycin or erythromycin.

Children

Do not give this product to children under twelve years of age. It is not known whether it is effective or safe in this age group.

Are you using any other medications?

Are you using any other medications besides Duac Acne Gel, or have you done so recently, or is there a possibility that you will use other medications in the near future? If so, tell your doctor or pharmacist.

Inform your doctor or pharmacist if you are using the following:

any other acne treatment including the use of antibiotics on your skin

medicated soap or abrasive soaps and cleansers  
soaps or cosmetics that have a strong drying effect  
products that contain a large amount of alcohol or have an astringent effect on the skin.

This is because when used simultaneously with this product, it can cause skin irritation. If you are unsure whether the above applies to you, contact your doctor or pharmacist before using it.

Duac Acne Gel can make some acne medications less effective when used simultaneously. This concerns:

Some acne medications applied to the skin that contain tretinoin, isotretinoin, or tazarotene.

Tell your doctor or pharmacist if you are also using any of these medications. You may need to apply the two products at different times (e.g., one in the morning and the other in the evening). Concurrent use of other medications with this product may increase the risk of skin irritation.

Stop the treatment and contact your doctor if the skin irritation becomes severe (intense redness, dryness, itching, stinging, or burning sensation).

This product should not be used concurrently with medications containing erythromycin. Applying this product at the same time as medications like dapsone and sulfacetamide may cause temporary discoloration of the hair on your skin and face (yellow/orange discoloration). This is not permanent.

One of the substances in this product may affect the action of certain anesthetic drugs for general anesthesia ("neuromuscular blocking agents" named).

Tell your doctor or pharmacist if you need to undergo surgery.

If you are not sure whether the above applies to you, contact your doctor or pharmacist before starting to use this product.

Pregnancy, breastfeeding, and fertility

There is only limited information on the safety of this product in pregnant women.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

The doctor will consider the benefits of using this product for you and the risks to your baby during your pregnancy.

It is not known whether the ingredients of this product are excreted in breast milk. One of the medications in this product is clindamycin. When clindamycin is taken orally or by injection, it can be excreted in breast milk. Before starting to use this product, contact your doctor if you are breastfeeding. Do not apply this product to your breasts if you are breastfeeding.

### 3. How do you use this product?

Always use this medication exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

use this product once a day in the evening

it may take two to five weeks before you notice the effect of this medicine

do not use for more than twelve consecutive weeks. Your doctor will tell you how long your treatment should last.

How should you apply this medicine?

1. Your make-up must be completely removed.
2. Wash the affected skin area thoroughly. Then rinse with warm water and gently pat dry.
3. With your fingertips, apply a thin layer of the gel to the entire affected skin.
4. Apply to all surfaces with acne, not just individual spots. If the gel cannot be easily rubbed into the skin, you are using too much.  
one fingertip (this is the amount of gel squeezed from the tube from fingertip to the first finger joint) is enough to treat the face

- two and a half fingertips in total is enough to treat your face and back
5. If the skin becomes very dry or flaky, you can use an oil-free moisturizer, use this medicine less frequently, or stop the treatment for a short time to allow your skin to adjust to the treatment. This medicine may not work optimally if it is not applied every day.
  6. Wash your hands after using the gel.
  7. After the gel has dried, you can use a non-greasy make-up.

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Have you used too much of this medicine?

Make sure not to apply too much. Applying the gel too much or too often does not help the spots disappear faster and can cause skin irritation. If that happens, you should use the gel less frequently or stop using it for a few days and then start again.

Have you accidentally swallowed this medicine?

Contact your doctor or pharmacist if you have accidentally swallowed the gel. You may experience the same complaints as when you take antibiotics orally (stomach upset).

Did you forget to use this medicine?

do not take a double dose to make up for a forgotten dose  
use the next dose at the usual time

Do not stop this medicine without advice

Do not use the gel for more than 12 consecutive weeks without consulting your doctor. Use this medicine for as long as your doctor recommends. Stop only on your doctor's advice. It is important that you continue to use the gel as prescribed by your doctor. If you stop too early, your acne may return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

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

Stop using this medicine immediately and see your doctor immediately if you notice any of the following serious side effects - you need immediate medical treatment:

- signs of an allergic reaction (such as swelling of the face, eyes, lips, or tongue, hives, difficulty breathing, or fainting (collapse))
- severe or persistent diarrhea, or abdominal cramps
- severe burning sensation, severe peeling, or itching

Other possible side effects:

If you experience any of these side effects, try using this medicine less frequently, or stop using it for one or two days and then start again.

#### Very common side effects

These may occur in at least 1 in 10 people

At the application site:

redness, peeling, dryness of the skin

These side effects are usually mild.

#### Common side effects

These may occur in less than 1 in 10 people

headache

At the application site:

burning sensation, pain, sensitivity to sunlight

#### Uncommon side effects

These may occur in less than 1 in 100 people

tingling due to nerve irritation (paresthesia), worsening of acne, red itchy skin, rash (skin inflammation (dermatitis), skin rash (erythematous rash))

#### Other side effects

Other side effects occurred in very small numbers of people, but how often this occurs is not known:

allergic reactions

intestinal inflammation, diarrhea (including bloody diarrhea), stomach pain

At the application site:

skin reactions, skin discoloration

raised itchy rash (hives)

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. How do you store this medicine?

Keep out of the sight and reach of children.

Pharmacy: store in the refrigerator (2°C - 8°C). Do not store in the freezer.

Patient: after receiving this medicine from your pharmacy, store below 25°C. Discard after two months.

Do not use this medicine after the expiry date. It can be found on the tube and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. Contents of the package and other information

What substances are in this medicine?

the active substances in this medicine are: clindamycin phosphate, equivalent to clindamycin 1% w/w (10 mg/g) and benzoyl peroxide hydrate equivalent to benzoyl peroxide anhydrous 5% w/w (50 mg/g)

the other substances in this medicine are: carbomer, dimethicone, disodium lauryl sulfosuccinate, disodium edetate, glycerin, colloidal hydrated silica, poloxamer 182, purified water, sodium hydroxide

What does Duac Acne Gel look like and what is in a package?

Duac Acne Gel is supplied in tubes of 5, 6, 15, 25, 30, 50, 55, 60, and 70 grams

the gel is off-white in color

each package contains a tube

not all mentioned pack sizes are marketed

Registered under RVG 31531.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Stiefel Laboratories Legacy (Ireland) Ltd.

Unit 2, Building 2500,

Avenue 2000,

Cork Airport Business Park,

Cork,

Ireland

For all information regarding this medicine, contact the local representative of the marketing authorization holder:

Netherlands

GlaxoSmithKline BV

Van Asch van Wijckstraat 55H

3811 LP Amersfoort

033 2081100

Manufacturer:

GlaxoSmithKline Pharmaceuticals S.A.

ul. Grunwaldzka 189

60-322 Poznan

Poland

or

GlaxoSmithKline Trading Services Limited

12 Riverwalk,

Citywest Business Campus

Dublin 24,

Ireland

This medicine is registered in 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, Slovakia, Spain, Sweden: Duac Gel  
Finland: Clindoxyl Geeli  
Germany: Duac Akne Gel  
Netherlands: Duac Acne Gel 10 mg/g + 50 mg/g, gel  
Czech Republic, Lithuania, Poland: Duac  
Ireland, Malta, United Kingdom (Northern Ireland): Duac Once Daily Gel

This leaflet was last approved in September 2021.

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