

ACNATAC[®] Topical Gel

(akna-tek)

clindamycin (as phosphate) 1% w/w and tretinoin
0.025% w/w (klin-da-mye-sin fos-fate) and (tret- i-noin)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ACNATAC.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ACNATAC against the benefits they expect it will have for you.

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

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

What ACNATAC is used for

ACNATAC is used on the skin to treat acne in patients 12 years and older.

ACNATAC contains two active ingredients: clindamycin (as phosphate) and tretinoin.

Clindamycin is an antimicrobial agent. It limits the growth of bacteria associated with acne and the inflammation caused by these bacteria.

Tretinoin normalises the growth of superficial skin cells and causes normal shedding of the cells that clog the hair follicles in areas with acne. This prevents the build-up of sebum and the formation of early acne lesions (blackheads and whiteheads).

ACNATAC combines clindamycin and tretinoin and therefore is more effective at treating acne than when these active ingredients are used separately.

Ask your doctor if you have any questions about why ACNATAC has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

ACNATAC is only available with a doctor's prescription.

There is not enough information to recommend the use of this medicine in children under 12 years of age.

Before you use ACNATAC

When you must not use it

Do not use ACNATAC if you have ever had an allergic reaction to:

- clindamycin or
- tretinoin or
- any of the other ingredients listed at the end of this leaflet or
- lincomycin.

Do not use ACNATAC:

- **if you are suffering from acute eczema which is characterised by inflamed, itchy, red, dry and scaly skin.**

- **if you are suffering from rosacea, a skin disease which affects the face and is characterised by redness, pimples and peeling.**
- **if you are suffering from other acute inflammatory conditions of the skin (e.g. folliculitis), especially around the mouth (perioral dermatitis).**
- **if your skin is sunburnt.**
- **if you are using any other medication on your skin which may lead to skin irritation e.g. an exfoliator.**
- **if you are pregnant or become pregnant.**
- **if you are planning a pregnancy .**
- **if you are breast-feeding.**
- **if you have a chronic inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).**
- **if you are suffering from certain special forms of acne vulgaris characterised by pustular and deep cystic nodular acne lesions (acne conglobata and acne fulminans).**
- **if you have or have had severe diarrhoea associated with the use of antibiotics.**

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

You must tell your doctor if:

- **you have allergies to any medicines, foods, preservatives or dyes.**
- **you suffer from eczema, rosacea and/or perioral dermatitis.**
- **you are using other topical preparations such as soaps, cleansers, creams, lotions, gels or ointments (including cosmetics).**

This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some topical preparations are not compatible with ACNATAC and may interact with it. Others may increase your chance of experiencing side effects. If you have used any preparations that contain sulfur, salicylic acid, benzoyl peroxide or rescinol or any chemical abrasives, you will need to wait until the effect of those has subsided until you start using this medicine. Your doctor will tell you when you can start using ACNATAC.

- **you have or have had severe diarrhoea associated with the use of antibiotics.**
- **you are breastfeeding, pregnant or planning to become pregnant.**

Female patients should seek advice from a doctor or pharmacist on appropriate contraceptive methods before using ACNATAC to prevent pregnancy.

If you have not told your doctor about any of the above, tell them before you start using the medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking or using:

- a corticosteroid.
- any erythromycin-containing products.
- medicinal products containing other antibiotics.
- neuromuscular blocking medicines e.g. muscle relaxants used in anaesthesia.
- medicines to thin the blood e.g. warfarin (increased coagulation tests and/or bleeding have been reported).

These medicines may be affected by ACNATAC or may affect how ACNATAC works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use ACNATAC

How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

Use ACNATAC once daily at night time on the affected area. Do not exceed the recommended dose.

How to apply it

ACNATAC is for application to the skin only.

Wash your hands.

Wash the affected area with a mild soap and water, and gently pat dry.

Squeeze a small amount of ACNATAC onto one fingertip and dot onto the affected area. For example, a pea-sized amount should be enough to cover the entire face.

Gently smooth it over the skin to ensure the entire affected area is covered.

Keep ACNATAC away from your lips, eyes, eyelids, mouth, nostrils and other mucous membranes. In case of

accidental contact with the eyes, rinse with plenty of lukewarm water.

Wash your hands after using ACNATAC.

How long to use it for

You may not notice improvement in your condition for several weeks after starting treatment. Do not be alarmed with this and continue treatment with ACNATAC. Typically, it may take several weeks to have an optimal effect. In some cases, it may take up to 12 weeks. If you have any concerns speak with your doctor or pharmacist.

To get the best results with ACNATAC it is necessary to use it properly and not stop using it as soon as your acne starts to get better.

Treatment with ACNATAC should not exceed 12 weeks of continuous use without careful evaluation by your doctor.

How often to use it

Adults and adolescents 12 years and older: apply once daily at night time.

Children under 12 years: this medicine is not recommended for children under 12 years.

If you forget to use it

If you miss a dose, use ACNATAC when the next dose is due at the usual time.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

If you swallow it

Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126) if you think you or anyone else may have swallowed ACNATAC. Do this even if there are no signs or symptoms of discomfort or poisoning.

If you apply too much

You could experience stomach pain, nausea, vomiting or diarrhoea. If this occurs discontinue the use of ACNATAC and contact your doctor.

If you apply ACNATAC excessively you may experience marked redness, peeling or discomfort. If this occurs, gently wash the skin with a mild soap and lukewarm water.

Discontinue ACNATAC for several days and wait until symptoms have resolved before resuming therapy.

Discuss any worries you may have about this with your doctor or pharmacist.

While you are using ACNATAC

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using ACNATAC.

Tell any other doctors, dentists, and pharmacists who treat you that you are using ACNATAC.

Women must use adequate contraceptive methods to minimise the risk of becoming pregnant while using ACNATAC and at least one month after discontinuing ACNATAC.

If you become pregnant while you are using this medicine, stop treatment immediately and tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not apply to any irritated areas of your skin; for example, if you have cuts, grazes, sunburn or eczema.

Do not use medicated soaps cleansers or scrubbing solutions with strong drying effect during treatment with ACNATAC. You should be careful when using the following that may have a drying effect: abrasive soaps, soaps and cosmetics and products with high concentrations of alcohol, astringents, spices or lime.

Things to be careful of

ACNATAC may make your skin more susceptible to sunburn and other adverse effects of the sun. Therefore, minimise your exposure to sunlight and always use appropriate broad-spectrum sunscreen with at least 30 Sun Protection Factor (SPF30+), together with suitable protective clothing (e.g. a hat) when outdoors.

If you are sunburnt do not use ACNATAC until your skin has fully recovered.

Avoid the use of sun lamps, UV lamps or sun beds during treatment.

ACNATAC is administered on the skin and is unlikely to have an effect on the ability to drive or operate machines.

Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while using ACNATAC, even if you don't think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following and they continue to worry you:

- acne
- dry skin
- redness of the skin
- increased sebum production
- sensitivity to sunlight (that may result in sunburn)
- itching
- rash
- scaling of the skin
- cold-like symptoms e.g. cough, sinusitis
- application site skin reactions such as burning, inflamed skin, dryness, redness of the skin. These symptoms are often mild and temporary when starting treatment with ACNATAC. Talk to your doctor if these symptoms are prolonged or intense.

Stop using ACNATAC and tell your doctor immediately if you notice any of the following:

- cold sores (herpes simplex)
- symptoms of underactive thyroid gland: fatigue, weakness, weight gain, dry hair, rough pale skin, hair loss, increased sensitivity to cold
- headache
- eye irritation
- nausea
- abdominal cramps
- vomiting
- diarrhoea
- pain
- severe or persistent skin irritation such as very red, swollen, itchy, scaly, blistered, crusted skin
- skin bleeding
- loss of skin pigmentation
- application site symptoms such as swelling, superficial skin damage, discolouration
- feeling hot.

Stop using ACNATAC and immediately contact your doctor if you become pregnant.

STOP using ACNATAC and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have an allergic reaction.

Some of the symptoms of an allergic reaction may include:

- shortness of breath wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

After using ACNATAC

Storage

Keep ACNATAC in a cool dry place where the temperature stays below 25°C. Do not refrigerate or freeze this medicine.

Discard after 3 months of first opening the tube.

Do not store ACNATAC or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep ACNATAC 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 ACNATAC or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ACNATAC is an aqueous translucent yellow gel that is available in tubes of 30 grams and 60 grams.

Ingredients

ACNATAC contains the following active ingredients:

- clindamycin phosphate 1.2% w/w (equivalent to 1% w/w of clindamycin) and
- tretinoin 0.025% w/w.

Each gram of ACNATAC contains 12 mg clindamycin phosphate (equivalent to 10 mg clindamycin) and tretinoin 0.25 mg.

ACNATAC also contains the following inactive ingredients:

- glycerol

- carbomer 981
- trometamol
- propyl hydroxybenzoate
- methyl hydroxybenzoate
- polysorbate 80
- disodium edetate
- citric acid
- butylated hydroxytoluene
- purified water.

Sponsor

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