

ACNATAC® Topical 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 ACNATAC?

ACNATAC contains the active ingredients clindamycin (as phosphate) and tretinoin. ACNATAC is used on the skin to treat acne in patients 12 years and older. For more information, see Section [1. Why am I using ACNATAC?](#) in the full CMI.

2. What should I know before I use ACNATAC?

Do not use if you have ever had an allergic reaction to ACNATAC 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 ACNATAC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACNATAC 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 ACNATAC?

- 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.

More instructions can be found in Section [4. How do I use ACNATAC?](#) in the full CMI.

5. What should I know while using ACNATAC?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ACNATAC.• If you become pregnant while you are using this medicine, stop treatment immediately and tell your doctor.• Women must use adequate contraceptive methods to minimise the risk of becoming pregnant while using ACNATAC and at least one month after discontinuing ACNATAC.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• ACNATAC is administered on the skin and is unlikely to have an effect on the ability to drive or operate machines.
Looking after your medicine	<ul style="list-style-type: none">• 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.• Keep ACNATAC where young children cannot reach it.

For more information, see Section [5. What should I know while using ACNATAC?](#) in the full CMI.

6. Are there any side effects?

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, 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. **Stop using ACNATAC and tell your doctor immediately if you notice any of the following:** cold sores, headache, eye irritation, nausea, abdominal cramps, vomiting, diarrhoea, pain. **Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:** shortness of breath wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body. 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.

ACNATAC[®] Topical Gel

(akna-tek)

Active ingredient(s): *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 (CMI)

This leaflet provides important information about using ACNATAC. **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 ACNATAC.**

Where to find information in this leaflet:

- [1. Why am I using ACNATAC?](#)
- [2. What should I know before I use ACNATAC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ACNATAC?](#)
- [5. What should I know while using ACNATAC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ACNATAC?

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.

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

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.

2. What should I know before I use ACNATAC?

Warnings

Do not use ACNATAC if:

- you are allergic to clindamycin, tretinoin, lincomycin 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 are suffering from acute eczema which is characterised by inflamed, itchy, red, dry and scaly skin.**

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

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

Check with your doctor if you:

- have allergies to any medicines, foods, preservatives or dyes.
- suffer from eczema, rosacea and/or perioral dermatitis.
- 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 resorcinol 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.

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

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

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use ACNATAC if you are pregnant or are planning a pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant.

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

Do not use ACNATAC if you are breastfeeding or intend to breastfeed.

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

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.

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.

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

4. How do I use ACNATAC?

How much to use

- **Follow all directions given to you by your doctor and pharmacist carefully.**
- Adults and adolescents 12 years and older: Use a small amount of ACNATAC once daily at night time on the affected area. Do not exceed the recommended dose.
- Children under 12 years: this medicine is not recommended for children under 12 years.

When to use ACNATAC

- ACNATAC should be used once daily at night time.

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.

If you forget to use ACNATAC

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 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 apply too much ACNATAC

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.

If you swallow it

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 ACNATAC?

Things you should 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 should 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.

Driving or using machines

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store 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.

Heat and dampness can destroy some medicines.

Keep it 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.

When to discard your medicine

Discard after 3 months of first opening the tube.

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?

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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

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
<ul style="list-style-type: none"> • 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. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • skin bleeding • loss of skin pigmentation • application site symptoms such as swelling, superficial skin damage, discolouration • feeling hot. 	

More serious side effects

More serious side effects	What to do
<ul style="list-style-type: none"> • 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 • 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 ACNATAC contains

<p>Active ingredient (main ingredient)</p>	<ul style="list-style-type: none"> • clindamycin phosphate 1.2% w/w (equivalent to 1% w/w of clindamycin) and • tretinoin 0.025% w/w. <p>Each gram of ACNATAC contains 12 mg clindamycin phosphate (equivalent to 10 mg clindamycin) and tretinoin 0.25 mg.</p>
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> • glycerol • carbomer 981 • trometamol • propyl hydroxybenzoate • methyl hydroxybenzoate • polysorbate 80 • disodium edetate • citric acid • butylated hydroxytoluene

	<ul style="list-style-type: none"> • purified water
<p>Potential allergens</p>	<p>ACNATAC contains hydroxybenzoates (as antimicrobial preservatives).</p>

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

What ACNATAC looks like

ACNATAC is an aqueous translucent yellow gel that is available in tubes of 30 grams and 60 grams (AUST R 232394).

Who distributes ACNATAC

Viatris Pty Ltd
 Level 1, 30 The Bond
 30-34 Hickson Road
 Millers Point NSW 2000
www.viatris.com.au
 Phone: 1800 274 276

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