Package leaflet: Information for the user

Acnatac Gel 10mg/g + 0.25mg/g
clindamycin 10 mg/g and tretinoin 0.25 mg/g

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

1. What Acnatac is and what it is used for

Acnatac contains the active substances clindamycin and tretinoin.

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

Tretinoin normalizes 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).

These active substances are more effective when combined than when used separately.

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

2. What you need to know before you use Acnatac

DO NOT use Acnatac:

- if you are pregnant
- if you are planning a pregnancy
- if you are allergic to clindamycin, tretinoin, or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to lincomycin.
- if you have a chronic inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- if you have a history of colitis with past antibiotic use which is characterised by prolonged or significant diarrhoea or abdominal cramps.
- if you or a member of your family have ever suffered from skin cancer.
- if you are suffering from acute eczema which is characterised by inflamed, 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 you are suffering from certain special forms of acne vulgaris characterized by pustular and deep cystic nodular acne lesions (acne conglobata and acne fulminans).

If any of the above applies to you, do not use this medicine and talk to your doctor.

Warnings and precautions

- Avoid contact of this medicine with the mouth, eyes, mucous membranes and with abraded or eczematous skin. Be careful when applying to sensitive areas of skin. In case of accidental contact with the eyes, rinse with plenty of lukewarm water.
- Acnatac If you are a woman of childbearing potential, you should not use Acnatac unless you are using contraception (see also section "Pregnancy, breast-feeding and fertility").
- If prolonged or significant diarrhoea or abdominal cramps occur, stop using this medicine and talk to your doctor immediately.
- If you have atopic eczema (chronic, itching inflammation of the skin), please talk to your doctor before using this medicine.
- Exposure to natural or artificial light (such as a sunlamp) should be avoided. This is because this medicine may make your skin more sensitive to sunburn and other adverse effects of the sun.
  An effective sunscreen with Sun Protection Factor (SPF) of at least 30 and protective clothing (such as a hat) should be used any time you are outside.
  If nevertheless your face becomes sunburnt, stop medication until your skin has healed**.**
- Talk to your doctor in case an acute inflammation of the skin occurs when using this medicine.
- Acnatac should not be applied at the same time as other preparations used on the skin including cosmetics (see also section "Other medicines and Treclin").

Other medicines and Treclin

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. This is because Acnatac can affect the way some other medicines work. Also some other medicines can affect the way Acnatac works.

If you have used any preparations that contain sulphur, salicylic acid, benzoyl peroxide or rescinol or any chemical abrasives; you will need to wait until the effect of those have subsided until you start using this medicine. Your doctor will tell you when you can start using Acnatac.

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.

You should ask your doctor for advice before using this medicine together with other medicinal products containing erythromycin or metronidazole, aminoglycosides, other antibiotics or corticosteroids or if you are receiving neuromuscular blocking medicines e.g muscle relaxants used in anesthesia.

Warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.

Pregnancy, breast-feeding and fertility

DO NOT use Acnatac if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

You should not use this medicine if you are breastfeeding. It is not known if Acnatac may pass through your milk and harm your baby.

If you are a woman of child-bearing age you should use contraception while using this medicine and for one month after discontinuation of treatment.

Driving and using machines

Acnatac is unlikely to have an effect on the ability to drive or operate machines.

Acnatac contains methylparahydroxybenzoate, propylparahydroxybenzoate butyl hydroxytoluene and polysorbate 80.

Methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

Butyl hydroxytoluene (E321) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Polysorbate 80 (E433) can cause allergic reactions

3. How to use Acnatac

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

The recommended dose is:
A pea-sized amount of Acnatac should be applied once daily at bedtime.

Method of administration
Wash your face gently with mild soap and warm water and pat your skin dry with a towel. Squeeze a pea-sized amount of gel onto the fingertip. Dab the gel on your forehead, chin, nose and both cheeks, and then gently spread it evenly over your whole face.

Do not use more than the amount that has been suggested by your doctor, or apply the product more frequently than instructed. Too much medication may irritate the skin, and will not give faster or better results.

Duration of treatment
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. Typically, it may take several weeks to have an optimal effect. In some cases, it may take up to 12 weeks. Please contact your doctor if symptoms persist for more than 12 weeks, as your doctor will need to reevaluate your treatment.

If you use more Acnatac than you should
You will not get faster or better results by using more Acnatac than recommended. If you use to much marked redness, peeling, or discomfort may occur. In such cases, the face should be gently washed with a mild soap and lukewarm water. The use of this medicine should be stopped until all these symptoms have gone away.

Overdose may also result in side effects from you stomach and intenstine; including stomach pain, nausea, vomiting and diarrhoea. In such cases, the use of this medicine should be discontinued and your doctor should be contacted.

Acnatac is only for use on the skin. In case of accidental ingestion, contact your doctor or go to the nearest hospital casualty department immediately.

If you forget to use Treclin
If you forget to use Acnatac at bedtime, you should apply the next dose at the usual time. You should not double the dose to make up for the forgotten dose.

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

4. Possible side effects

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

Uncommon: may affect up to 1 in 100 people

- Acne, dry skin, redness of the skin, increased sebum production, photosensitivity reaction, itching, rash, scaly rash, scaling of the skin, sunburn
- Application site reactions such as burning, inflamed skin, dryness, redness of the skin

Rare: may affect up to 1 in 1,000 people

- Hypersensitivity
- Underactive thyroid gland (symptoms may include fatigue, weakness, weight gain, dry hair, rough pale skin, hair loss, increased sensitivity to cold).
- Headache
- Eye irritation
- Gastroenteritis (inflammation of any part of the gastrointestinal tract), nausea
- Inflamed skin, herpes simplex (cold sore), rash macular (small, flat, red spots), skin bleeding, skin burning sensation, loss of skin pigmentation, skin irritation
- Application site symptoms such as irritation, swelling, superficial skin damage, discolouration, itching, scaling
- Feeling hot, pain

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 the 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 Acnatac

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

Do not store above 25°C. Do not freeze.

Keep the tube tightly closed.

Do not use this medicine after the expiry date which is stated on the carton and tube after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening: 3 months

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 Acnatac contains

- The active substances are clindamycin and tretinoin.
  1 g of gel contains 10 mg (1%) clindamycin (as clindamycin phosphate) and 0.25 mg (0.025%) tretinoin.

- The other ingredients are purified water, glycerol, carbomer, methyl parahydroxybenzoate (E 218), polysorbate 80 (E433),, disodium edetate, anhydrous citric acid, propyl parahydroxybenzoate (E 216), butyl hydroxytoluene (E321), trometamol.

What Acnatac looks like and contents of the pack
This medicinal product is a translucent yellow gel.

This medicinal product is available in aluminium tubes containing 30 g gel or 60 g gel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Viatris Healthcare Limited
Damastown Industrial Park,
Mulhuddart,
Dublin 15, DUBLIN,
Ireland

Manufacturer:

Meda Pharma GmbH & Co. KG
Benzstrasse 1
61352 Bad Homburg
Germany

Madaus GmbH
Lütticher Straße 5
53842 Troisdorf
Germany

This leaflet was last revised in December 2025.