PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TRECLIN GEL 10 mg/g + 0,25 mg/g gel

Clindamycin (as clindamycin phosphate) and tretinoin

Read all of this leaflet carefully before you start using TRECLIN GEL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **TRECLIN GEL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TRECLIN GEL is and what it is used for

TRECLIN GEL 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 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).

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

TRECLIN GEL is used on the skin to treat moderately severe acne if you are 12 years of age or older.

2. What you need to know before you use TRECLIN GEL

Do not use TRECLIN GEL:

- If you are hypersensitive (allergic) to clindamycin, tretinoin, or any of the other ingredients of **TRECLIN GEL** (listed in section 6).
- if you are allergic to lincomycin.
- if you are pregnant or if you are planning a pregnancy.
- if you are of childbearing potential/age and not on effective contraception.
- if you are breastfeeding your baby.
- 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).

Warnings and precautions

Avoid contact of **TRECLIN GEL** with the mouth/lips, 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.

If you are a woman of childbearing potential, you should not use **TRECLIN GEL** unless you are using contraception (see also section **Pregnancy, breast-feeding and fertility**).

If prolonged or significant diarrhoea or abdominal cramps occur, stop using **TRECLIN GEL** and talk to your doctor immediately.

If you have atopic eczema (chronic, itching inflammation of the skin), please talk to your doctor before using **TRECLIN GEL**.

Exposure to natural or artificial light (such as a sunlamp) should be avoided. This is because **TRECLIN GEL** 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 **TRECLIN GEL**.

TRECLIN GEL should not be applied at the same time as other preparations used on the skin including cosmetics (see also section **Other medicines and TRECLIN GEL**).

Other medicines and TRECLIN GEL

Always tell your doctor if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 **TRECLIN GEL**. Your doctor will tell you when you can start using **TRECLIN GEL**.

Do not use medicated soaps cleansers or scrubbing solutions with strong drying effect during treatment with **TRECLIN GEL**. 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 **TRECLIN GEL** together with other medicines containing erythromycin or metronidazole, aminoglycosides, other antibiotics or corticosteroids or if you are to receive neuromuscular blocking medicines e.g. muscle relaxants used in anaesthesia.

Warfarin or similar medicines – used to prevent blood clots. 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, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

DO NOT use TRECLIN GEL if you are pregnant or thinking of becoming pregnant as TRECLIN GEL will cause harm to your baby. Your doctor can give you more information.

You should not use TRECLIN GEL if you are breastfeeding your baby. The active components of **TRECLIN GEL** may pass through your milk and harm your baby.

If you are a woman of child-bearing age you should use contraception while using TRECLIN GEL and for one month after discontinuation of treatment. Your pregnancy test performed 24 hours before starting treatment with TRECLIN GEL must be negative.

Fertility

The tretinoin component of **TRECLIN GEL** may negatively affect your fertility.

Driving and using machines

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

TRECLIN GEL contains methylparahydroxybenzoate, propylparahydroxy-benzoate and butyl hydroxytoluene.

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.

3. How to use TRECLIN GEL

Do not share **TRECLIN GEL** prescribed for you with any other person.

Always use **TRECLIN GEL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

A pea-sized amount of **TRECLIN GEL** 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 onto 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 **TRECLIN GEL** more frequently than instructed. Too much medication may irritate the skin and will not give faster or better results.

Avoid contact with your eyes, nostrils and mouth/lips when applying **TRECLIN GEL**. Wash your hands after applying **TRECLIN GEL**.

Duration of treatment

To get the best results with **TRECLIN GEL**, it is necessary to use it properly and not stop using it as soon as your acne starts to get better. It may take several weeks to have an optimal effect. In some cases, it may take up to 12 weeks. Do not exceed 12 weeks of treatment. Please contact your doctor if symptoms persist for more than 12 weeks, as your doctor will need to re-evaluate your treatment. Safety of repeated courses of **TRECLIN GEL** has not been established.

If you use more TRECLIN GEL than you should

You will not get faster or better results by using more **TRECLIN GEL** 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 **TRECLIN GEL** 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 **TRECLIN GEL** should be discontinued and your doctor should be contacted.

TRECLIN GEL 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 GEL

If you forget to use **TRECLIN GEL** 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 **TRECLIN GEL**, ask your doctor or pharmacist.

4. Possible side effects

TRECLIN GEL can have side effects.

Not all side effects reported for **TRECLIN GEL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **TRECLIN GEL**, please consult your doctor for advice.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **TRECLIN GEL**.

5. How to store TRECLIN GEL

Store all medicines out of reach of children.

- Store at or below 25°C. Do not freeze.
- Keep the tube tightly closed.
- Shelf life after first opening: 3 months
- Do not use after the expiry date stated on the label or carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TRECLIN GEL 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, disodium edetate, anhydrous citric acid, propyl parahydroxybenzoate (E 216), butyl hydroxytoluene (E321), trometamol.

What TRECLIN GEL looks like and contents of the pack

TRECLIN GEL is a translucent yellow gel.

TRECLIN GEL is available in aluminium tubes containing 30 g gel or 60 g gel.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris South Africa (Pty) Ltd.

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1609

This leaflet was last revised in

28 February 2025

Registration number

49/13.12/0499

Access to the corresponding Professional Information

To follow