1.6.3 PATIENT INFORMATION LEAFLET (PIL)

CLEAR T GEL (Clindamycin & Tretinoin Gel)

Read all of this leaflet carefully before you start taking this medicine.
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.

What is in this leaflet?

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

1. WHAT CLEAR T GEL IS AND WHAT IT IS USED FOR

CLEAR T 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 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.
CLEAR T GEL is used on the skin to treat acne in patients 12 years and older.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CLEAR T GEL

DO NOT use CLEAR T GEL:
• if you are allergic to clindamycin, tretinoin, or any of the other ingredients of this medicine.
• 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.
• You should not use CLEAR T GEL if you are pregnant, especially during the first three months of the pregnancy. If you are a woman of childbearing potential, you should not use CLEAR T 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 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.
• CLEAR T GEL should not be applied at the same time as other preparations used on the skin including cosmetics (see also section "Other medicines and CLEAR T GEL ").Other medicines and CLEAR T GEL 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 CLEAR T GEL can affect the way some other medicines work. Also some other medicines can affect the way CLEAR T GEL 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 CLEAR T GEL. Do not use medicated soaps cleansers or scrubbing solutionswith strong drying effect during treatment with CLEAR T 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 this medicine together with other medicinal products containing erythromycin or metronidazole, aminoglycosides, other antibiotics or corticosteroids or if you are receiving neuro
-muscular blocking medicines e.g muscle relaxants used in anaesthesia.
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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not use this medicine if you are pregnant, especially during the first three months of the pregnancy, or if you are breastfeeding. It is not known if CLEAR T GEL may harm your unborn baby or 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 machinesCLEAR T GEL is unlikely to have an effect on the ability to drive or operate machines.
CLEAR T GEL contains methylparahydroxybenzoate, propyl-parahydroxybenzoate and butyl hydroxytoluene. Methylparahydroxybenzoate (E 218) and propylparahydroxy-benzoate (E 216) may cause allergic reactions (possibly delayed)
Butyl hydroxytoluene (E 321) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. HOW TO USE CLEAR T GEL
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 CLEAR T 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 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 CLEAR T GEL, 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 re-evaluate your treatment.

If you use more CLEAR T GEL than you should
You will not get faster or better results by using more CLEAR T GEL than recommended. If you use too much a 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 your 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.
CLEAR T 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 CLEAR T GEL
If you forget to use CLEAR T 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 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 skinRare: 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 gastro-intestinal tract), nausea
• Inflamed skin, herpes simplex (cold sore), macular rash (small, flat, red spots), skin bleeding, skin burning sens-tion, loss of skin pigmentation, skin irritation
• Application site symptoms such as irritation, swelling, superficial skin damage, discolouration, itching, scaling
• Feeling hot, painReporting 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine

5. HOW TO STORE CLEAR T GEL

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.
Once opened use within3 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. FURTHER INFORMATION

What CLEAR T GEL contains

• The active substances are clindamycin and tretinoin.1 g of gel contains 10 mg (1% w/w) clindamycin (as clindamycin phosphate) and 0.25 mg (0.025% w/w) tretinoin.
• The other ingredients are Sodium Methyl Hydroxybenzoate BP, Sodium Propyl Hydroxybenzoate BP, Propylene Glycol BP, Carbomer 940 USP, Disodium Edetate BP, Isopropyl Alcohol BP, Polyoxyl 40 Hydrogenated Castor Oil (Creshmer RH40) USP, Triethanolamine BP, Fragrance Lemon Cologne IHS, Butylated Hydroxytoluene BP, Purified Water BP.

7. What CLEAR T GEL looks like and contents of the pack

This medicinal product is a light yellow to yellow coloured gel.
This medicinal product is available in Lami Tubes containing 20g gel.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ochoa Laboratories
430, Mzz. F, Gundecha Indl. Complex
Akurli Road, kandivali (E).
Mumbai – 400101. India.
E-mail: maheshshah@aurochemgroup.com

Manufacturer
Aurochem Laboratories (I) pvt. Ltd.
333, Gundecha Ind. Complex,
Akurli Rd, Kandivali East
Mumbai - 400 101,
(India)
Phone: + (91)-(22)-28858503/28858504/28858505
Fax: + (91)-(22)-28873236
E-mail: maheshshah@aurochemgroup.com

8 Date of Revision of PIL