Package leaflet: Information for the patient
Tolak 40 mg/g cream
fluorouracil

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 Tolak is and what it is used for

Tolak contains the active substance fluorouracil.

Fluorouracil belongs to a group of medicines known as antimetabolites which inhibit the growth of cells (cytostatic agent).

Tolak is used to treat skin conditions called actinic keratosis (sun damaged skin) Grade I and II on the face, ears, and/or scalp in adults.

Information About How Tolak Works
When you use Tolak it is likely that the area of the skin that you are treating will become red.
Tolak destroys cancerous and pre-cancerous cells of the skin, while having less effect on normal cells.
Tolak will also treat abnormalities of the skin that were previously not visible to the naked eye, and these abnormalities may become red and inflamed.

This will probably be followed by inflammation/swelling, possibly some discomfort, skin erosion and, eventually, healing. This is the expected normal response to treatment and shows that Tolak is working.

Sometimes the response is more severe (see section 4 “Possible Side Effects”). If your skin becomes much worse, you experience pain or if you are worried, talk to your doctor. Your doctor may prescribe another cream to relieve any discomfort.

The skin reactions are transient and resolve within 2-4 weeks after the end of treatment. Therefore, after stopping treatment, you may find that your skin takes approximately 4 weeks to heal.

2. What you need to know before you use Tolak

Do not use Tolak:

- if you are allergic (hypersensitive) to fluorouracil or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic (hypersensitive) to peanut or soya
- If you are pregnant
- If you are breast-feeding
- If you are using any medicines known as antiviral nucleosides (e.g. brivudine and sorivudine). These medicines are usually used to treat chickenpox or shingles.

Warnings and precautions

Talk to your doctor or pharmacist before using Tolak.

- Do not apply Tolak directly into eyes, nose, mouth, or other mucous membranes because irritation, local inflammation and ulceration can occur.
- Do not apply Tolak on open wounds or damaged skin.
- It is likely that the area of the skin treated will become red, probably followed by inflammation/swelling, possibly some discomfort, skin erosion and eventually, healing. This is the expected normal response to treatment and it shows that Tolak is working. Talk to your doctor if your skin becomes much worse, you experience pain or if you are worried. Your doctor may prescribe you another cream to relieve any discomfort.
- Do not apply Tolak under bandages or dressing as this may increase inflammatory reactions of the skin.
- To avoid transfer of the drug into the eyes and/or contact lenses and to the area around the eyes during and after application, you should wash hands well after applying Tolak.
- If accidental exposure occurs, you should flush eye(s) with large amounts of water.
- Allergic reactions (contact eczema) can occur. Tell your doctor if you experience severe itching or if redness develops beyond the treated lesions.
- Exposure to UV-radiation (e.g. natural sunlight, tanning salon) should be avoided.
- If you know that you have reduced or no activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (partial or complete DPD deficiency)

Tolak might cause serious side effects in people who do not have enough of the enzyme dihydropyrimidine dehydrogenase (DPD). Stop using Tolak and call your doctor immediately if you present any of the following symptoms: mouth ulceration (mucositis), stomach-area (abdominal) pain, bloody diarrhea, vomiting, fever and chills.

Children and adolescents

Tolak is not intended for use in children and adolescents under 18 years of age.

Other medicines and Tolak

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. In particular, tell your doctor if you are using medicines to treat chickenpox or shingles (brivudine and sorivudine) or have used them in the last 4 weeks. These medicines may increase the possibility of unwanted effects with Tolak. Therefore, these medicines must not be used with Tolak.

Pregnancy, breast-feeding and fertility
Tolak must not be used during pregnancy.

If you become pregnant during treatment, Tolak treatment must be interrupted, contact your doctor immediately for advice about the risk for the child.

Women of childbearing potential on treatment with Tolak must use an effective contraception during treatment and up to 6 months after the last dose of Tolak. Talk to your doctor if you need advice on contraception.

Men under Tolak treatment must use effective contraception and not father a child during treatment and up to 3 months after the last dose of Tolak.

It is not known if Tolak passes into your breast milk. Tolak must not be used during breast-feeding. If use during breastfeeding is absolutely necessary, breastfeeding must be discontinued.

The use of Tolak may impair female and male fertility. Tolak is not recommended in women and men attempting to have a child.

Driving and using machines
It is unlikely that treatment will have any effect on the ability to drive and use machines.

Tolak contains :
- Butylhydroxytoluene (E321):

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

- Cetyl alcohol and stearyl alcohol

They may cause local skin reactions (e.g., contact dermatitis).

- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate

They may cause allergic reactions (possibly delayed).

- Arachis oil, refined (peanut oil)

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use Tolak

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

How to apply Tolak
Apply Tolak once daily to cover the areas of your skin to be treated, for 4 weeks as follows:
- Wash, rinse, and pat dry gently the skin areas to be treated.
- Apply a thin film of Tolak to the areas to be treated.
- Massage gently Tolak evenly into your skin.
- Avoid contact with other areas of your body, and transfer of Tolak from your body to other people.
- Wash your hands well after you have applied Tolak.

If you use more Tolak than you should
If you apply Tolak more often than once daily, you will be more likely to experience skin reactions and they may be more severe.
If you or a child by mistake swallow Tolak please contact a doctor or go to your nearest emergency department immediately.

If you forget to use Tolak
Do not use a double dose to make up for a forgotten dose. Continue your treatment as the doctor has told you or as described in this leaflet.

If you stop using Tolak
Please contact your doctor before stopping treatment unless you present any of the following symptoms: mouth ulceration, stomach-area pain, bloody diarrhea, vomiting, fever and chills. In that case, stop using Tolak and call your doctor immediately (see section 2).

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

4. Possible side effects

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

Common side effects (may affect up to 1 in 10 people)
- Skin reactions on the site of application (irritation, pain, reaction, redness, itching, inflammation, oedema (swelling))
- Eye irritation

Uncommon side effects (may affect up to 1 in 100 people)
- Impetigo (bacterial infection of the skin),
- Sore throat (pharyngitis),
- Insomnia,
- Nasal discomfort,
- Lip blister,
- Nausea,
- Swelling around the eyes (oedema),
- Increased watery eyes (lacrimation),
- Redness,
- Skin reactions on the site of application: bleeding, erosion, eczema, discomfort, dryness, burning/tingling, photosensitivity reaction (increase in the reactivity of the skin to sunlight).

The frequency of the following side effects is not known (frequency cannot be estimated from the available data)
- Allergic reactions (contact eczema)

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 Yellow Card Scheme Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tolak

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

Do not store Tolak above 25°C.
Do not use this medicine after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month.

Do not use Tolak after 4 weeks following the first opening of the tube (being pierced by the cap).

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 Tolak contains
- **The active substance is**: fluorouracil
- **The other ingredients are**: stearoyl macrogolglycerides, butylhydroxytoluene (E321), cetyl alcohol, citric acid (E330), glycerol (E422), isopropyl myristate, methyl gluceth-10, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate, purified water, Arachis oil, refined (peanut oil), sodium hydroxide (E524), stearic acid, and stearyl alcohol.

What Tolak looks like and contents of the pack
White to off white cream in tube of 20 or 40 g
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder is PIERRE FABRE LIMITED, 250 Longwater Avenue, Green Park, Reading RG2 6GP United Kingdom.

The Manufacturer is PIERRE FABRE MEDICAMENT PRODUCTION, Parc Industriel de la Chartreuse, 81100 Castres France.

This leaflet was last revised in 02/2024.

Other sources of information

Detailed information on this medicine is available on the web site of the MHRA.