

TOLAK[®] 4% ONCE DAILY cream

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 TOLAK 4% ONCE DAILY?

TOLAK 4% ONCE DAILY contains the active ingredient fluorouracil. TOLAK 4% ONCE DAILY is used to treat a skin condition called actinic keratosis, also known as solar keratoses or sunspots. Fluorouracil belongs to a group of medicines known as antimetabolites that inhibit the growth of cells (cytostatic agent).

For more information, see Section [1. Why am I using TOLAK 4% ONCE DAILY?](#) in the full CMI.

2. What should I know before I use TOLAK 4% ONCE DAILY?

Do not use if you have ever had an allergic reaction to fluorouracil 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 TOLAK 4% ONCE DAILY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TOLAK 4% ONCE DAILY 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 TOLAK 4% ONCE DAILY?

TOLAK 4% ONCE DAILY is usually used for 4 weeks. Apply the cream once daily to cover the areas of your skin to be treated.

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

5. What should I know while using TOLAK 4% ONCE DAILY?

Things you should do	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 4% ONCE DAILY 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.
Things you should not do	<ul style="list-style-type: none">• Avoid exposure to UV-radiation (e.g. sun, tanning salon) during and immediately following treatment with TOLAK 4% ONCE DAILY. Your skin can become more sensitive to sunlight.• Do not apply TOLAK 4% ONCE DAILY directly into eyes, nose, mouth, or other mucous membranes because irritation, local inflammation and ulceration can occur.• Do not apply TOLAK 4% ONCE DAILY on open wounds or damaged skin• Do not apply TOLAK 4% ONCE DAILY under bandages or dressing as this may increase inflammatory reactions of the skin.
Driving or using machines	It is unlikely that treatment with TOLAK 4% ONCE DAILY will have any effect on the ability to drive and use machines.
Drinking alcohol	It is unlikely that alcohol will have any effect on you while you are using TOLAK 4% ONCE DAILY
Looking after your medicine	Store it in a cool dry place – where the temperature stays below 25°C – away from moisture, heat or sunlight

For more information, see Section [5. What should I know while using TOLAK 4% ONCE DAILY?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are skin reactions on the site of application (irritation, pain, reaction, redness, itching, inflammation, oedema, (swelling)).

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.

TOLAK[®] 4% ONCE DAILY cream

Active ingredient(s): Fluorouracil

Consumer Medicine Information (CMI)

This leaflet provides important information about using TOLAK 4% ONCE DAILY. **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 TOLAK 4% ONCE DAILY.**

Where to find information in this leaflet:

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

1. Why am I using TOLAK 4% ONCE DAILY?

TOLAK 4% ONCE DAILY contains the active ingredient fluorouracil. Fluorouracil belongs to a group of medicines known as antimetabolites that inhibit the growth of cells (cytostatic agent).

TOLAK 4% ONCE DAILY is used to treat a skin condition called actinic keratosis, also known as solar keratoses or sunspots.

Solar keratoses are rough, red, scaly, or crusty spots on the skin that are caused by too much exposure to sunlight. They are more common on sun-exposed areas, such as the face, nose, ears, chest, forearms, and back of the hands.

Solar keratoses are usually harmless, but there is a risk that they may eventually turn into skin cancer.

What should I know before I use TOLAK 4% ONCE DAILY?

2. What should I know before I use TOLAK 4% ONCE DAILY?

Warnings

Do not use TOLAK 4% ONCE DAILY if:

- you are allergic to fluorouracil, 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 allergic to peanuts or soya
- you are taking medicines known as antiviral nucleosides which are used to treat chickenpox or shingles (eg brivudine, sorivudine)
- Do not use this medicine if you have a dihydropyrimidine dehydrogenase (DPD) enzyme deficiency

Some of the symptoms of an allergic reaction may include:

- 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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have an inflammatory skin conditions such as darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea).
- you work outside for long periods of time during the day. TOLAK 4% ONCE DAILY is not recommended for people who work outdoors for long periods of time.

TOLAK 4% ONCE DAILY also contains stearyl alcohol, which may cause skin irritation.

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 this medicine if you are pregnant or intend to become pregnant.

TOLAK 4% ONCE DAILY must not be used during pregnancy. Women who can become pregnant should use an effective method of birth control during treatment with TOLAK 4% ONCE DAILY and for 6 months after the last application. Men must not father a child and must use an effective method of contraception during treatment and for 3 months after the last application. Talk to your doctor if you need advice on contraception. If you become pregnant during treatment inform your doctor immediately and make use of genetic counselling.

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

It is not known if TOLAK 4% ONCE DAILY passes into your breast milk. If use of TOLAK 4% ONCE DAILY is absolutely necessary, breastfeeding must be discontinued.

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.

Medicines that may increase the effect of TOLAK 4% ONCE DAILY include:

- medicines to treat chickenpox or shingles (brivudine and sorivudine). These medicines may increase the possibility of side effects with TOLAK 4% ONCE DAILY. Therefore these medicines must not be used with; or

within 4 weeks prior to starting TOLAK 4% ONCE DAILY.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TOLAK 4% ONCE DAILY.

4. How do I use TOLAK 4% ONCE DAILY?

How much to use

Apply the cream once daily to cover the areas of your skin to be treated as follows:

- Wash, rinse, and pat dry gently the skin areas to be treated.
- Apply a thin film of cream to the areas to be treated.
- Massage gently the cream evenly into your skin.
- Avoid contact with other areas of your body, and transfer of the cream from your body to other people.
- Wash your hands well after you have applied TOLAK 4% ONCE DAILY.

When you use TOLAK 4% ONCE DAILY it is likely that the area of the skin that you are treating will become red.

TOLAK 4% ONCE DAILY destroys cancerous and pre-cancerous cells of the skin, while having less effect on normal cells.

TOLAK 4% ONCE DAILY 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 4% ONCE DAILY is working.

Sometimes the response is more severe (see 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.

Wash the skin to be treated using lukewarm water. Avoid soap or other cleansing products which may sting or irritate your skin, especially as treatment progresses.

Be very careful not to allow TOLAK 4% ONCE DAILY to come into contact with mucous membranes, such as eyes, eyelids, nostrils and lips.

Do not apply TOLAK 4% ONCE DAILY under bandages or dressing as this may increase inflammatory reactions of the skin.

Follow the instructions provided and use TOLAK 4% ONCE DAILY until your doctor tells you to stop.

TOLAK 4% ONCE DAILY should only be used by adults 18 years of age and older.

When to use TOLAK 4% ONCE DAILY

TOLAK 4% ONCE DAILY should be used once daily 1.5 – 2 hours before bedtime to enable complete absorption.

TOLAK 4% ONCE DAILY should be used for 4 weeks unless your Doctor has given you a different instruction.

If you forget to use TOLAK 4% ONCE DAILY

TOLAK 4% ONCE DAILY should be used regularly at the same time each day. If you have forgotten to use the cream at the usual time, apply TOLAK 4% ONCE DAILY as soon as you remember.

If it is almost time for your next application, skip the one you missed and apply TOLAK 4% ONCE DAILY when you are next meant to.

Do not apply twice as much to make up for the application you missed.

If you use too much TOLAK 4% ONCE DAILY

If you apply TOLAK 4% ONCE DAILY more often than once daily, you will be more likely to experience skin reactions and they may be more severe.

If you think that you or anyone else may have swallowed TOLAK 4% ONCE DAILY by mistake, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 TOLAK 4% ONCE DAILY?

Things you should do

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 4% ONCE DAILY 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.

Limit your exposure to sun during and immediately following treatment with TOLAK 4% ONCE DAILY.

This will help reduce the likelihood and severity of unwanted side effects.

Apply a broad spectrum sunscreen (SPF 30 or higher) every day before going outdoors, and regularly reapply during the day, except directly on the treatment area.

TOLAK 4% ONCE DAILY can make you more sensitive to sunlight. In addition to sunscreen, wear a wide-brimmed hat, long sleeves and trousers (or a long skirt) to protect your skin.

Remind any doctor, dentist or pharmacist you visit that you are using TOLAK 4% ONCE DAILY.

Keep all of your doctor's appointments so that your progress can be checked. Always discuss with your doctor any problems or difficulties experienced during or after using TOLAK 4% ONCE DAILY.

Things you should not do

- Avoid exposure to UV-radiation (e.g. sun, tanning salon) during and immediately following treatment with TOLAK 4% ONCE DAILY. Your skin can become more sensitive to sunlight.
- Do not apply directly or let TOLAK 4% ONCE DAILY come into contact with eyes, eyelids, nostrils, mouth, or other mucous membranes because irritation, local inflammation and ulceration can occur.
- Do not apply TOLAK 4% ONCE DAILY on open wounds or damaged skin

Things to be careful of

While treatment is in progress follow these personal care tips:

- Avoid using cosmetics or other topical medications, directly on the treatment area, unless directed by your doctor.
- Your treated skin is expected to become irritated and uncomfortable whilst using TOLAK 4% ONCE DAILY. Applying other products directly on the treatment area may make your discomfort worse.
- You may continue to shave whilst using TOLAK 4% ONCE DAILY, but take care not to cut your skin in the treatment area.
- As facial skin becomes inflamed during TOLAK 4% ONCE DAILY treatment shaving with a conventional razor may become unpleasant. You may prefer instead to lightly shave with an electric razor or clip the facial hair.

Driving or using machines

It is unlikely that treatment with TOLAK 4% ONCE DAILY will have any effect on the ability to drive and use machines.

Drinking alcohol

It is unlikely that alcohol will have any effect on you while you are using TOLAK 4% ONCE DAILY

Looking after your medicine

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

Store it in a cool dry place - where the temperature stays below 25°C - 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.

Keep it where young children cannot reach it.

When to discard your medicine

Once you have opened the tube of TOLAK 4% ONCE DAILY, it should be discarded after 4 weeks.

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?

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.

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
<p>Common (may affect up to 1 in 10)</p> <ul style="list-style-type: none">• Skin reactions on the site of application: irritation, pain, reaction, redness, itching, inflammation, oedema (swelling)• Eye irritation <p>Uncommon (may affect up to 1 in 100)</p> <ul style="list-style-type: none">• 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)	<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">• mouth ulceration (mucositis)• stomach-area (abdominal) pain• bloody diarrhea• vomiting• fever• chills	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.

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 TOLAK 4% ONCE DAILY contains

Active ingredient (main ingredient)	Fluorouracil
Other ingredients (inactive ingredients)	Stearoyl macrogolglycerides Butylated hydroxytoluene Cetyl alcohol Citric acid Glycerol Isopropyl myristate Methyl gluceth-10 Methyl hydroxybenzoate Propyl hydroxybenzoate Purified water Arachis oil (peanut oil) Sodium hydroxide Stearic acid Stearyl alcohol

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

What TOLAK 4% ONCE DAILY looks like

TOLAK 4% ONCE DAILY is a white to off-white cream.

AUST R: 328512

Sponsor

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