

TOLAK® 4% ONCE DAILY cream

Fluorouracil

Consumer Medicine Information

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?
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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 are able to become pregnant should use an effective method of birth control during treatment with TOLAK 4% ONCE DAILY and for one month 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.