

Patient Education - Fluorouracil 6%, Niacinamide 1% Topical Gel

Hillcrest Pharmacy 781 E FT Union Blvd Midvale, UT 84047 – Direct 385-900-1400, Toll Free 1-855-499-2556

Patient Education Insert

- Apply medication to affected area as prescribed

This medication was compounded by a pharmacy per prescriber request. For external use only. Wash hands before and after use unless the medication is for your hands. Store at room temperature (68 to 77 degrees Fahrenheit). Keep away from children and pets. Do not flush unused medications or pour down a sink or drain. Do not swallow and avoid contact with eyes. Do not use more than your medical provider has instructed you to use. Do not use more often or for longer than you were instructed. Doing any of these may increase the chance of undesirable side effects.

The “Do not use after” date printed on the prescription label is generated using State & Federal compounding laws. Some preparations are made 1-3 days before the prescription is issued, in anticipation of expected demand. If you have any questions or concerns regarding this, please do not hesitate to call and speak to one of our pharmacists.

Do not use if an allergic reaction occurs due to any of the listed active ingredients on the prescription label. Signs of an allergic reaction may include rash hives itching shortness of breath wheezing cough swelling of face, lips, tongue or throat or any other signs.

Contact your medical provider or pharmacy if you have concerns about listed side effects or if you experience unexpected irritation. Notify your medical provider of any medical updates and of all drug changes including over-the-counter and herbal medications.

If you miss an application, apply as soon as you remember. If it is close to the next application, skip the missed application. Do not double applications.

We want to offer you the best service possible. In the event you have a concern or complaint please call the pharmacy at 385-900-1400.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

Website address: <https://www.fda.gov/Safety/MedWatch/default.htm>

Toll free number: 1-888-463-6332

Your medication contains the following active ingredients. Please review the following:

Fluorouracil – an antineoplastic agent, interferes with the growth of skin cells by causing the death of cells which are growing fastest, such as abnormal skin cells. It is used to treat scaly overgrowths of skin (actinic or solar keratoses) & may also be used in the treatment of superficial basal cell carcinoma. It may also be used for purposes not listed in this medication guide.

Fluorouracil topical can harm an unborn baby or cause birth defects. Do not use if you are pregnant. If you become pregnant, stop using the medicine and tell your doctor right away. Use effective birth control to avoid pregnancy during treatment. Follow your doctor's instructions about how long to prevent pregnancy after your treatment ends.

It is not known whether fluorouracil topical passes into breast milk or if it could harm a nursing baby. You should not breast-feed while using fluorouracil topical.

Follow all directions on your prescription label. Do not use this medicine in larger or smaller amounts or for longer than recommended.

Do not take by mouth. Topical medicine is for use only on the skin.

Clean the area where you will apply fluorouracil topical. Rinse well and dry the area with a towel and wait ten minutes before applying the medication. Wash your hands before and immediately after applying this medicine, unless it is being used to treat a hand condition.

Apply fluorouracil topical to the affected area with the finger tips or a non-metal applicator, smoothing it gently onto the affected skin. Use enough to cover the entire area with a thin film.

Do not use fluorouracil topical on skin that is irritated, peeling, or infected or on open wounds. Wait until these conditions have fully healed before using fluorouracil topical. Do not cover the treated skin area unless your doctor tells you to.

A moisturizer or sun screen may be applied 2 hours after fluorouracil topical has been applied.

Store at room temperature away from moisture and heat. Do not freeze. Keep the medicine container tightly closed when not in use.

Do not use fluorouracil topical on your eyelids or in your eyes, nose, or mouth. Rinse with water or saline if this medicine gets in your eyes.

Do not let fluorouracil topical build up in the skin folds around your mouth, nose, or eyes. Use caution when applying the medicine around these areas. Avoid using other medications on the areas you treat with fluorouracil topical unless your doctor tells you to.

Avoid exposure to sunlight or tanning beds. Fluorouracil topical can make you sunburn more easily. Wear protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

This medicine can pass into body fluids (urine, feces, vomit). Caregivers should wear rubber gloves while cleaning up a patient's body fluids, handling contaminated trash or laundry or changing diapers. Wash hands before and after removing gloves. Wash soiled clothing and linens separately from other laundry.

If you miss a dose, use the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not use extra medicine to make up the missed dose.

Get emergency medical help if you have signs of an allergic reaction: hives difficult breathing swelling of your face, lips, tongue, or throat.

Stop using fluorouracil topical and call your doctor at once if you have: severe pain or swelling of treated skin severe itching, burning, or irritation open skin sores or shedding of dead skin.

Common side effects may include: skin redness, followed by dryness, tenderness, and crusting skin peeling or flaking skin darkening or scarring small blood vessels under the skin mild rash or mild irritation where the medicine was applied.

This is not a complete list of side effects and others may occur.

Niacinamide – Topical anti-inflammatory

When applied topically, niacinamide has been shown to have anti-inflammatory effects on the skin. It has been used to treat skin conditions like acne and rosacea, a facial skin disorder characterized by redness.

Possible side effects include: mild burning, itching, or redness.