

Patient Information  
FLUOROPLEX<sup>®</sup> (FLOOR-oh-plex)  
(fluorouracil)  
1% Topical Cream

**Important: FLUOROPLEX Cream is for use on skin only (topical). Apply with care near the eyes, nose and mouth.**

**What is FLUOROPLEX Cream?**

FLUOROPLEX Cream is a prescription medicine used on the skin to treat multiple actinic (solar) keratosis.

It is not known if FLUOROPLEX Cream is safe and effective in children.

**Who should not use FLUOROPLEX Cream?**

**Do not use FLUOROPLEX Cream if:**

- you are pregnant or may become pregnant. FLUOROPLEX Cream may harm your unborn baby. Stop using FLUOROPLEX Cream and tell your healthcare provider right away if you become pregnant while using FLUOROPLEX Cream.
- you are allergic to any of the ingredients in FLUOROPLEX Cream. See the end of this leaflet for a list of ingredients in FLUOROPLEX Cream.

**Before using FLUOROPLEX Cream, tell your healthcare provider about all of your medical conditions, including if you:**

- are breastfeeding or plan to breastfeed. It is not known if FLUOROPLEX Cream passes into your breast milk. You should not breastfeed during treatment with FLUOROPLEX Cream.

**How should I use FLUOROPLEX<sup>®</sup> Topical Cream?**

- Use FLUOROPLEX Cream exactly as your healthcare provider tells you. Your healthcare provider will tell you where to apply FLUOROPLEX Cream, how often and how long to apply it.
- FLUOROPLEX Cream is usually applied 2 times a day for 2 to 6 weeks.
- Use your fingertips to apply enough FLUOROPLEX Cream to cover the areas to be treated on your face or other affected areas, as instructed by your healthcare provider.
- Skin reactions are expected when you use FLUOROPLEX Cream. These skin reactions begin with redness, usually followed by dryness or tenderness and crusting of your skin. Before you see any healing of your skin, these skin reactions continue to progress. Stop using FLUOROPLEX Cream when you see raw areas (erosion and ulcers) and shedding of dead skin (sloughing). Be sure to follow your healthcare provider's instructions about when to stop using FLUOROPLEX Cream.
- If your skin reaction bothers you or is severe, or if you are not sure what to do, call your healthcare provider for instructions.
- Avoid letting FLUOROPLEX Cream build up in the skin folds around your eyes, nose or mouth.
- Wash your hands right away after you apply FLUOROPLEX Cream. If you accidentally get FLUOROPLEX Cream in your eyes, flush your eyes with water or normal saline.

**What should I avoid while using FLUOROPLEX Cream?**

- Avoid covering the treated areas with an airtight dressing, unless your healthcare provider tells you to.
- Avoid sunlight and ultraviolet lights, such as sun lamps and tanning machines. FLUOROPLEX Cream can make your skin sensitive to light. You could get a severe sunburn.

**What are the possible side effects of FLUOROPLEX Cream?**

- Skin reactions including possible allergic reactions (allergic contact dermatitis). You may get skin reactions such as:
  - pain
  - irritation
  - darkening of the skin
  - itching
  - redness and swelling
  - scarring
  - burning
  - small blood vessels that can be seen under the skin

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FLUOROPLEX Cream. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store FLUOROPLEX Cream?**

- Do not freeze FLUOROPLEX Cream.
- Store FLUOROPLEX Cream between 59°F to 86°F (15°C to 30°C) in tight containers.

**Keep FLUOROPLEX Cream and all medicines out of the reach of children.**

**General Information about the safe and effective use of FLUOROPLEX Cream.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use FLUOROPLEX Cream for a condition for which it was not prescribed. Do not give FLUOROPLEX Cream to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about FLUOROPLEX Cream that is written for the health professionals.

**What are the ingredients in FLUOROPLEX Cream?**

**Active ingredient:** fluorouracil

**Inactive ingredients:** benzyl alcohol, emulsifying wax, isopropyl myristate, mineral oil, purified water, and sodium hydroxide

Manufactured by: Aqua Pharmaceuticals, an Almirall Company, Exton, PA 19341 U.S.A. ® Marks owned by Aqua Pharmaceuticals

Made in Germany For more information, call 1-866-665-2782.

This Patient Information has been approved by the U.S. Food and Drug Administration

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