

APOC-5FU Cream

Contains the active ingredient fluorouracil

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOC-5FU. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APOC-5FU Cream. It contains the active ingredient fluorouracil.

It is used to treat:

- Solar keratosis
- Bowen's disease (type of skin cancer)

APOC-5FU belongs to a group of medicines called topical anti-cancer (also called anti-neoplastic or cytotoxic) drugs.

Topical anti-cancer drugs are used on the skin to treat conditions caused by ageing or exposure to sunlight (solar keratoses). If left untreated, these conditions may develop into skin cancer.

APOC-5FU is also used to treat Bowen's disease, which is a type of skin cancer.

You should be aware that you may look worse while treatment is in progress before you see any improvement in your condition.

When APOC-5FU is applied to the skin, the following usually happens: a redness of the affected area (generally within 3 to 5 days) followed by blistering, peeling, and cracking (within 11 to 14 days) with occasional open sores and some discomfort. Although the skin seems to be worse, it is a sign that the medication is working. The treated skin will flake away. Some redness of the skin will continue for some time after the drug is stopped. Scarring would not be expected.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you use this medicine

When you must not use it

Do not use this medicine if:

- **You have a dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.**
- **You are pregnant or planning to become pregnant.**
Fluorouracil may affect your developing baby if you use it during pregnancy.
- **You are hypersensitive to, or have had an allergic reaction to, fluorouracil or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not use any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using APOC-5FU, talk to your doctor.

Before you start to use it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have any inflammatory skin conditions such as darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea).
3. You are currently breastfeeding or you plan to breastfeed. Do not use this medicine whilst breastfeeding.
It is not known if the active ingredient in APOC-5FU passes into breast milk and there is a possibility that your baby may be affected.
4. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

If you have not told your doctor about any of the above, tell them before you use APOC-5FU.

Taking other medicines

Some medicines and APOC-5FU may interact with each other.

How to use this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to use

Your doctor will tell you how much of this medicine you should use and where to apply it.

This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your usage without first checking with your doctor.

How to use it

Apply a thin layer of APOC-5FU to the affected areas of your skin. Avoid eyelids nose and lips.

Apply APOC-5FU preferably with a non-metal applicator or a rubber glove. If you use your fingers to apply APOC-5FU or your hands come into contact with APOC-5FU wash them thoroughly. Do this immediately after use.

Although not generally required, your doctor may recommend that you apply a fresh occlusive dressing to the area(s) daily.

When to use it

Apply APOC-5FU once or twice daily as advised by your doctor. It should be applied in the morning and late afternoon or early evening.

Do not apply APOC-5FU immediately before going to bed.

Use this medicine at the same time each day. Using it at the same time each day will have the best effect and will also help you remember when to use it.

How long to use it for

Continue using your medicine for as long as your doctor tells you.

Always follow your doctors' directions and apply APOC-5FU for the length of time that has been prescribed to achieve the best results.

Treatment should continue up until the ulceration stage, usually three to four weeks. The healing process is usually complete one to two months after the end of treatment. The healthy skin surrounding the area being treated may occasionally become reddened, but soon resumes its normal colour once treatment is stopped.

Make sure you have enough to last over weekends and holidays.

If you forget to use it

Do not try to make up for the application you missed by applying more at the next application.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints to help you remember.

If you use too much or ingest the cream (overdose)

If you think that you or anyone else may have ingested or used too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Incorrect use of APOC-5FU may result in more severe irritation of the skin around the areas being treated. This will subside when the treatment is stopped.

While you are using this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant, planning to become pregnant or become pregnant while taking APOC-5FU stop using it and tell your doctor immediately.
- you are breastfeeding or are planning to breastfeed
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Always discuss with your doctor any problems or difficulties experienced during or after using APOC-5FU.

Tell any other doctors, dentists and pharmacists who are treating you that you use this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Use your medicine to treat any other condition unless your doctor tells you to.
- Stop using your medicine, or change the dosage, without first checking with your doctor.
- Let APOC-5FU come into contact with mucous membranes or the eyes. APOC-5FU is highly irritating to sensitive skin and the eyes.

Things to be careful of

While treatment is in progress, avoid:

- cosmetics or other topical medication applied to the treatment area, unless directed by your doctor.
- exposing treated areas to sun (ultraviolet rays) during and immediately following treatment because the intensity of the reaction may be increased. This may increase irritation in the areas being treated.
- treatment around the eyes, nose or mouth unless directed by your doctor.

Be aware that you may look worse while treatment is in progress.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are using APOC-5FU or if you have any questions or concerns.

APOC-5FU helps most people with skin conditions caused by ageing or exposure to sunlight, but it may have unwanted side effects in a few people.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- pain
- itchiness
- darkening of the skin
- burning at the site of application
- crusting
- swelling

- irritation
- photosensitivity
- rash
- ulceration.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- dermatitis
- scarring
- soreness
- tenderness.

Other side effects not listed above may occur in some patients.

During treatment with APOC-5FU temporary unsightly appearance and local discomfort is to be expected.

Allergic reactions

If you think you are having an allergic reaction to fluorouracil, do not use any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing, difficulty breathing or tightness in chest
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to use it.

If you use your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APOC-5FU Cream looks like

APOC-5FU is a white cream. APOC- 5FU comes in a 20g aluminium tube.

Ingredients

APOC-5FU contains 5% w/w (50mg/g) of fluorouracil as the active ingredient.

It also contains the following inactive ingredients:

- methyl hydroxybenzoate
- paraffin - soft white
- polysorbate 60
- propyl hydroxybenzoate
- propylene glycol

- stearyl alcohol
- water - purified

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APOC-5FU 5% w/w cream 20 g aluminium tube: AUST R 231556.

Sponsor

Apotex Pty Ltd
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Macquarie Park NSW 2113

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This leaflet was last updated in:
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