

APOC-5FU Cream

Fluorouracil

Consumer Medicine Information

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

What is in this leaflet

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.

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.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What this medicine is used for

APOC-5FU cream contains the active ingredient fluorouracil.

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

APOC-5FU is used to treat:

- Solar keratosis, also known as sun spots
- Bowen's disease (type of skin cancer)

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

if left untreated these conditions may develop into skin cancer.

Bowen's disease causes one or more small patches of scaly red skin. It occurs when there is a growth of abnormal cells in the outer layer of skin. It is most commonly found on the lower leg.

How it works

APOC-5FU works by destroying precancerous and cancerous cells, while having little effect on normal cells.

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.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you use this medicine

When you must not use it

Do not use this medicine if you have an allergy to:

- fluorouracil
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- 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

Do not take this medicine if you have a dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.

Do not take this medicine if you are pregnant or plan to become pregnant.

Fluorouracil may affect your developing baby if you use it during pregnancy.

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.

Do not take this medicine after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

APOC-5FU contains the parabens methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions. It also contains stearyl alcohol and propylene glycol, which may cause skin irritation.

Tell your doctor if you have or have had any inflammatory skin conditions such as darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea).

Tell your doctor if you work outside for long periods of time during the day or are exposed to UV radiation.

APOC-5FU is not recommended for people who work outdoors for long periods of time or are exposed to UV radiation, either from natural sunlight or tanning salons.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

How to use this medicine

Follow all directions given to you by your doctor carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the tube, ask your doctor or pharmacist for help.

How much to use

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

How to use it

- 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.
- Pat dry the affected area with a soft white paper towel. Allow 15

minutes for your skin to completely dry.

- Apply a thin layer of APOC-5FU to the affected areas of your skin as directed by your doctor, preferably with a non-metal applicator, cotton bud or a rubber glove. Do not use too much cream.
- Be very careful not to allow APOC-5FU cream to come into contact with mucous membranes, such as eyes, eyelids, nostrils and lips.
- Do not apply to broken skin or open cuts as it may be absorbed into the bloodstream and may cause side effects.
- Wash your hands carefully and thoroughly immediately after using APOC-5FU.
- Do not cover the treated area unless your doctor tells you to.
- Your doctor may recommend that you apply a fresh occlusive dressing to the area(s) daily.
- The total area of skin treated with APOC-5FU at any time should not exceed 500 square cm (approx. 23 x 23cm). Treat larger areas a section at a time.

When to use it

Apply APOC-5FU once or twice daily as advised by your doctor.

Apply in the morning and then again in the late afternoon or early evening, as per your doctor's instructions.

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

Apply at least 1.5 - 2 hours before bedtime to enable complete absorption and prevent wiping off onto pillowcases and sheets. Contact with pillowcases or sheets may result in undesirable spreading of APOC-5FU cream to normal skin that does not need treatment.

Use this medicine at about the same time each day.

Using it at the same time each day will have the best effect. It 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 duration is usually 3 to 4 weeks. The healing process is usually complete 1 to 2 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.

If you forget to use it

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

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have ingested or used too much of this medicine. 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

You should be aware that your skin 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.

Things you must do

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using APOC-5FU.

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

Tell your doctor immediately and stop using APOC-5FU if you become pregnant during your treatment.

Limit your exposure to sun and UV radiation during and immediately following treatment with APOC-5FU.

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.

APOC-5FU can make you more sensitive to sunlight and UV radiation. In addition to sunscreen, wear wide-brimmed hat, long sleeves and trousers (or a long skirt) to protect your skin.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to make sure the medicine is working and review

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

Things you must not do

Do not expose yourself to UV radiation during treatment (e.g. tanning salons).

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use your medicine to treat any other complaints unless your doctor tells you to.

Do not stop using your medicine or change the dosage without first checking with your doctor.

Do not let APOC-5FU come into contact with the eyes, eyelids, nostrils or mouth.

APOC-5FU is highly irritating to sensitive skin and the eyes.

Things to be careful of

While treatment is in progress, avoid cosmetics, other topical medication or sunscreens applied to the treatment area, unless directed by your doctor.

Your treated skin is expected to become irritated and uncomfortable whilst using APOC-5FU. Applying other products directly on the treatment area may make your discomfort worse.

You may continue to shave whilst using APOC-5FU but take care not to cut your skin in the treatment area.

As facial skin becomes inflamed during APOC-5FU 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.

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

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness and headache in some people. If you have any of these symptoms, do not drive, operate machinery or do

anything else that could be dangerous.

Side effects

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

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. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

During treatment with APOC-5FU, you should expect to have a temporary unsightly appearance and local discomfort at the sites of cream application.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist if you have any questions.

Below is a list of common side effects which are a sign that APOC-5FU is working. Tell your doctor if you notice any of the following and they become too uncomfortable for you:

- pain, soreness, tenderness
- itchiness, irritation
- darkening or reddening of the skin
- burning at the site of application
- crusting
- swelling
- increased sensitivity of the skin to the sun
- rash
- dermatitis

The above side effects are usually short-lived.

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

- severe pain and ulceration
- scarring

- dizziness or headaches

The above list includes some serious side effects that may need medical attention.

If any of the following happen, do not use any more of this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- stomach problems such as severe pain, cramps, bloody diarrhoea and vomiting
- fever and chills
- shortness of breath, wheezing, difficulty breathing or tightness in chest;
- swelling and soreness of the face, lips, tongue, throat or other parts of the body;
- rash, itching or hives on the skin (signs of an allergic reaction)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor or pharmacist if anything else is making you unwell while you are using APOC-5FU.

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

Storage and disposal

Storage

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

If you remove the cream from the tube it may not keep well.

Keep your medicine in a cool dry place where the temperature stays 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

After opening the tube, the cream can be used for up to 8 weeks before it must be disposed.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any leftover medicine.

Product description

What it looks like

White cream in a 20 g aluminium tube.

AUST R 231556.

Ingredients

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

It also contains the following:

- methyl hydroxybenzoate
- white soft paraffin
- polysorbate 60
- propyl hydroxybenzoate
- propylene glycol
- stearyl alcohol
- water – purified

This medicine contains hydroxybenzoates.

This medicine does not contain gluten, lactose, sucrose, tartrazine and other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel St,
Cremorne VIC 3121

APOC-F5U is a registered trade mark used under licence.

This leaflet was prepared in September 2022.