

5-FLUOROURACIL CREAM

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about 5-fluorouracil (5-FU) cream. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more information about it.

WHAT IS 5-FU CREAM AND HOW DOES IT WORK?

5-FU cream is a treatment that targets sun-damaged cells known as actinic keratoses, without affecting normal healthy skin cells.

During treatment with the cream, the skin will become inflamed. You may have redness, soreness, oozing, crusts, and scabs. This reaction will settle over a few weeks. Sometimes your healthcare professional may recommend using a steroid cream to help settle the inflammation more quickly.

In the UK, different forms of the 5-FU cream are available:

- 5% 5-FU cream (Efudix® cream has been discontinued, and a generic version is available)
- 4% 5-FU cream (brand names include Tolak™)
- 0.5% 5-FU combined with 10% salicylic acid (brand name Actikerall®).

There is a suggestion that combining 5-FU cream and calcipotriol ointment may help you tolerate the treatment better. Calcipotriol is based on vitamin D and used for treating psoriasis. Studies have shown that calcipotriol could make 5-FU cream more effective. It could also reduce the duration of treatment.

However, this combination product is not available in the UK yet. At the moment, it is

provided as two separate creams that you mix together. Your healthcare professional will provide more information on how to use this combination if they would like you to use it.

WHAT SKIN CONDITIONS ARE TREATED WITH 5-FU CREAM?

- 5% 5-FU cream is used for the treatment of pre-cancerous skin lesions, such as:
 - actinic keratoses
 - Bowen disease
 - superficial basal cell carcinoma
- Sometimes, it is also used to treat other skin conditions such as viral warts, and rarer conditions disseminated superficial actinic porokeratosis.
- 4% 5-FU cream (Tolak™) is used to treat thinner actinic keratosis (Grade I and II) on the face, ears, and/or scalp in adults.
- 0.5% 5-FU with 10% salicylic acid solution (Actikerall®) is useful for actinic keratosis with thicker surface scale/crusting.

WILL 5-FU CREAM CURE MY SKIN CONDITION?

Depending on your skin condition, 5-FU cream may cure or improve it, but it does not work for everybody. If you have more severe sun-damage, you may require additional courses of treatment.

HOW DO I APPLY 5-FU CREAM?

5-FU cream can be applied with a clean fingertip. Apply a thin layer of the cream to the entire treatment area. Massage gently and evenly into your skin. You should wash your hands thoroughly after applying 5-FU cream.

5-FU cream works by causing temporary inflammation to the skin. Try to apply the cream only to the areas that need treatment.

It is also important to avoid skin-to-skin contact of the treated areas with other people's skin. This is to prevent transferring the 5-FU cream to other people through bodily contact.

If you are using Actikerall®, dab the solution using the brush applicator provided onto the area of skin to be treated. The solution will dry and leave a film. After 20 minutes, you can apply moisturisers and/or make-up as part of your usual skincare routine.

Just before the next application, peel the film off to remove it. Warm water can be used to help loosen the film. Specific instructions will be provided by your healthcare professional.

If you have widespread sun-damage it is usually advisable to divide the affected area into smaller areas and to complete treatment in one area before moving on to the next. This will help make the treatment reaction more tolerable. Your healthcare professional will provide further advice about this.

Only cover 5-FU cream with a plaster / dressing if advised to do so by your healthcare professional, otherwise leave the treated area uncovered.

HOW OFTEN SHOULD I USE 5-FU CREAM?

How often and for how long you should use 5-FU cream will depend on your skin condition and other factors – for example, which part of your skin is affected.

- 5% 5-FU cream should be applied once or twice a day, for 3-4 weeks when treating [actinic keratosis](#) and [Bowen disease](#), and for 6 weeks when treating superficial [basal cell carcinoma](#). Occasionally, more prolonged courses may be required.
- Tolak™ 4% 5-FU cream should be applied once daily, for 4 weeks to treat thinner actinic keratosis (Grade I and II) on the face, ears, and/or scalp.

- Actikerall® should be applied once daily until the lesions have cleared or for up to a maximum of 12 weeks.

Your healthcare professional will recommend a specific treatment schedule for you.

AT WHAT TIME OF DAY SHOULD I APPLY 5-FU CREAM?

If you are asked by your healthcare professional to use 5-FU cream once a day, you should apply it at night. If twice-daily application is recommended, then it is best to apply 5-FU cream in the morning and at night.

When should I not apply 5-FU cream?

5-FU cream should not be used around the eyes, and lips, or inside the nostrils, unless specifically recommended by your healthcare professional for use in that area.

Do not use 5-FU cream if you are allergic to any of the ingredients.

It is recommended that 5-FU is not taken if pregnant or planning to have a baby.

It is important that an effective method of contraception is used while using 5-FU cream, as the medicine may carry risks of harmful effects to unborn babies. Although there have not been any studies carried out to show if 5-FU cream affects pregnancy or the unborn baby, this advice is based on use of 5-FU as a **systemic treatment** (given through a drip in the vein as cancer treatment). Therefore, the level of absorption is likely to be different when using the cream. However, as we do not have sufficient evidence regarding 5-FU cream's safety, we have based our advice on the available evidence.

In the case of pregnancy (yours or your partner's), you must inform your healthcare professional immediately.

Pregnancy and trying for a baby after treatment with 5-FU:

- If you can get pregnant, you must use effective contraception during your



treatment and for **6 months after the course of treatment is complete.**

- If you can get someone pregnant, you must use effective barrier contraception (condoms) during your treatment and for **3 months after the course of treatment is complete.**
- 5-FU cream may affect fertility. It is not recommended for people trying for a baby.

Breastfeeding:

5-FU cream should not be used during breastfeeding as it may pose a risk to nursing children. If it is necessary to use the cream, then breastfeeding should be stopped immediately.

WHAT ARE THE COMMON SIDE EFFECTS OF 5-FU CREAM?

As mentioned above, inflammation of the skin is expected, but if the skin becomes very sore or uncomfortable, stop using 5-FU cream.

Bathe the area with water, dab the skin dry and apply petroleum jelly (Vaseline) daily. The petroleum jelly that you apply should be newly opened and free from potential contamination from fingertips. When the skin settles, you may be able to continue 5-FU cream to complete the course of treatment.

If you have any concerns about the severity of the reaction at the treatment area or are uncertain about whether you should continue treatment, get in touch with your healthcare professional who may recommend a change to your treatment schedule. Your healthcare professional may also have additional advice which may include applying a steroid cream to settle the inflammation.

Tolak™ 4% 5-FU cream contains peanut oil – do not use if you have peanut or soya allergy.

5-FU cream can cause a discolouration of the treated skin. This means that the treated skin will appear lighter than the surrounding

skin. However, this is temporary and will resolve over time.

5-FU cream makes the treated skin more sensitive to sunlight. Exposure to the sun should be avoided during treatment and for a while after. This may include modifying activities to limit sun exposure, wearing clothing and/or a hat to cover the treatment area, and the use of sunscreens.

What are the rare side effects of 5-FU cream?

If you have a severe reaction to 5-FU cream, there is a risk of prolonged inflammation, delayed healing and the potential for the development of an ulcer, particularly on the lower legs.

Following a severe reaction, there is a small risk of altered skin pigmentation and scarring.

Skin infections at the area of application of 5-FU cream are rare but possible. If you have concerns about the severity of the skin reaction, get in touch with your healthcare professional.

Very rarely, 5-FU cream can cause an allergic reaction. This usually causes a severe localised skin reaction. If you have concerns about the severity of your reaction to 5-FU cream, get in touch with your healthcare professional.

Like all medications, 5-FU should be kept out of reach of children and pets. There have been reports of pets dying or being harmed from licking their owners' skin after 5-FU had been applied, or from consuming the cream from the tube. It is important to wash your hands after application of the cream.

WHERE CAN I GET MORE INFORMATION ABOUT 5-FU CREAM?

Weblinks to other relevant sources:

DermNetNZ:

dermnetnz.org/topics/5-fluorouracil-cream



EMC:

www.medicines.org.uk/emc/product/15802/pil

Jargon Buster:

www.skinhealthinfo.org.uk/support-resources/jargon-buster/

It is important to report suspected side effects of medicines. The Medicines and Healthcare products Regulatory Agency (MHRA) manages the Yellow Card scheme. This scheme collects information and safety concerns about medicines and medical devices. Anyone can report these side effects or concerns by using:

- the Yellow Card website
www.mhra.gov.uk/yellowcard or
- the Yellow Card app

Please note that the BAD provides web links to additional resources to help people access a range of information about their treatment or skin condition. The views expressed in these external resources may not be shared by the BAD or its members. The BAD has no control of and does not endorse the content of external links.

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your healthcare professional.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

BRITISH ASSOCIATION OF DERMATOLOGISTS

PATIENT INFORMATION LEAFLET

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