PATIENT INFORMATION LEAFLET

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 sundamaged cells known as actinic keratoses, whilst not 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 doctor may recommend using a steroid cream to help settle the inflammation more quickly.

In the UK, two forms are available: 5% 5-FU cream (Efudix®) and 0.5% 5-FU combined with 10% salicylic acid (Actikerall®).

There is a suggestion that combining Efudix® 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 Efudix® 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 doctor 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-FU cream is prescribed for the treatment of the pre-cancerous skin lesions, actinic keratoses and Bowen disease. It is also used for the treatment of superficial basal cell carcinoma.

It is sometimes used to treat other skin conditions such as viral warts, and rarer conditions such as disseminated superficial actinic porokeratosis.

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?

Efudix® cream can be applied with a clean fingertip. Apply a thin layer of the cream to the entire treatment area. You should wash your hands thoroughly after applying 5-FU cream.

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 skin care routine.

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

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 doctor will provide further advice about this.

Only cover 5-FU cream with a plaster / dressing if advised to do so by your doctor, 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. Efudix® cream is usually applied once or twice a day, for 3-4 weeks when treating actinic keratosis and Bowen's disease, and for 6 weeks when treating superficial basal cell carcinoma. Occasionally, more prolonged courses may be required. Actikerall® should be applied once daily until the lesions have cleared or for up to a maximum of 12 weeks. Your doctor 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 doctor 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, nose or lips, unless specifically recommended by your doctor for use in that area.

Do not apply 5-FU cream if you are pregnant or breastfeeding. 5-FU cream may be harmful to unborn children. 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' - i.e. given through a drip in the vein for cancer treatments. , 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.

If you are a person of child-bearing potential (someone able to become pregnant), you should use effective contraception throughout the duration of treatment, and for

7 months after the course of treatment is complete. If you become pregnant during treatment with 5-FU cream, there may be a risk of harmful effects to your baby, and it is recommended that you contact and inform your doctor immediately.

Men using 5-FU are also recommended to use effective barrier contraception (condoms) and should not father a child during their treatment and for 4 months after the course of treatment is complete.

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, breastfeeding should be stopped immediately.

5-FU cream may affect male and female fertility. 5-FU cream is not recommended for men attempting to father a child.

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

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 doctor who may recommend a change to your treatment schedule. Your doctor may also have additional advice which may include applying a steroid cream to settle the inflammation.

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 doctor.

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 doctor.

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:

patient.info/medicine/fluorouracil-for-sundamaged-skin-efudix-actikerall-carac

dermnetnz.org/topics/5-fluorouracil-cream

www.medicines.org.uk/emc/medicine/6219/S PC/Efudix+Cream

www.medicinenet.com/fluorouracil-topical/article.htm

Jargon Buster:

https://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 doctor.

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

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