

FOR TOPICAL USE ON THE FACE ONLY

What is the Most Important Information about ReFissa® [Tretinoin Cream, USP (Emollient) 0.05%]?

ReFissa® is a serious medication. It does not eliminate wrinkles or repair sun-damaged skin. It may help treat fine wrinkles, spotty discoloration, and rough feeling skin, but it does not “cure” these conditions. ReFissa® should only be used under supervision of your health care provider as part of a broad skin care program. This program should include avoiding direct sunlight (by using protective clothing and sunscreens with a minimum SPF of 15) and using other moisturizing facial creams that do not contain tretinoin.

You should use ReFissa® only at bedtime. Do not use drying skin care products. Use the smallest amount of ReFissa® needed and avoid getting it in your eyes, ears, nose or mouth.

WARNING: Do not use ReFissa® if you are pregnant or attempting to become pregnant. Avoid sunlight and any other medicines that may increase your sensitivity to sunlight (see below).

ReFissa® has not been studied in people who are over 50 years of age or in people with moderately or darkly pigmented skin.

What is ReFissa®? (What can I expect from ReFissa®?)

ReFissa® is a serious medication that may help treat but will not “cure” fine wrinkles, spotty skin discoloration, and rough feeling skin.

Studies show that after 24 weeks, about 30% of the people who used Tretinoin Cream, USP (Emollient) 0.05% for fine wrinkles or spotty discoloration had moderate improvement, another 35% had minimal improvement and 35% had no improvement. About 16% of the people who used Tretinoin Cream, USP (Emollient) 0.05% for rough skin had moderate improvement, 35% had minimal improvement, and 49% had no improvement. There is no evidence that ReFissa® treats coarse skin, deep wrinkles, yellowing skin, or other skin care problems.

ReFissa® should be used as part of a broad skin care program. This program should include avoiding direct sunlight (by using protective clothing and sunscreens with a minimum SPF of 15) and using other moisturizing facial creams that do not contain tretinoin. Many people can achieve desired effects by using this program without using ReFissa®. You should not use ReFissa® until you have tried a broad skin treatment program without ReFissa®.

When you use ReFissa®, improvement in fine wrinkling, spotty skin discoloration and rough skin is not immediate and occurs gradually over time. Generally, you may notice some effects in 3 to 4 months. The effects are usually most noticeable at about 6 months with little additional improvement after that time. If ReFissa® is stopped, the improvement will gradually diminish.

The safety of using ReFissa® daily for more than 48 weeks has not been established.

Who Should Not Use ReFissa®?

You should not use ReFissa® if you are sunburned or highly sensitive to the sun, if you have eczema, or if your skin is irritated. ReFissa® can cause increased skin irritation and increased susceptibility to sunburn.

Since ReFissa® may make your skin more sensitive to sunlight, you should tell your health care professional if you are also using other medicines that increase sensitivity to sunlight because you should not be using ReFissa® with these medicines. These include but are not limited to: thiazides (used to treat high blood pressure), tetracyclines, fluoroquinolones or sulfonamides (used to treat infection), and phenothiazines (used to treat serious emotional problems). If you are taking any prescription medicines, non-prescription medicines or using any facial creams, check with a health care professional to make sure they do not interact with ReFissa®.

Pregnancy Warning: Safe use during pregnancy has not been shown. There are reports of birth defects with laboratory animals and humans that were given tretinoin by mouth. You should not use ReFissa® [Tretinoin Cream, USP (Emollient) 0.05%] if you are pregnant or trying to become pregnant.

It is not known if ReFissa® is passed to infants through breast milk. Safe use in children has not been shown.

The safety and effectiveness of ReFissa® for people over age 50 or with darker skin coloration has not been proven.

How should I use ReFissa®?

You should apply ReFissa® to your face once a day before retiring using only enough to cover the entire affected area lightly. Gently wash your face with a mild soap, pat the skin dry, and wait 20 to 30 minutes before applying ReFissa®. Apply a pea-sized amount of cream to cover your entire face. You may feel a warmth or slight stinging when ReFissa® is first applied.

You must be especially careful when applying the cream to avoid eyes, ears, nostrils, or mouth. ReFissa® may cause severe redness, itching, burning, stinging, and peeling if applied to these areas.

Using larger than necessary amounts of ReFissa® will not speed results and can cause an overdose. An overdose can result in red and peeling skin as well as some pain or discomfort.

You may use cosmetics after applying ReFissa®. Make sure to clean your face thoroughly before applying ReFissa® again.

What Should I Avoid While Using ReFissa®?

ReFissa® increases your sensitivity to sunlight. Avoid sunlight as much as possible. Use protective clothing and a sunscreen with a minimum SPF of 15. Do not sunbathe or use sunlamps. If you are sensitive to sunlight or have a job that requires you to be out in the sun for long periods, you must use extreme caution.

While using ReFissa®, avoid using any products that can dry or irritate the skin. For example, avoid products applied to the skin that contain alcohol, spices, or lime. Also, avoid cleansers, hair removal, or other products that can irritate the skin.

What Are the Possible Side Effects of ReFissa®?

The most common side effects are skin reactions. Itching, red, and dry skin have been reported. So have burning, stinging, and peeling skin. These are most often mild and are most common when treatment is started.

How Can I Get Additional Information?

This leaflet summarizes the most important information about ReFissa®. If you would like more information, talk to your doctor or other health care provider. There is also a leaflet written for health professionals that your pharmacist can provide for you.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO FDA AT 1-800-FDA-1088.

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Safety Information

ReFissa® does not eliminate wrinkles, repair sun-damaged skin, reverse photo-aging, or restore more youthful or younger dermal histologic pattern. ReFissa® should be used under medical supervision as an adjunct to a comprehensive skin care program that includes avoiding direct sunlight (by using protective clothing and sunscreens with a minimum SPF of 15) and using other moisturizing facial creams that do not contain tretinoin. The effectiveness of ReFissa® has not been established in people greater than 50 years of age or in people with moderately to heavily pigmented skin. It has not been studied in people with visible actinic keratoses, a history of skin cancer, or during pregnancy. You should not use ReFissa® if you are pregnant or trying to become pregnant. In some cases, ReFissa® may cause redness, dry skin, itching, burning, stinging and peeling. It should be discontinued if hypersensitivity to any of its ingredients is noted. Please see full Prescribing Information at www.refissa.com.