

How to Apply Refissa

STEP

1



Each night, gently wash your face with a mild soap or cleanser and pat dry.

STEP

2



Let your face dry for 20 to 30 minutes before applying Refissa.

STEP

3



Squeeze about a pearl-sized amount (1/4" in diameter) of Refissa onto your finger.

STEP

4



Dot Refissa onto your cheeks, forehead and chin. Spread evenly. Avoid getting into your eyes and the skin around your ears, lips and nostrils.

Track Your Progress

To get the full effect of Refissa, use it for at least 24 weeks. Use this chart to check off each week you're treating your skin.

WEEK



Skin care tips while using Refissa

- Maintain your current skin care program of soap or cleanser and daily sunscreen.
- Continue your usual makeup routine.
- Avoid the sun (including sunlamps) and always use a sunscreen (minimum SPF 15) when outdoors — even on a cloudy day.
- Avoid hair and face products that contain alcohol, astringents, menthol, spices or lime. These ingredients may irritate your skin.
- Avoid using electrolysis, hair depilatories or waxes on your face.
- Be careful to keep hair dye or permanent wave solutions off your face.
- The most common side effects with Refissa are itching, red and dry skin, as well as burning, stinging and flaky skin. These side effects are most often mild and are most common when treatment begins.

Refissa 0.05% is a prescription medicine that may reduce fine facial wrinkles and mottled hyperpigmentation in patients who also protect their skin from the sun and wear sunscreen daily. Refissa does not eliminate wrinkles, repair sun damaged skin or reverse photo-aging. Do not use if you are pregnant, attempting pregnancy, or nursing. Do not use if taking medicines that may increase your sensitivity to sunlight. Use of Refissa may make your skin more likely to burn from sunlight. Refissa, early in treatment, may cause redness, itching, burning, stinging and peeling. If you have questions about side effects, contact your physician. If you are uncomfortable, use less medication and decrease the frequency of application. If discomfort is still significant, discontinue use and consult your physician. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Please see full Prescribing Information and Patient Package Insert. Refissa is a trademark of Spear Pharmaceuticals, Inc. © 2009 Spear Dermatology Products.

Refissa™

[Tretinoin Cream, USP (Emollient) 0.05%]

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 your 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 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.



Manufactured by DPT Laboratories, San Antonio, TX 78215
Distributed by Spear Dermatology Products, Randolph, NJ 07869