ReFissa®
(Tretinoin Cream, USP (Emollient) 0.05%)

ReFissa® contains vitamin A. Avoid prolonged contact with eyes or mucous membranes. ReFissa® is contraindicated in individuals with a history of sensitivity reactions to any of its components. It is not known whether ReFissa is excreted in human milk. The safety and effectiveness of ReFissa in nursing mothers have not been determined.

LESS COMMON SIDE EFFECTS:

- Dryness
- Increased skin sensitivity to sunlight
- Irritation
- Peeling

WARNING: Avoid contact with eyes or mucous membranes.

ReFissa® is a serious medication that may help treat but will not “cure” fine wrinkles, spotty skin discoloration, and rough facial skin. It does not eliminate wrinkles or repair sun-damaged skin. It may help reduce the appearance of fine wrinkles, spotty discoloration, and rough feeling skin, but it does not “cure” these conditions.

ReFissa® has not been studied in people who are over 50 years of age or in people with moderately to heavily pigmented skin. In addition, the role of ReFissa in the treatment of moderate to severe actinic keratoses has not yet been fully determined. In addition, the role of ReFissa in the treatment of moderate to severe actinic keratoses has not yet been fully determined. In addition, the role of ReFissa in the treatment of moderate to severe actinic keratoses has not yet been fully determined.

ReFissa® may cause increased skin irritation and increased susceptibility to sunburn. You should not use ReFissa if you are sunburned or highly sensitive to the sun, if you have eczema, or if you have not completed the recommended treatment for your condition. ReFissa patients must be instructed to use sunscreens and other protective measures during sunlight exposure.

The safety of using ReFissa® for more than 48 weeks in chronic long-term use is not known. There is evidence of increased phototoxicity when using ReFissa® in combination with other medications that increase your sensitivity to sunlight.

The safety and effectiveness of ReFissa® for any condition other than fine wrinkles, spotty skin discoloration, and rough facial skin have not been established.

You should 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 because you should not be using ReFissa® if you are also using other medicines that increase sensitivity to sunlight. You should 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 because you should not be using ReFissa® if you are also using other medicines that increase sensitivity to sunlight.

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

What is ReFissa®?

ReFissa® is a surgical medicine that may help treat but will not “cure” fine wrinkles, spotty skin discoloration.

Studies show that 32 weeks, about 30% of the people who used Tretinoin Cream, USP (0.05%) had some improvement, while 25% of those who used Tretinoin Cream, USP (0.05%) for fine wrinkles or spotty discoloration had moderate improvement, another 25% had minimal improvement, and another 25% had no improvement. About 30% of the people who used Tretinoin Cream, USP (0.05%) had some improvement, while 25% of those who used Tretinoin Cream, USP (0.05%) for fine wrinkles or spotty discoloration had moderate improvement, another 25% had minimal improvement, and another 25% had no improvement. About 30% of the people who used Tretinoin Cream, USP (0.05%) had some improvement, while 25% of those who used Tretinoin Cream, USP (0.05%) for fine wrinkles or spotty discoloration had moderate improvement, another 25% had minimal improvement, and another 25% had no improvement.

Who Should Not Use ReFissa®?

- Pregnant women or women who may become pregnant
- Nursing mothers
- People under 18 years of age
- People taking photosensitizing medications
- People who are allergic to vitamin A derivatives

ReFissa® should be used with caution in people who are taking photosensitizing medications. These include but are not limited to: thiazides (used to treat high blood pressure), diuretics, antibiotics, and certain medicines used to treat coronary artery disease. If you are using ReFissa® and take any of these medicines, you should not be using ReFissa® if you are also using other medicines that increase sensitivity to sunlight because you should not be using ReFissa® if you are also using other medicines that increase sensitivity to sunlight because you should not be using ReFissa® if you are also using other medicines that increase sensitivity to sunlight.

The safety and effectiveness of ReFissa® for more than 48 weeks has not been established. (See WARNINGS section.)

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How can I get additional information?

What are the possible side effects of ReFissa?

Avoid using ReFissa on the lips or around the eyes, ears, nostrils, or mouth. ReFissa should be applied to the skin that contain alcohol, spices, or lime. Also, avoid cleansers, hair removal, or other products applied to the skin. You must be especially careful when applying the cream to avoid your eyes, ears, nostrils, or mouth. ReFissa should be applied to the face once daily 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 again. 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 should apply ReFissa to your face once daily before retiring using only enough to cover the entire affected area. You may use cosmetics after applying ReFissa. Make sure to clean your face thoroughly before applying ReFissa.

How should I use ReFissa?

Dermal tretinoin has been shown to be fetotoxic in rabbits when administered in doses 100 times the average recommended human topical clinical dose. However, variations in teratogenic doses among various strains of rats have been reported. In the cynomolgus monkey, which, metabolically, is closer to humans for tretinoin absorption, no teratogenic effects were observed at 1000 times the average recommended human topical clinical dose. For purposes of comparisons of the animal test results, no strict comparison of these disparate data is possible at this time. Although the significance of the comparisons of the animal test results is unknown, it is advisable to use ReFissa with caution in women of childbearing potential.

What should I avoid while using ReFissa?

Drug Interactions: Concurrent topical medications, medicaments or abrasive soaps, shampoo, cleansing lotions, and emollients are not recommended during use. ReFissa should not be applied to broken or inflamed skin, or on areas with eczema. Avoid using any facial creams, check with a health care professional to make sure they do not interact with ReFissa. Do NOT use ReFissa if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a lifetime study performed in CD-1 mice, tretinoin did not induce any neoplastic or non-neoplastic tumors. In a 2 year study performed in Wistar rats, no tumors were observed at 0.1 mg/kg/day (1000 times the average recommended human topical clinical dose). Over a 2 year study in CD-1 mice, no tumors were observed at 1 mg/kg/day (10,000 times the average recommended human topical clinical dose).

OVERDOSAGE: A large amount of medication that has been shown not to be hazardous does not mean that an overdose will not be hazardous. The dosage of ReFissa may be increased in response to the clinical course of the disease. The effects of overdosage are not known. There are no reports in New Zealand White rabbits administered with doses of approximately 80 times (200 times the recommended human topical clinical dose). Anomalies (humerus: short 13%, bent 6%; os calcis: 5%, short 10%, twisted 3%) were seen in rabbits treated with oral tretinoin. Similar results have also been reported in pigtail macaques. Oral tretinoin in mice has been shown to be teratogenic and fetotoxic in rats when given orally or topically in doses 1000 times the average recommended human topical clinical dose. For purposes of comparisons of the animal test results, no strict comparison of these disparate data is possible at this time. Although the significance of the comparisons of the animal test results is unknown, it is advisable to use ReFissa with caution in women of childbearing potential.

Pregnancy: The safety and effectiveness of using ReFissa daily for greater than 48 weeks have not been established.

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