

TRI-LUMA™ CREAM

Consumer Medication Information Leaflet (RiMUP)

Fluocinolone acetonide/ Hydroquinone/Tretinoin (0.01% w/w / 4% w/w / 0.05% w/w)

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What TRI-LUMA Cream is used for

TRI-LUMA cream is indicated for short term intermittent treatment of moderate to severe melasma (dark skin patches) of the face, in the presence of measures for sun avoidance, including the use of sunscreens.

How TRI-LUMA Cream works

TRI-LUMA Cream, a combination of three active ingredients fluocinolone acetonide (anti-inflammatory), hydroquinone (depigmenting agent) and tretinoin (form of Vitamin A) that work together to lighten the dark spots.

Before you use TRI-LUMA Cream

- When you must not use it

Do not use TRI-LUMA Cream if you have a history of hypersensitivity, allergy, or intolerance to this product or any of its components.

Do not use TRI-LUMA Cream if you are pregnant or thinking of becoming pregnant. TRI-LUMA Cream contains tretinoin, which may cause harm to the baby. Your doctor can give you more information.

If you are a nursing mother, ask your doctor or pharmacist for advice before using any medicine.

- Before you start to use it

Consult your doctor or pharmacist if you are using any other medicines or topical creams before using TRI-LUMA Cream.

For nursing mother, avoid contact between the baby being nursed and TRI-LUMA Cream during the use of this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You should avoid medicated or abrasive cleansers, soaps and cosmetics with drying effects, products with high concentration of alcohol and astringent, and other irritants or skin thinning medicine while on TRI-LUMA Cream treatment. Concomitant use of medications that are known to be photosensitizing should be avoided.

How to use TRI-LUMA Cream

- How much to use

Apply a thin film of the cream to the hyperpigmented areas once daily at night.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

TRI-LUMA Cream should be applied at least 30 minutes before bedtime.

Follow these steps:

- Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry.
- Apply a thin film of the cream to the hyperpigmented areas of melasma about 1/2 inch surrounding each lesion.
- Rub lightly and uniformly into the skin.
- Do not use occlusive dressing.
- During the day, use a sunscreen of SPF 30, and wear protective clothing. Avoid excessive sunlight exposure.

- You may use moisturizers and/or cosmetics during the day.

Use as directed by your doctor or pharmacist.

- How long to use it

TRI-LUMA cream is indicated for short term intermittent treatment.

Therapeutic effects may be observed as early as 4 weeks. Treatment should be discontinued when melasma is resolved. When melasma recurs, treat with TRI-LUMA cream until condition clears.

Continue using TRI-LUMA Cream according to the duration that your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Apply the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not apply a double dose to make up for the missed dose.

- If you use too much (overdose)

Do not use TRI-LUMA Cream more often than what is recommended by your doctor. Too much TRI-LUMA Cream may cause irritation and discomfort to your skin.

If excessive redness, peeling, or discomfort occurs at the application site, TRI-LUMA Cream should be used less frequently or discontinued altogether.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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While you are using it

- Things you must do

Application of TRI-LUMA Cream should be kept away from the eyes, nose, or angles of the mouth, because these areas are much more sensitive than the skin to the irritant effect.

Tell all the doctors, dentists and pharmacists treating you that you are using TRI-LUMA Cream.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Exposure to sunlight, sunlamp, or ultraviolet light may make your skin more likely to get sunburned or develop other unwanted effects.

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give TRI-LUMA Cream to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Extremes weather such as heat or cold, may be irritating to your skin treated with TRI-LUMA Cream. Because of the drying effect of this medication, a moisturizer may be applied to the face in the morning after washing.

If you are using hormonal contraception, you need to change to a non-hormonal birth control (condom, diaphragm with spermicide).

Excessive bleaching resulting in undesirable cosmetic effect in people with darker skin may occur.

Side effects

Like all medicines, TRI-LUMA Cream can cause side effects, although not everybody gets them.

TRI-LUMA Cream may cause mild to moderate irritation. Local irritation, such as rashes, skin reddening, peeling, burning sensation, dryness, and itching may be expected at the site of application.

Other side effects may include acne, tingling or prickly sensation, small broken blood vessels on the skin's surface, excessive skin sensitivity and darkening or lightening of original skin color.

Transient skin reddening or mild burning sensation does not preclude treatment.

If a reaction suggests hypersensitivity or chemical irritation, the use of the medication should be discontinued.

TRI-LUMA Cream contains hydroquinone, which may produce a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy.

Allergic skin inflammation, blistering, crusting, and severe burning or swelling of the skin and irritation of the eyes, nose, and mouth require medical attention.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TRI-LUMA Cream

- Storage

Keep out of the reach and sight of children.

Store in a refrigerator (2-8 °C). Protect from freezing

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask

your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TRI-LUMA Cream is a light-yellow cream.

TRI-LUMA Cream is packed in 15 g and 30 g aluminum tubes.

- Ingredients

Active ingredient(s)

Each gram of TRI-LUMA cream contains:

- 0.1mg Fluocinolone acetonide
- 40mg Hydroquinone
- 0.5mg Tretinoin

Inactive ingredients

Butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, magnesium aluminum silicate, methyl gluceth-10, methyl-paraben 0.18% (1.8 mg), arlacel 165, propylparaben 0.02% (0.2 mg), purified water, sodium metabisulfite, stearic acid, and stearyl alcohol.

- MAL number:

MAL20061541ACRZ

Manufacturer

Hill Dermaceuticals Inc
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Product Registration Holder

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