

TRI-LUCENT CREAM

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

What is in this leaflet

1. What Tri-Lucent Cream is used for
2. How Tri-Lucent Cream works
3. Before you use Tri-Lucent Cream
4. How to use Tri-Lucent Cream
5. While you are using it
6. Side effects
7. Storage and Disposal of Tri-Lucent Cream
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

This leaflet answers some common questions about Tri-Lucent Cream. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Tri-Lucent Cream against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What Tri-Lucent Cream is used for

Tri-Lucent Cream is a triple-combination topical therapy for the short-term treatment of moderate to severe melasma (causes brown to gray-brown patches) of the face in the presence of measures for sun avoidance, including the use of sunscreens.

How Tri-Lucent Cream works

Tri-Lucent Cream has three active ingredients that work together and may help lighten the dark spots associated with moderate to severe melasma.

These three active ingredients are:

- Fluocinolone acetonide is a low potency anti-inflammatory (cortisone).
- Hydroquinone is a bleaching (depigmenting) agent.
- Tretinoin is a form of vitamin A.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Tri-Lucent Cream

-When you must not use it

Do not take Tri-Lucent Cream if you have an allergy to:

- Sulfites, as you may have a serious allergic reaction.
- Any of the ingredients listed at the end of this leaflet

You should also be aware that the use of Tri-Lucent Cream in pregnant women may carry the chance of causing birth defects in the baby.

Tell your doctor if you are pregnant, may be pregnant, or plan to become pregnant.

Tri-Lucent Cream contains a corticosteroid that may produce reversible effects on the adrenal gland called hypothalamic-pituitary-adrenal (HPA) axis suppression, so tell your doctor if you have any condition that may affect your adrenal function, such as Addison's disease, high blood sugar level and presence of sugar in the urine. If HPA axis suppression is noted, the use of TRI-LUCENT cream should be discontinued.

-Before you start to use it

Consult your doctor or pharmacist if you are taking any other medicines or topical creams before using Tri-Lucent Cream.

For nursing mother, caution should be exercised when Tri-Lucent Cream is used to avoid contact between the baby being nursed and Tri-Lucent Cream.

-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 be cautioned if you are on medicated or abrasive soaps and cleansers, soaps and cosmetics with drying effects, products with high concentration of alcohol and astringent, and other irritants or skin thinning medicines while on treatment. Concomitant use of medications that are known to be photosensitizing should be avoided.

How to use TRI-LUCENT CREAM

-How much to use

Apply a thin coat onto the discolored spot(s). Include about ½ inch of normal skin surrounding the affected area.

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

Apply Tri-Lucent Cream at night, at least 30 minutes before bedtime.

Follow these steps:

- Gently wash your face with a mild cleanser. Rinse and pat your skin dry.
- Apply a thin coat onto the discolored spot(s). Include about ½ inch of normal skin surrounding the affected area.
- After you have used the medicine for a while, you may find that you need slightly less to do the job. Rub the medicine lightly and uniformly into your skin. If you can still see it, you are using too much.

TRI-LUCENT CREAM

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

- Keep the medicine away from the corners of your nose, mouth and eyes. Spread it away from these areas when applying it.
- Do not cover the treated area with anything after applying Tri-Lucent Cream.
- To help avoid skin dryness, you may use a moisturizer in the morning after you wash your face.

-How long to use it

Tri-Lucent Cream is a short-term treatment.

-If you forget to use it

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

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

-If you use too much (overdose)

Do not use more Tri-Lucent Cream or apply it more often than what is recommended by your doctor. Too much Tri-Lucent Cream may irritate your skin and won't give you faster or better results.

If excessive marked redness, peeling, or discomfort occurs at the application site, Tri-Lucent Cream should be used less frequently or discontinued altogether. A symptomatic treatment might be prescribed as appropriate.

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

While you are using Tri-Lucent Cream

-Things you must do

Protect your skin from the sun to help prevent further darkening of existing dark patches and the formation of new ones.

Use an effective or protective covering (such as a wide brimmed hat) at any time you are outside, even on hazy days and protect the treated area from sunlight exposure.

-Things you must not do

When using Tri-Lucent Cream you must:

- Avoid exposure of treated area to sunlight and ultraviolet light. Tri-Lucent Cream may make your skin more likely to get sunburned or develop other unwanted effects from natural or artificial sunlight (as from a sunlamp or tanning bed).
- Avoid products that may dry or irritate your skin. (Alcohol-containing products, or certain soaps)

-Things to be careful of

Skin treated with Tri-Lucent Cream may be more likely to react to heat and cold than untreated skin. If a reaction suggests hypersensitivity or chemical irritation, the use of the medication should be discontinued and consult a doctor. Your doctor can recommend ways to manage your melasma under these conditions.

Side effects

Like other medicines, Tri-Lucent Cream can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Your skin may develop mild to moderate irritation:

- Redness
- Peeling
- Burning sensation
- Dryness

- Itching

Some people may have very severe allergic reactions to Tri-Lucent Cream due to the sulfites contained in the product.

Tri-Lucent Cream may also cause a gradual blue-black darkening of your skin. If this happens, stop using the product immediately and speak to your doctor.

Check with your doctor or pharmacist as soon as possible if you have any problems while using Tri-Lucent Cream, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problem / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Tri-Lucent Cream

-Storage

Keep containers tightly closed. Protect from light. Store below 30°C. Keep out of reach of children.

-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-LUCENT CREAM is an orange, opaque, viscous cream with a characteristic odour.

Tri-Lucent Cream is packed in 15g aluminium tube.

TRI-LUCENT CREAM

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

-Ingredients

-Active ingredient(s):

Each tube contains Hydroquinone
4% w/w, Tretinoin 0.05% w/w and
Fluocinolone Acetonide
0.01% w/w.

-Inactive ingredients:

Propylparaben, Methylparaben,
Lycopene, Titanium Dioxide,
Lactic Acid, Polyethylene Glycol
400, Butylated Hydroxytoluene,
Sodium Metabisulfite, Xanthan
Gum, Polysorbate 60, Sorbitan
Monostearate, Aluminium Oxide,
Dicaprylyl Carbonate, Simethicone,
Cetearyl Glucoside (and) Cetearyl
Alcohol, Cetostearyl Alcohol,
Cetyl Palmitate, Alcohol and
Purified Water.

-MAL number:

MAL12065083AZ

Manufacturer

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohamed 6,
Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
Malaysia.

Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohamed 6,
Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
Malaysia.

Date of revision

- 20/04/2017

Serial Number:

BPFK(R4/1)040417/00055