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Patient Information Leaflet

HiQuin™ 2% & 4% w/w cream

Hydroquinone

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What is HiQuin™ cream is and what it is used for
2. Before you use HiQuin™ cream
3. How to use HiQuin™ cream
4. Possible side effects
5. How to store HiQuin™ cream
6. Further information

1. What HiQuin™ cream is and what it is used for

HiQuin™ cream is a medicine which is used for the gradual bleaching of hyper pigmented skin conditions such as chloasma, melasma, freckles, senile lentigines and other unwanted areas of melanin hyper pigmentation.

2. Before you use HiQuin™ cream**Do not use HiQuin™ cream if:**

- You are allergic (hypersensitive) to hydroquinone or any of the other ingredients of HiQuin™ cream.
- Do not use this medicine for sunburn or depilatory usage.

Take special care with HiQuin™ cream

Check with your doctor or pharmacist before using this medicine:

- If the inflamed skin is on your face. You should not use the cream on your face, unless your doctor has told you to use.

Pregnancy and breast-feeding

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a

pregnant woman or affect reproductive capacity. Topical hydroquinone should be used in pregnant women only when clearly indicated.

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

Pediatric Use:

Safety and effectiveness for pediatric patients below the age of 12 years have not been established.

Important information about some of the ingredients of HiQuin™ cream

HiQuin™ cream contains sodium metabisulphite, a sulfite that may cause serious allergic type reactions (e.g. itching, wheezing, anaphylaxis, serious asthma attacks) in certain susceptible persons.

3. How to use HiQuin™ cream

- Apply a thin film twice daily to the area in need of bleaching or as directed by physician. HiQuin™ should be rubbed into the skin well. Make-up can be applied after the treated area has dried. Most discolorations begin to lighten after four weeks of treatment but it may take longer. After desired bleaching, use only as needed to maintain results. After clearing and during maintenance therapy, sun exposure should be avoided on bleached skin by application of a sunscreen or by wearing protective clothing to prevent darkening from recurring.

Always use HiQuin™ cream exactly as your doctor has told you.

Warnings and Precautions

1. Test for skin sensitivity before using by applying the product to an unbroken patch of skin. If no redness or itching occurs within 24 hours, begin treatment.
2. If no bleaching effect is noted after two months of treatment, use of hydroquinone products should be discontinued.
3. Lightening effect of hydroquinone may not be noticeable when used on very dark skin.
4. These products are formulated for use as skin bleaching agents and should not be used for the prevention of sunburn.

If you use more HiQuin Cream than you should

There are no reports of overdosage using topical hydroquinone preparations.

If you swallow HiQuin™ cream

Hydroquinone cream may cause harm if it is swallowed. If you may have taken it by mouth, contact your doctor or pharmacist right away.

If you forget to use HiQuin™ cream

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

4. Possible side effects

No systemic adverse reactions have been reported.

Occasional hypersensitivity (localized contact dermatitis, erythema, stinging, inflammatory reaction) may occur in which case the medication should be discontinued and the physician notified immediately.

5. How to store HiQuin™ cream

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use HiQuin™ after the expiry date which is stamped on the pack and tube.

Discard the tube after 3 months from opening.

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.

6. Further information**What HiQuin™ contains**

The active substance in HiQuin™ cream is hydroquinone 2% w/w or 4% w/w.

The other ingredients are Liquid paraffin, Methylparaben, Polyoxyl 40 stearate, Propylene glycol, Propylparaben, Sodium lauryl sulphate, Sodium metabisulphite, Stearic acid, Stearyl alcohol and Purified water.

What HiQuin™ cream looks like and contents of the pack**HiQuin 2% or 4% Cream**

White homogenous smooth cream.

HiQuin 2% or 4% Cream

Comes in aluminium collapsible tube of 30g.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Jeddah, Saudi Arabia.

Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

To report any side effect(s):**• Saudi Arabia:**

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfda.gov.sa/npc

• Other GCC States:

– Please contact the relevant competent authority.

This leaflet was last approved in 06/2015;

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



HiQuin™ Cream is a quality product manufactured by:



P.O.Box 6267 Jeddah - 21442- Saudi Arabia

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180 x 280 mm