

AVOQUIN

1.9% & 4% CREAM

Hydroquinone 1.9 & 4% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- You must talk to a doctor if you do not feel better or if you feel worse, This includes any possible side effects not listed in this leaflet

What is in this leaflet:

1. What Avoquin 1.9% & 4% Cream is and what it is used for
2. What you need to know before you use Avoquin 1.9% & 4% Cream
3. How to use Avoquin 1.9% & 4% Cream
4. Possible side effects
5. How to store Avoquin 1.9% & 4% Cream
6. Further information

1. What Avoquin 1.9% & 4% Cream is and what it is used for:

Avoquin 1.9% & 4% Cream is used for the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation. Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (dopa) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause depigmentation of bleached areas.

2. What you need to know before you use Avoquin 1.9% & 4% Cream.

• Do not use Avoquin 1.9 & 4% Cream:
Prior history of sensitivity or allergic reaction to Avoquin 1.9% & 4% Cream or to any of the ingredients of the products. The safety of Avoquin 1.9% & 4% Cream uses during pregnancy or for children (12 years and under) has not been established.

• Pregnancy, nursing mothers:

• Teratogenic Effects:

Pregnancy Category C :-

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether topical hydroquinone can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Topical hydroquinone should be given to a pregnant woman only if clearly needed.

Nursing Mothers:-

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when topical hydroquinone is administered to a nursing woman.

• Pediatric Use: -

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

• Warnings and Precautions:

Contains sodium met bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Since this product contains no sunscreen, an effective broad-spectrum sun blocking agent should be used and unnecessary solar exposure avoided, or protective clothing should be worn to cover bleached skin in order to prevent re-pigmentation from occurring. Hydroquinone may produce exogenous ochronosis, a gradual blue-black darkening of the skin. If this condition occurs, discontinue treatment and consult your physician. Most patients developing this condition are Black, but it may also occur in Caucasians and Hispanics.

• Information for Patients -

- Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight sustains melanocytic activity. To prevent depigmentation, during treatment and maintenance therapy, sun exposure on treated skin should be avoided by application of a broad-spectrum sunscreen (SPF 15 or greater) or by use of protective clothing. Avoid contact with eyes and mucous membranes.
- Keep this and all medications out of reach of children. In case of accidental ingestion, call a physician or a poison control center immediately.
- Carcinogenes is, Mutagenes is, Impairment of Fertility Studies of hydroquinone in animals have demonstrated some evidence of carcinogenicity. The carcinogenic potential of hydroquinone in humans is unknown.
- Published studies have demonstrated that hydroquinone is a mutagen and a clastogen. Treatment with hydroquinone has resulted in positive findings for genetic toxicity in the Ames assay in bacterial strains sensitive to oxidizing mutagens, in vitro studies in mammalian cells, and in the in vivo mouse micronucleus assay.

• Drug Interactions -

Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

3. How to use Avoquin 1.9% & 4% Cream:

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure
- General Skin sensitivity test before using Avoquin 1.9% & 4% Cream by applying a small amount to an unbroken patch of skin; check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response further treatment is not advised. Close patient supervision is recommended.
- Avoquin 1.9% & 4% Cream should be applied to affected areas and rubbed in well twice daily, in the morning and before bedtime, or as directed by a physician. If no improvement

is seen after 2 months of treatment, use of this product should be discontinued. There is no recommended dosage for pediatric patients under 12 years of age except under the advice and supervision of a physician.

- Avoquin 1.9% & 4% Cream for EXTERNAL USE ONLY.
- Avoquin 1.9% & 4% Cream not for OPHTHALMIC USE.

• Over Dosage:

- There have been no systemic reactions reported from the use of topical hydroquinone. However, treatment should be limited to relatively small areas of the body at one time, since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

If you forget to use Avoquin 1.9% & 4% Cream:

- Do not worry if you forget to use your cream at the right time. When you remember, start using the medicine again as you did before.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following adverse reactions have been reported: dryness and fissuring of paranasal and infraorbital areas, erythema, and stinging. Occasional hypersensitivity (localized contact dermatitis) may develop. If this occurs, the medication should be discontinued and the physician notified immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below).

By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

• Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority.

5- How to store Avoquin 1.9% & 4% Cream.

- Keep out of the sight and reach of children
- store Below 30°C
- Shelf life of Unopened Tube: 2 Years
- Shelf life after first opening is 30 days
- Do not use after the expiry date on the box

6- Further information:

What Avoquin 1.9% & 4% Cream contains:

Avoquin 1.9% Cream:

- Each gram of active substances Hydroquinone contains 19 mg.
- Other ingredients are Emulgin B2, Cetostearyl Alcohol, Paraffin Oil, Benzoic Acid, Glycerin, Propylene Glycol, Sodium Lauryl Sulphate, Citric Acid, Sodium Metabisulphite, Lavanda Perfume and Purified Water.

Avoquin 4% Cream:

- Each gram of active substances Hydroquinone contains 40 mg.
- Other ingredients are Emulgin B2, Cetostearyl Alcohol, Paraffin Oil, Benzoic Acid, Glycerin, Vitamin E Acetate, Propylene Glycol, Vitamin C (Ascorbic acid), Citric Acid, Sodium Lauryl Sulphate, Sodium Metabisulphite, Octyl Methoxycinnamate and Purified Water.

What Avoquin 1.9% & 4% Cream looks like and contents of the pack:

Avoquin 1.9% is a White homogenous smooth cream, Free from foreign matters It is available in 50ml tubes. Avoquin 4% is a White homogenous smooth cream. Free from foreign matters It is available in 50g tubes.

Marketing Authorisation Holder and Manufacturer:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491, Kingdom of Saudi Arabia
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948 -2653427
Fax: +966 (11) 2654723

For further information about this medicinal product, or to report a suspected adverse drug event please contact the Marketing authorization Holder.

E-mail: pharmacovigilance@avalon.com.sa

Call: +966 (11) 4635247, Ext: 3328

This leaflet was last approved in (01/2018)

THIS IS A MEDICAMENT
- Medicament is a product which 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 the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists