

CLEARSKIN (10-20-40) Capsules



Composition:

Each CLEARSKIN Capsule contains: Isotretinoin 10-20-40 mg.

Pharmacological Classification:

Anti-acne (Vitamin A derivatives).

Intended Use (Common Use of the Drug):

Treatment of severe nodular acne in patients 12 years of age and older.

Mechanism of Action:

Isotretinoin is a retinoid inhibits sebaceous gland function and keratinization.

Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secretion.

Pharmacokinetics:

- **Absorption:** Oral absorption of Isotretinoin is increased when given with a high-fat meal due to its high lipophilicity.

- **Distribution:** Isotretinoin is more than 99.9% bound to plasma proteins, primarily albumin.

- **Metabolism:** Following oral administration of Isotretinoin, at least three metabolites have been identified in human plasma: 4-oxo-isotretinoin, retinoic acid (tretinoin), and 4-oxo-retinoic acid (4-oxo-tretinoin).

- **Elimination:** The metabolites of Isotretinoin and any conjugates are ultimately excreted in the feces and urine in relatively equal amounts (total of 65% to 83%).

Indications:

- Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

- Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older who are not pregnant and who have with multiple inflammatory nodules with a diameter of 5 mm or greater.

Contraindications:

- This medicine should not be used if you are hypersensitive to the active substance (Isotretinoin or any chemical structure similar to vitamin A) or any of the excipients.

- Pregnancy.

Side Effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.

- Dose Relationship Effects: Cheilitis and hypertriglyceridemia.

- Side effects such as fatigue, hypersensitivity, edema, palpitations, nausea, diarrhea, abdominal pain, hepatitis, esophagitis and ulceration, anemia, elevations creatine phosphokinase, elevations of serum cholesterol, decrease in serum high-density lipoprotein (HDL) levels, muscle pain and arthritis, headache, dry skin, hyperpigmentation, photosensitivity, tinnitus and hearing impairment, dry eyes and decreased night vision have been reported.

- Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- Teratogenic effect: Significant birth defects, spontaneous abortions, and premature births have been documented following exposure to Isotretinoin during pregnancy.

- Patients should be advised not to donate blood during Isotretinoin therapy and for one month after stopping treatment with the drug because the blood can be transmitted to a pregnant woman whose fetus should not be exposed to Isotretinoin.

- Psychiatric disorders: Before starting Isotretinoin therapy, the patient and family members should be asked about any history of psychiatric disorders and at each visit during treatment, patients should be evaluated for symptoms of depression, mood disorders, psychosis, and aggression to determine the need for further evaluation. The physician should decide whether Isotretinoin therapy is appropriate in this case. In some patients, the risks may outweigh the benefits of Isotretinoin therapy.

- Increased intracranial pressure (pseudotumor cerebri): Isotretinoin has been associated with cases of increased intracranial pressure (pseudotumor cerebri), some of which have involved concomitant use of tetracyclines. If any symptoms occur, contact your doctor immediately.

- Monitor for severe skin side effects and consider discontinuing treatment if necessary.

- Stop treatment and consult your doctor if symptoms of pancreatitis, hearing impairment, hepatitis, abdominal pain, or rectal bleeding occur.

- Patients with juvenile osteoporosis, osteomalacia, or other metabolic bone disorders should be cautioned before using Isotretinoin.

- Patients with visual impairment should be monitored while taking Isotretinoin.

- Liver function tests should be performed every one to two weeks to assess response to Isotretinoin.

Drug and Food Interactions:

- Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

- Vitamin A: Isotretinoin is closely related to vitamin A. Therefore, the use of both vitamin A and Isotretinoin at the same time may lead to vitamin A side effects. Patients should be advised against taking vitamin supplements containing Vitamin A to avoid additive toxic effects.

- Tetracyclines: Concomitant treatment with Isotretinoin and tetracyclines should be avoided because Isotretinoin use has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension).

- Phenytoin: Caution should be exercised when using these drugs together.

- Systemic Corticosteroids: Caution should be exercised when using these drugs together.

Pregnancy & Lactation & Fertility:

Pregnancy: Pregnancy Category X, Isotretinoin can cause fetal harm when administered to a pregnant woman. Isotretinoin is contraindicated in females who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued and the patient should be apprised of the potential hazard to the fetus.

Lactation: There is no data on the presence of Isotretinoin in either animal or human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in nursing infants from Isotretinoin, advise patients that breastfeeding is not recommended during treatment with Isotretinoin, and for at least 8 days after the last dose of CLEARSKIN capsules.

Fertility: Clinical trials have shown no effects on male fertility.

Effects on ability to drive and use machines:

Isotretinoin may have an effect on the ability to drive and use machines. Several cases of decreased night vision have occurred during Isotretinoin treatment and, in rare cases, persisted after treatment. Because the onset of symptoms in some patients was sudden, patients should be informed of this potential problem and warned to exercise caution when driving or operating machinery.

Dosage and method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

- The recommended dosage range for Isotretinoin is 0.5 to 1 mg/kg/day given in two divided doses without regard to meals for 15 to 20 weeks to decrease the risk of esophageal irritation, patients should swallow the capsules with a full glass of liquid.

- Inform your doctor or pharmacist if you forget take medicine and before stopping its use.

Overdoses/Toxicity/methods of treatment:

Isotretinoin overdose has been associated with vomiting, facial flushing, cheilitis, abdominal pain, headache, dizziness, and ataxia. These symptoms resolved quickly without apparent residual effects. Because overdose would be expected to result in higher semen levels of Isotretinoin than would be found during a normal course of therapy, male patients treated with Isotretinoin should use a condom or avoid reproductive sexual activity with a female patient who is pregnant or may become pregnant for one month following the overdose. All patients who experience an Isotretinoin overdose should not donate blood for at least one month.

Physical Properties:

Hard gelatin, size 2, colour Blue /Yellow (10), Purple/Blue (20), Grey/Yellow (40) Capsules.

Storage Conditions:

Store at a temperature below 25° C.

Keep out of reach of children.

Packaging:

Each CLEARSKIN 10-20-40 mg Carton box of contains 30 capsules in 3 Alu/Alu strips.

القاء مستحضر يوتر على مسعته واستعماله خلافا للتعليمات بحركه الخطر
التي بداهه وصيغه التعليمات وطريقه الاستعمال اللذين صمما هما تعليمات الصنعي
الذي صرفها ك فاطميه الصنعي كما اخبرنا في التواء ونفعه وضروره
الانكار صرف القواء بدون وصفه طبيه
الانكار الادويه بمقتضى ابدى الاطفال
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