

Patient Information Leaflet:

ISOTRETINOIN 5MG AND 20MG CAPSULES

Please read this leaflet carefully before taking Isotretinoin Capsules. Keep the leaflet in case you want to refer to it again. If you want to know more about Isotretinoin Capsules or have any questions, you should ask your doctor or pharmacist.

1. WHAT ISOTRETINOIN IS USED FOR

Isotretinoin belongs to a group of medicines known as retinoids that are normally used to treat skin problems. Isotretinoin Capsules are used to treat severe acne, for patients whose acne has not responded to other treatments. Their use must be supervised by a dermatologist (a doctor who specialises in the treatment of skin problems). Isotretinoin Capsules should not be used to treat acne occurring before the onset of puberty.

2. BEFORE TAKING ISOTRETINOIN CAPSULES

You must not take Isotretinoin Capsules and should talk to your doctor immediately if you:

- are pregnant or think you may be pregnant (see 'Important advice for female patients' in the box opposite)
- have liver disease
- are breast-feeding
- are taking certain antibiotics called tetracyclines
- are allergic to Isotretinoin Capsules or any of the ingredients it contains
- have very high levels of vitamin A in your body (Hypervitaminosis A)
- have very high levels of cholesterol or triglycerides (a fat like substance) in your blood
- are allergic to soya

Beacon Isotretinoin capsules do not contain peanut oil but do contain soya oil and some patients who are allergic to peanuts may suffer a cross reactivity to soya protein. If you have a

peanut allergy you should discuss this with your doctor.

Important Advice for Female Patients.

Isotretinoin will damage an unborn baby so:

- You must not take Isotretinoin Capsules if you are pregnant or think you may be pregnant.
- You must not take Isotretinoin Capsules if you are breast-feeding.
- You must use one, preferably two, effective methods of contraception (including condom, cap or spermicide) for one month before Isotretinoin treatment, during treatment and for one month after treatment ends.
- Your doctor will ask you to take a pregnancy test before, during and after your treatment. These must be negative. You should start taking Isotretinoin Capsules on the second or third day of your menstrual cycle.
- You must not become pregnant at any time during treatment or for one month after treatment ends.
- Contact your dermatologist immediately if you do become pregnant or think you may be pregnant during treatment or in the first month after treatment ends.

Advice for Male patients

Isotretinoin treatment does not appear to damage sperm. Isotretinoin and its metabolites are present at very low levels in your semen. These levels are considered too low to harm the unborn baby of your female partner.

Advice for all patients:

- Tell your doctor if you have or have had any mental illness including depression, psychosis or suicidal behaviour.
- Tell your doctor if you, or members of your family, have a history of high fat levels in the blood. Your doctor may reduce the dose of isotretinoin or suggest you go on a low-fat diet. Isotretinoin may increase blood fats and may also increase liver enzymes (transaminases).

Blood tests will be performed before, during and after Isotretinoin treatment to check your blood fat and liver enzyme levels.

- Tell your doctor if you have diabetes mellitus (sugar diabetes), are overweight, have a rare intolerance to some sugars or you are an alcoholic. Isotretinoin may increase your blood sugar levels, so your doctor may want to monitor this during treatment.
- Your skin and lips are likely to get dry. Use a moisturiser and lip balm during treatment.
- Avoid chemical dermabrasion and laser treatment of the skin and wax depilation during and for at least 6 months after treatment as they could cause scarring or irritation of the skin.
- Avoid too much sun and do not use a sunlamp or sunbed as your skin may be more sensitive. Before going out in the sun apply a sun block to exposed skin, particularly in strong sunlight.
- Do not donate blood during therapy or for at least one month after treatment with isotretinoin.
- Do not give your medication to anyone else. Return any unused capsules to the pharmacy.

Taking/using other medicines

- Do not use any other acne treatments unless your doctor has told you to.
- Do not take tetracycline antibiotics when on isotretinoin treatment.
- Do not take any vitamin A supplements. Tell your doctor or pharmacist if you are taking or have recently taken any other medicine including those obtained without a prescription.

Driving and using machinery

Your night vision may be affected by this medicine and you may develop dry eyes or sight problems. These changes can happen quite suddenly, so always be cautious when driving or operating machinery at night. Other visual disturbances, drowsiness or dizziness have been reported very rarely. If you experience any of these, you should not drive or operate machinery.

3. HOW TO TAKE ISOTRETINOIN CAPSULES

Always take the capsules as your doctor tells you to. Your doctor will tell you how many to take, which may change after a few weeks of treatment. This will depend on how you respond to your medicine.

Adolescents, adults and the elderly:

The usual starting dose is 0.5mg/kg daily, e.g. if you weigh 60kg your starting dose will be 30mg/day. Normally, you should not take more than 1mg of isotretinoin per kilogram of bodyweight per day.

- The capsules can be taken either once a day or in two divided doses during the day.
- Take them with a meal or with a glass of milk.
- Swallow the capsules whole, do not suck or chew them.

A normal course of treatment lasts between 4-6 months.

For a few patients, the acne may get worse during the first 7-10 days of treatment. Your acne should improve with continued treatment and may continue to improve for a few months after completion of the treatment course. **Do not** carry on taking this medicine unless your dermatologist tells you to.

Children:

Isotretinoin must NOT be used to treat children less than 12 years of age or before the onset of puberty.

If you forget a dose take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose.

If you take too many Isotretinoin Capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

Your doctor has prescribed this medicine for you. Never give it to others as it may harm them, even if their symptoms are the same as yours.

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4. POSSIBLE SIDE EFFECTS

As with all medicines Isotretinoin Capsules may cause some undesirable effects in some patients. These effects often wear off as your treatment continues and your doctor can help you to deal with them.

Stop taking the capsules and contact your doctor IMMEDIATELY if any of the following occur:

- symptoms of a severe allergic (hypersensitivity) reaction such as wheezing or difficulty in breathing, swelling of face, tongue or throat, itching, rash
- severe diarrhoea, especially if it contains blood
- persistent headache, nausea, vomiting and blurred vision. You may have a rare condition called intracranial hypertension
- dry eyes, sight problems, colour vision disturbances or reduced night vision. These changes can happen quite suddenly, but rarely persist after treatment. Always be cautious when driving or operating machinery at night. Your doctor may want to monitor your vision.

Contact your doctor IMMEDIATELY if you get any of the following symptoms. Your doctor may tell you to stop taking this medicine.

- mood changes, anxiety, depression or worsening of depression, aggressive tendencies, thoughts or attempts of suicide, abnormal behaviour or mental disorder.

Very common and common side effects:

- inflammation, dryness and cracking of the skin and lips. These can be relieved by the regular use of a good moisturising cream and lip balm from the start of treatment
- the inside of the nose may become dry and "crusted", which may lead to mild nosebleeds. Applying a thin layer of petroleum jelly gently to the inside of the nose will help
- skin rash, mild itching and slight peeling of the skin, or red, fragile skin
- inflammation of the eyelids
- dry, irritated eyes or conjunctivitis. This may be a problem if you wear contact lenses. Ask your pharmacist for suitable eye drops to help

- back pain, muscle and joint aches and pains, which may be more likely if you take vigorous exercise
- blood or protein in the urine
- changes in blood glucose levels especially in diabetics
- increased blood cholesterol
- anaemia
- headaches
- blood clotting may be affected, which means that you may bruise or bleed more easily.

Rare side effects:

- changes to your hair (either a loss or, more rarely, an increase). This is usually only temporary and persistent hair thinning is rare. Your hair should return to normal after the treatment ends.

Very rare side effects:

- tiredness
- feeling sick
- sweating
- diabetes
- dizziness, drowsiness, fits (convulsions)
- worsening of acne, which usually subsides within 7-10 days of treatment
- swellings discharging pus
- abdominal pain, diarrhoea, inflammatory bowel disease
- inflammation of the pancreas, causing severe pain in the abdomen and back
- inflammation of the liver
- kidney disease
- difficulty breathing (especially in people who have previously suffered from asthma or have allergies to certain substances)
- dry throat, hoarseness
- blurred vision, inflammation of the cornea
- increased skin pigmentation
- increased sensitivity to sunlight
- slight loss of hearing
- changes in the nails
- local bacterial infections such as infection of the tissue around the base of the nail

- increased levels of a substance in your blood known as uric acid. If you suffer from gout, this could trigger an attack. Very high levels of uric acid may affect your kidney function
- inflammation of blood vessels (sometimes with bruising and red patches)
- disease of the lymph nodes
- increased risk of infection, as leukocytes, which are cells in your blood involved in fighting infections, may decrease in number
- arthritic pain, soreness of the tendons
- changes in the bone may occur with use of high doses of Isotretinoin for periods in excess of the normal course of treatment, but these are very unlikely during a normal course of treatment.

Most of the unwanted effects of Isotretinoin will disappear when you stop treatment.

If you are concerned about these or any other side effect talk to your doctor.

5. STORING ISOTRETINOIN CAPSULES

Keep this medicine out of the reach and sight of children.

Do not store above 25°C. Store in the original container to protect from light. Do not use after the expiry date printed on the pack. Return any left over medicine to your pharmacist.

6. FURTHER INFORMATION

What is in this medicine:

Each capsule contains 5 or 20mg of the active ingredient isotretinoin.

The capsules also contain refined soya-bean oil, yellow beeswax, hydrogenated soya-bean oil and partially hydrogenated vegetable oil. The capsules are made from gelatin, glycerol, titanium dioxide (E171), ferrous oxide red (E172) and ferrous oxide yellow (E172). The printing ink (432BL) contains Brilliant Blue FCF dye, sorbitol, maltitol, phosphatidylcholine and lysophosphatidylcholine.

What this medicine looks like and contents of the pack:

The soft gelatine capsules are red and orange, the 5mg are marked 'P5', the 20mg are marked 'P20'. Each pack contains 56 capsules.

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