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 PACKAGE LEAFLET:
 INFORMATION FOR THE USER

Isotretinoin 10mg Capsules, soft

Isotretinoin

WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
 Women must use effective contraception. Do not use if you are pregnant or think you may be pregnant.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- What Isotretinoin is and what it is used for
- What you need to know before you take Isotretinoin
- How to take Isotretinoin
- Possible side effects
- How to store Isotretinoin
- Contents of the pack and other information

1. WHAT ISOTRETINOIN IS AND WHAT IT IS USED FOR

Isotretinoin soft capsules contains the active ingredient isotretinoin. This is a vitamin A derivative, belonging to the retinoid class of medicines. Isotretinoin is used to treat severe forms of acne (such as nodular or conglobate acne, or acne at risk of permanent scarring) which has not got better after other anti-acne treatments, including oral antibiotics.

Isotretinoin treatment must be supervised by a dermatologist (a doctor specialised in the treatment of skin problems).

Your prescriber must have considered that there is no other appropriate treatment before starting your isotretinoin therapy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOTRETINOIN

Isotretinoin should only be prescribed by or under the supervision of a dermatologist (a doctor specialised in the treatment of skin problems) with understanding of the risks of isotretinoin therapy and monitoring requirements.

Your doctor will inform you about the precautions you have to fulfil when you take Isotretinoin. Additionally, you should receive information materials from your doctor. If not, ask your doctor for this information. If your doctor has not explained the precautions to you or you have not understood them, please contact your doctor before you start taking Isotretinoin.

Do not take Isotretinoin

- If you are pregnant or breast-feeding.
- If there is any chance you could become pregnant, you must follow the precautions under "Pregnancy and prevention programme", see section on "Warnings and precautions".
- If you are allergic (hypersensitive) to isotretinoin, soya, peanut or any of the excipients
- If you have liver disease
- If you have very high levels of lipids (cholesterol, triglycerides) in your blood
- If you have very high levels of vitamin A in your body (hypervitaminosis A)
- If you are taking tetracyclines (a type of antibiotic medicine)
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking isotretinoin

Due to the high risk that a child with congenital defects will result if pregnancy occurs you should only take Isotretinoin if all the conditions of the pregnancy prevention programme are met. Please talk about these issues with your doctor.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Isotretinoin.
- If you have ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes. It also includes thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking Isotretinoin.

Your doctor will discuss how best to monitor your mental health during your treatment.

Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with Isotretinoin 10mg. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Isotretinoin 10mg and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including imaging modalities such as MRI.

Pregnancy Prevention Programme

Women who are pregnant must not take Isotretinoin

This medicine can seriously harm an unborn baby (the medicine is said to be 'teratogenic') – it can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid glands). It also makes a miscarriage more likely. This may happen even if Isotretinoin is taken only for a short time during pregnancy.

- You must not take Isotretinoin if you are pregnant or if you think you might be pregnant.
- You must not take Isotretinoin if you are breast-feeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take Isotretinoin if you could get pregnant during treatment.
- You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed Isotretinoin under strict rules. This is because of the risk of serious harm to the unborn baby.

These are the rules:

- Your doctor must explain the risk of harm to the unborn baby – you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.
- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with Isotretinoin.

Women must use effective contraception before, during and after taking Isotretinoin

- You must agree to use at least one very reliable method of contraception (for example an intra uterine device or contraceptive implant) or two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking Isotretinoin, during treatment and for a month afterwards.
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking Isotretinoin

- You must agree to regular follow-up visits, ideally every month.
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month after stopping Isotretinoin (unless your doctor decides this is not necessary in your case).
- You must agree to extra pregnancy tests if your doctor asks you.
- You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body.
- Your doctor will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking Isotretinoin, stop taking the medicine straight away and contact your doctor. Your doctor may send you to a specialist for advice.

Also, if you become pregnant within one month after you stop taking Isotretinoin, you should contact your doctor. Your doctor may send you to a specialist for advice.

Written information on this subject is available from your doctor. If you haven't received this material please contact your doctor.

Prescriptions are limited to 30 days treatment for women of childbearing potential. Continuation of treatment requires a new prescription, and each prescription is only valid for seven days.

Pregnancy tests
Your doctor will provide you with information brochures that you must read carefully and may refer you to a gynaecologist, who will discuss about contraception and recommend the contraceptive methods suitable for you. **Your doctor or gynaecologist will carry out a medically supervised pregnancy test before you start to use Isotretinoin** (during the first 3 days of your menstrual cycle) in order to exclude the possibility that you might already be pregnant. If you do not have a regular period the test should be carried out about 3 weeks after the last unprotected sexual intercourse. The test must have a minimum sensitivity of 25 mIU/mL. Your doctor will document the date and result of this pregnancy test.

If the first pregnancy test is negative, you must start using an effective contraceptive method. A second medically supervised pregnancy test must be carried out a month after starting a consistent and effective contraceptive method and before starting the treatment, and not more than 3 days before the visit to the prescribing doctor. If the result of this second pregnancy test is negative, your doctor will issue your first prescription for Isotretinoin 10 mg. This prescription is limited to 30 days of treatment.

After this you must see your doctor at regular intervals, ideally every month. As a rule further medically supervised pregnancy tests must be carried out monthly on the day of the prescribing visit or in the 3 days before the visit throughout the course of treatment.

Afterwards you will receive a new prescription covering your needs for another 30 days.

One month after the end of treatment with isotretinoin another medically supervised pregnancy test must be carried out, because it takes about 1 month before the active substance contained in Isotretinoin is completely eliminated from the body. This test will exclude the possibility of a pregnancy during this period.

For those patients that are considered by the prescriber to have compelling reasons to indicate that there is no risk of pregnancy, once stable on isotretinoin (after the first 1-3 months), the prescription duration may be for longer than 30 days (up to 12 weeks).

Advice for men

The levels of oral retinoid in the semen of men taking Isotretinoin are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.

Additional precautions

You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month after stopping Isotretinoin because an unborn baby could be harmed if a pregnant patient receives your blood.

This medicine can cause serious skin reactions. Stop using Isotretinoin 10 mg and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Mental health problems

You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.

Other precautions

- Isotretinoin may increase the levels of fats such as triglycerides or cholesterol in your blood.** Your doctor will do some blood tests in order to monitor these levels before, during and at the end of your Isotretinoin treatment. Tell your doctor if you already have high levels of these substances in your blood or if you have diabetes, are overweight, or are an alcoholic, as you may need to have blood tests more frequently.
- Isotretinoin may increase your liver enzyme levels.** Your doctor will do some blood tests before, during and at the end of your Isotretinoin treatment to check your liver values. In cases where liver enzyme values remain high your doctor may reduce your dose or stop your Isotretinoin therapy.
- Isotretinoin may increase your blood sugar levels** and in rare cases diabetes mellitus has been diagnosed. Your doctor may monitor your blood sugar levels during your treatment, particularly if you have diabetes, are overweight, or are an alcoholic.
- Use a skin moisturising ointment or cream and a lip balm** during treatment as you may experience skin and/or lip dryness during Isotretinoin therapy.

Contact your doctor

- If you have any kind of mental problems, or if you think you have signs of depression while taking Isotretinoin such as feeling very sad for no reason, crying spells, difficulty concentrating or you become withdrawn from your friends or family. Your doctor may refer you to appropriate treatment if necessary. Stopping therapy with Isotretinoin may not be enough and you may require further psychiatric or psychological help. Rare cases of depression, worsening depression, anxiety, mood changes, psychotic symptoms and very rarely suicidal thoughts, suicide attempts and suicide have been reported.
- If you suffer from kidney failure. In this case therapy has to begin with a lower dose.
- Isotretinoin may cause dry eyes, intolerance to contact lenses and visual difficulties including decreased night vision. Cases of dry eyes not resolving after discontinuation of therapy have been reported. Always be cautious when driving or operating machinery at night because these slight changes can happen quite suddenly. Tell your doctor if you have any of these symptoms. Your doctor may ask you to use lubricating eye ointment or tear replacement therapy. If you use contact lenses and you have developed intolerance to contact lenses, you may be advised to wear glasses during the treatment. Your doctor may refer you to a specialist for advice if you develop visual difficulties and you may be asked to stop taking Isotretinoin.

Stop treatment immediately and contact your doctor as soon as possible

- If you experience an allergic reaction (skin redness, itching) or a serious anaphylactic reaction.
- If you experience a persistent headache, nausea, vomiting and blurred vision. Isotretinoin has been very rarely associated with a condition called benign intracranial hypertension.
- If you experience severe haemorrhagic diarrhoea (e.g. blood in your stool). Isotretinoin has on very rare occasions been associated with inflammatory bowel disease.

What to avoid when taking Isotretinoin

- Avoid too much sun and do not use a sun-lamp or sun-bed.** Your skin may become more sensitive to sunlight during Isotretinoin therapy. Before going out in the sun apply a sun protection product with a high protection factor of at least SPF 15.
- Cosmetic procedures** such as dermabrasion or laser treatments (removing horny skin or scars) and wax epilation should be avoided during and for at least 6 months after treatment; Isotretinoin may make your skin more fragile and this could cause scarring or irritation of the skin.
- Reduce intensive physical activity** during Isotretinoin therapy, because muscle and joint pain have been observed during Isotretinoin treatment.
- Do not donate blood** either during or for one month after Isotretinoin treatment. If someone who is pregnant receives your donated blood, her baby may be born with serious birth defects.
- Isotretinoin has been associated with sexual problems.** These include problems getting or maintaining an erection, lower libido, vaginal dryness, orgasm difficulties and reduced sensation in the genitals. There have been reports of long-lasting sexual problems where the symptoms have continued despite stopping treatment with isotretinoin. Talk to your doctor if you experience any sexual problems

Taking other medicines
 Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take vitamin A supplements or tetracyclines (a type of antibiotic) during therapy with Isotretinoin because the risk of getting side effects may increase.

Do not use any skin treatments for acne during treatment with Isotretinoin because local irritation may increase.

Pregnancy and breast-feeding
 If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
 Isotretinoin must not be used during pregnancy. If you are able to get pregnant, you should use effective contraception during and up to one month after Isotretinoin treatment.

If you do get pregnant while taking Isotretinoin, or in the month after treatment has stopped, stop

taking the medicine straight away, and contact your doctor. He or she may refer you to a specialist for advice.

If used during pregnancy, Isotretinoin is likely to damage an unborn baby (in medical language it is teratogenic). It also increases the risk of miscarriage.

2. BEFORE YOU TAKE ISOTRETINOIN continued...

Isotretinoin can cause serious abnormalities of brain, face, ear, eye, heart and some glands (called the thymus gland and parathyroid gland) of the unborn baby.

For more information on pregnancy and contraception, see section 2 "Pregnancy and prevention programme".

Breast-feeding

You must not take Isotretinoin if you are breast-feeding. The medicine is likely to pass into your breast milk and may harm your baby.

Driving and using machines

You should not see well at night during your treatment. This can happen suddenly. In rare cases this has continued after the treatment has stopped.

Drowsiness and dizziness have been reported very rarely. If this happens to you, you should not drive or operate machinery.

Important information about some of the ingredients of Isotretinoin:

Isotretinoin contains soya oil
 If you are allergic to peanut or soya, do not use this medicinal product.

Isotretinoin contains sorbitol
 This medicine contains 5.31 mg sorbitol in each capsule. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ISOTRETINOIN

Always take Isotretinoin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

- The capsules should be taken with food once or twice daily.**
- Swallow the capsules whole, do not chew or suck them.

Occasionally your acne may get worse during the first weeks of treatment. It should improve with continued treatment.

Dosage

Your doctor will prescribe an individual dose in accordance with your body weight and other clinical parameters like renal insufficiency, etc.

The specific individual doses might be better matched by other available strengths.

Adults including adolescents and the elderly
 The usual starting dose is 0.5 mg per kilogram body weight per day (0.5 mg/kg/day). **After a few weeks your doctor may adjust your dose.** This will depend on how you are getting on with your medicine.
 For most patients the dose will be between 0.5 and 1.0 mg/kg/day.

If you have the impression that the effect of Isotretinoin is too strong or too weak, talk to your doctor or pharmacist.

Patients with severe renal insufficiency
 If you have severe kidney problems, Isotretinoin should be started at a lower dose such as 10 mg/day and then increased up to the highest tolerated dose.

Children

Isotretinoin is not recommended for use in children less than 12 years of age due to insufficient data on efficacy and safety. Use in children over 12 years only after puberty.

Your prescriber must have considered that there is no other appropriate treatment before starting your isotretinoin therapy.

Patients with intolerance

If you cannot tolerate the recommended dose, your doctor may consider your treatment with a lower dose with the consequence of a longer therapy duration and a higher risk of relapse.

Duration of treatment
A course of treatment usually lasts for 16 to 24 weeks. Your acne may continue to improve for up to 8 weeks after the treatment finishes. Therefore, a further course of treatment should not be started until at least this period has elapsed. Most patients only need a single course of treatment.

Remember this medicine is for you
 Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms appear similar to yours.

If you take more Isotretinoin than you should
 The following symptoms are possible: severe headache, nausea or vomiting, somnolence, irritability and itching. If you take too many capsules or someone else accidentally takes your medicine, **contact your doctor, pharmacist or nearest hospital immediately.**

If you forget to take Isotretinoin
 If you miss 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The effects often wear off, or stop when treatment is stopped. Others can be serious and you must immediately contact your doctor.

Side effects requiring immediate medical attention

Serious skin reactions
Frequency not known (frequency cannot be estimated from available data)

- Reddish non-itching target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN)). Severe forms of rash may progress to widespread peeling of the skin which can be life threatening.
- Additional symptoms such as infection of the eye (conjunctivitis) or ulcers of the mouth, throat or nose may occur.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis (AGEP)).
- If you develop a serious rash or these skin symptoms, **stop taking Isotretinoin and contact your doctor immediately.**

Mental problems

Rare effects (may affect up to 1 in every 1000 people)

- Becoming violent or aggressive.

Very rare effects (may affect up to 1 in every 10,000 people)

- Unusual behaviour
- Signs of psychosis: a loss of contact with reality, such as hearing voices or seeing things that are not there.

Frequency not known (frequency cannot be estimated from available data)

- Depression or related disorders. Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort.
- Existing depression getting worse.
- Some people have had thoughts about hurting themselves or ending their own lives (suicidal thoughts), have tried to end their own lives (attempted suicide), or have ended their lives (suicide). These people may not appear to be depressed.

Contact your doctor straight away if you get signs of any of these mental problems. Your doctor may tell you to stop taking Isotretinoin. That may not be enough to stop the effects: you may need more help, and your doctor can arrange this.

Allergic reactions

Rare effects (may affect up to 1 in every 1000 people)

- Serious (anaphylactic) reactions: difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth. Also sudden swelling of the hands, feet and ankles.

Very rare effects (may affect up to 1 in every 10,000 people)

- Sudden tight chest, shortness of breath and wheezing, particularly if you have asthma.

If you have a serious reaction, get emergency medical help immediately.
 If you have any allergic reaction, stop taking Isotretinoin and contact your doctor.

Bones and muscles

Frequency not known (frequency cannot be estimated from available data)

- Muscle weakness which can be potentially life-threatening, may be associated with trouble moving arms or legs, painful, swollen, bruised areas of the body, dark-coloured urine, reduced or no urine output, confusion or dehydration. These are signs of rhabdomyolysis, a breakdown of muscle tissue which can lead to kidney failure. This may occur if you are doing intensive physical activity while you're on Isotretinoin.

Liver and kidney problems

Very rare effects (may affect up to 1 in every 10,000 people)

- Yellow skin or eyes, and feeling tired. These can be signs of hepatitis. **Stop taking Isotretinoin straight away and contact your doctor**

- Difficulty urinating (passing water), swollen and puffy eyelids, feeling excessively tired. These may be signs of kidney inflammation. **Stop taking Isotretinoin straight away and contact your doctor.**

Nervous system problems

Very rare effects (may affect up to 1 in every 10,000 people)

- Lasting headache, along with feeling sick (nausea), being sick (vomiting) and change in your eyesight including blurred vision. These may be signs of benign intracranial hypertension, especially if Isotretinoin is taken with antibiotics called tetracycline.

Stop taking Isotretinoin straight away and contact your doctor.

Gut and stomach problems

Very rare effects (may affect up to 1 in every 10,000 people)

- Severe abdominal (tummy) pain, with or without severe bloody diarrhoea, feeling sick (nausea) and being sick (vomiting). These can be signs of serious gut conditions.

Unknown frequency (frequency cannot be estimated from available data):

- Anus fissure (a small tear in the thin, moist tissue that lines the anus)
- Rectal bleeding or blood in your stools

Stop taking Isotretinoin straight away and contact your doctor.

Eye disorders

Very rare effects (may affect up to 1 in every 10,000 people)

- Blurred vision.

If you get blurred vision, stop taking Isotretinoin straight away and contact your doctor. If your sight is affected in any other way tell a doctor as soon as you can.

Other side effects: Very common side effects with Isotretinoin: (may affect more than 1 in 10 people)

- Dryness of the skin, especially of the lips and cracked, chapped and inflamed lips, rash, mild itching and slight peeling. Use a moisturising cream from the start of treatment
- Skin becomes more fragile and redder than normal, especially the face
- Back pain; muscle pain; joint pain particularly in children and teenagers. To avoid making any bone or muscle problems worse, cut down on intensive physical activity while you're on Isotretinoin
- Inflammation of the eye (conjunctivitis) and eyelid area; eyes feel dry and irritated. Ask a pharmacist for suitable eye drops. If you get dry eyes and wear contact lenses, you may need to wear glasses instead
- Raised liver enzymes seen in blood tests
- Changed levels of fats in the blood (including HDL or triglycerides)
- Bruising, bleeding or clotting more easily - if clotting cells are affected
- Anaemia - weakness, dizziness, pale skin - if red blood cells are affected.

Common side effects with Isotretinoin: (may affect up to 1 in 10 people)

- Headache
- Higher levels of cholesterol in the blood
- Protein or blood in the urine
- More liable to get infections if the white blood cells are affected
- Inside of the nose becomes dry and crusted, causing mild nosebleeds
- Sore or inflamed throat and nose
- Allergic reactions such as rash, itchiness. If you have any allergic reaction, stop taking Isotretinoin and contact your doctor.

Rare side effects with Isotretinoin: (may affect up to 1 in 1,000 people)

- Hair loss (alopecia). This is usually only temporary. Your hair should return to normal after the treatment ends.