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PACKAGE LEAFLET:
 INFORMATION FOR THE USER
**Isotretinoin
 5 mg capsules**
 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.

What is in this leaflet:

- What Isotretinoin 5 mg is and what is it used for
- What you need to know before you take Isotretinoin 5 mg
- How to take Isotretinoin 5 mg
- Possible side effects
- How to store Isotretinoin 5 mg
- Contents of the pack and other information

If used during pregnancy, isotretinoin 5 mg is likely to damage an unborn baby (in medical language it is teratogenic). It also increases the risk of miscarriage.

Isotretinoin 5 mg can cause serious abnormalities of brain, face, ear, eye, heart and some glands (called the thymus gland and parathyroid gland) of the unborn baby.

Breast-feeding
 You must not take Isotretinoin 5 mg 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 may not see as 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.

Isotretinoin 5 mg contains soya oil and sorbitol
 If you are allergic to peanut or soya, do not use this medicinal product.

This medicine contains 5 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 5 MG

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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). So if you weigh 60 kg, your dose will usually start at 30 mg a day.



1. WHAT ISOTRETINOIN 5 MG IS AND WHAT IT IS USED FOR

Isotretinoin 5 mg capsules contain the active ingredient isotretinoin. This is a vitamin A derivative, belonging to the retinoid class of medicines. Isotretinoin 5 mg is used to treat severe forms of acne (such as nodular or conglobate acne, or acne at risk of permanent scarring) in adults and adolescents from 12 years of age only after puberty. You will use Isotretinoin 5 mg when your acne has not got better after other anti-acne treatments, including oral antibiotics and skin treatments.

Isotretinoin 5 mg treatment must be supervised by a dermatologist (a doctor specialised in the treatment of skin problems).

If you are aged under 18 years of age, you must not take isotretinoin unless two prescribers have agreed that your condition does not respond adequately to other treatments and the benefits of treatment outweigh the risk (see under Section 2: 'Children and adolescents' below).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOTRETINOIN 5 MG

- Do not take Isotretinoin 5 mg:**
 - 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 to isotretinoin, peanut or soya or any other ingredients** of this medicine (listed in section 6)
 - If you have liver disease**
 - If you have very high levels of blood fats** (e.g. high cholesterol or triglycerides)
 - If you have very high levels of vitamin A** in your body (hypervitaminosis A)

Take the capsules once or twice daily
 Take on a full stomach. Swallow them whole, with a drink or a mouthful of food.

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 think that Isotretinoin 5 mg is too strong or too weak, talk to your doctor or pharmacist.

Patients with severe renal insufficiency
 If you have severe kidney problems, you will usually start on a lower dose (such as 10 mg/day) which will be increased up to the highest dose your body can tolerate. If your body can't tolerate the recommended dose, you may be prescribed a lower dose; that can mean you are treated for longer and your acne might be more likely to come back.

Use in 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.

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. You won't usually start another course until then.

Some people find their acne gets worse during the first weeks of treatment. It usually improves as treatment goes on.

If you take more Isotretinoin 5 mg 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 you are receiving treatment with tetracyclines** (a type of antibiotic) at the same time (see 'Other medicines and Isotretinoin 5 mg')

If any of these apply to you, go back to your doctor before taking any Isotretinoin 5 mg.

Warnings and precautions
 Talk to your doctor or pharmacist before taking Isotretinoin 5 mg.

- 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 5 mg.

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 5mg. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Isotretinoin 5mg 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 5 mg
 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 gland). It also makes a miscarriage more likely. This may happen even if Isotretinoin 5 mg is taken only for a short time during pregnancy.

- You must not take Isotretinoin 5 mg if you are pregnant or if you think you might be pregnant.

If you forget to take Isotretinoin 5 mg
 If you miss a dose take it as soon as you can. 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 to make up for a forgotten 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:
Skin problems
Unknown frequency (frequency cannot be estimated from available data):

- Serious skin rashes (erythema multiforme, Stevens-Johnsons syndrome and toxic epidermal necrolysis), which are potentially life-threatening and require immediate medical attention.

These appear initially as circular patches often with central blisters usually on arms and hands, or legs and feet, more severe rashes may include blistering of the chest and back. Additional symptoms such as infection of the eye (conjunctivitis) or ulcers of the mouth, throat or nose may occur. Severe forms of rash may progress to widespread peeling of the skin which can be life threatening. These serious skin rashes are often preceded by headache, fever, body aches (flu-like symptoms).

If you develop a serious rash or these skin symptoms, stop taking isotretinoin 5 mg and contact your doctor immediately.

- You must not take Isotretinoin 5 mg if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).
- You must not 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 5 mg 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.
- 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 5 mg.

Women who use effective contraception before, during and after taking Isotretinoin 5 mg

- 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 5 mg, during treatment and for a month afterwards.

Mental problems
Rare (may affect up to 1 in 10,000 people):

- Becoming violent or aggressive.

Very rare (may affect up to 1 in 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 5 mg. That may not be enough to stop the effects; you may need help, and your doctor can arrange this.

Allergic reactions
Rare (may affect up to 1 in 10,000 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 (may affect up to 1 in 10,000 people):

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

Stop taking Isotretinoin straight away and contact your doctor.

- 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 5 mg

- 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 5 mg (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 5 mg, 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 5 mg, you should contact your doctor which methods would be suitable for you.

Your doctor has written information on pregnancy and contraception for the users of Isotretinoin 5 mg which he or she should show you. If you haven't seen this material already, ask your doctor.

Prescriptions for women who could get pregnant are limited to 30 days treatment. A new prescription is needed for more treatment. Each

prescription is only valid for 7 days.

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 5 mg 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 5 mg because an unborn baby could be harmed if a pregnant patient receives your blood.

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.

- Advice for all patients**
- Tell your doctor if you have ever had any mental illness** (including depression, suicidal behaviour or psychosis), or if you take medicines for any of these conditions.
- Severe skin reactions** (e.g. erythema multiforme (EM), Stevens-Johnsons syndrome (SJS) and toxic epidermal

necrolysis (TEN)) have been reported with the use of Isotretinoin 5 mg. The rash may progress to widespread blistering or peeling of the skin. You should also look for ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

- Rarely, Isotretinoin 5 mg may cause severe allergic reactions** some of which can affect skin in the form of eczema, hives and bruises or red patches on arms and legs. If you develop an allergic reaction, stop taking Isotretinoin 5 mg, seek urgent advice from a doctor and tell him that you are taking this medicine.

- Cut down on intensive exercise and physical activity.** Isotretinoin 5 mg can cause muscle and joint pain particularly in children and teenagers undertaking vigorous physical activity.

- Isotretinoin 5 mg has been associated with inflammatory bowel disease.** Your doctor will take you off Isotretinoin 5 mg if you have severe bloody diarrhoea without any history of gastrointestinal disorders.
- Isotretinoin 5 mg 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. 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 5 mg.

- Benign intracranial hypertension has been reported with Isotretinoin 5 mg use and in some cases where**

- Calcium deposits in soft tissue, sore tendons, high levels of muscle breakdown products in your blood if you exercise vigorously.**
- Increased sensitivity to light.**
- Bacterial infections** at the base of the nail, changes to nails.
- Swellings, discharging, pus**
- 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 5 mg and contact your doctor.

Gut and stomach problems
Very rare (may affect up to 1 in 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.

Stop taking Isotretinoin 5 mg straight away and contact your doctor.

Eye disorders
Very rare (may affect up to 1 in 10,000 people):

- Blurred vision.

If you get blurred vision, stop taking Isotretinoin 5 mg 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 (may affect more than 1 in 10 people)

- Dryness of the skin, especially of the lips and face; inflamed lips, chapped and inflamed lips, rash, mild itching and slight peeling. Use a moisturising cream from the start of treatment.
- Skin becomes more fragile and tender than usual, 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 5 mg.
- 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.

Isotretinoin 5 mg was used together with tetracyclines (a type of antibiotic). Stop taking Isotretinoin 5 mg and seek urgent advice from your doctor if you develop symptoms like headache, nausea, vomiting and visual disturbances. Your doctor may refer you to a specialist to check for swelling of optic disk in the eye (papilloedema).

- Isotretinoin 5 mg may increase liver enzyme levels.** Your doctor will do blood tests before, during and after Isotretinoin 5 mg treatment to check these levels. If they stay high, your doctor may lower your dose or take you off Isotretinoin 5 mg.

- Isotretinoin 5 mg commonly increases blood fats,** such as cholesterol or triglycerides. Your doctor will test these levels before, during and after Isotretinoin 5 mg treatment. It is best that you do not drink alcoholic drinks or that you at least reduce the amount you drink while on treatment. Tell your doctor if you already have high blood fats, diabetes (high blood sugars), are overweight or an alcoholic. You may need blood tests more often. If your blood fats stay high, your doctor may lower your dose, or stop taking Isotretinoin 5 mg.
- Tell your doctor if you have any kidney problems.** Your doctor may start you on a lower dose of Isotretinoin 5 mg and then increase it to the maximum tolerated dose.
- Tell your doctor if you have problems of fructose intolerance.** Your doctor will not prescribe Isotretinoin 5 mg if you have intolerance to fructose or sorbitol.

- Isotretinoin 5 mg may increase blood sugar levels.** In rare cases, people become diabetic. Your doctor may monitor blood sugar levels during treatment, particularly if you already have diabetes, are overweight, or are an alcoholic.

- Your skin is likely to get dry.** Use a skin moisturising ointment or cream and a lip balm during treatment. To prevent skin irritation you should avoid using exfoliating or anti-acne products.
- Avoid too much sun and do not use a sun-lamp or sun-bed.** Your skin may become more sensitive to sunlight. Before you go out in the sun, use a sun-protection product with a high protection factor (SPF 15 or higher).

- Don't have any cosmetic skin treatments.** Isotretinoin 5 mg may make your skin more fragile. Don't have any waxing (hair removal), dermabrasion or laser treatments (removing horny skin or scars) during treatment, or for at least 6 months after treatment. They could cause scarring, skin irritation, or rarely, changes in the colour of your skin.

- You must remember not to share your medication with anyone else.** You should return unused capsules at the end of your treatment. Talk to your doctor or pharmacist regarding where to return the capsules.
- Avoid the use of topical keratolytic or exfoliative anti-acne agents** while you are on Isotretinoin 5 mg.

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.

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

Pregnancy
 Isotretinoin 5 mg 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 5 mg treatment.

If you do get pregnant while taking Isotretinoin 5 mg, 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.

United Kingdom
 Yellow Card Scheme
 Website: www.mhra.gov.uk/yellowcard

Österreich
 Bundesamt für Sicherheit im Gesundheitswesen
 Traisengasse 5
 1200 WIEN
 ÖSTERREICH
 Fax: + 43 (0) 50 555 36207
 Website: http://www.basg.gv.at/

5. HOW TO STORE ISOTRETINOIN 5 MG

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package.

Important! Please return any unused capsules to your pharmacist at the end of treatment. Only keep it if your doctor tells you to.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Isotretinoin 5 mg contains
 The active substance is Isotretinoin. Each capsule contains 5 mg of isotretinoin.

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Ennogen Healthcare



Use in adolescents over 12 years of age only after puberty.
 If you are aged under 18 years of age, you must not take isotretinoin unless two prescribers have agreed that your condition does not respond adequately to other treatments and the benefits of treatment outweigh the risks.

Other medicines and Isotretinoin 5 mg
 Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including herbal and non-prescription products.

- Do not take vitamin A supplements or tetracyclines** (a type of antibiotic), or use any skin treatments for acne while you are on Isotretinoin 5 mg. It is fine to use moisturisers and emollients (skin creams or preparations that prevent water loss and have a softening effect on the skin).
- Avoid the use of topical keratolytic or exfoliative anti-acne agents** while you are on Isotretinoin 5 mg.

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

Pregnancy
 Isotretinoin 5 mg 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 5 mg treatment.

If you do get pregnant while taking Isotretinoin 5 mg, 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.

The other ingredients are:
 Capsule filling:
 Soya-bean oil, refined all-rac- α -Tocopherol
 Disodium edetate
 Butylhydroxyanisole (E 320)
 Soya-bean oil, partially hydrogenated
 Hydrogenated vegetable oil
 Beeswax, yellow

Capsule shell:
 Gelatin
 Glycerol
 Sorbitol, liquid (non-crystallising) (E 420)
 Purified water
 Titanium dioxide (E 171)

What Isotretinoin 5 mg looks like and contents of the pack
 The soft-gelatin capsules are faint pinkish/cream to cream coloured oval, containing a yellow/orange, opaque, viscous liquid.

The capsules come in blister packs of 10, 15, 20, 30, 50, 56 or 60 capsules [Not all pack sizes may be marketed.]

Marketing Authorisation Holder and Manufacturer
 Ennogen Healthcare Limited
 Unit G4, Riverside Industrial Estate,
 Riverside Way, Dartford, UK

This leaflet was last revised in September 2023.

Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare Products Regulatory Agency website: www.mhra.gov.uk

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