

## Package leaflet: Information for the patient

### Isotretinoin 5 mg, 10 mg, 20 mg, 40 mg soft capsules Isotretinoin

#### WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception

Do not use if you are pregnant or you 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 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

- 1 – What Isotretinoin is and what it is used for
- 2 – What you need to know before you take Isotretinoin
- 3 – How to take Isotretinoin
- 4 – Possible side effects
- 5 – How to store Isotretinoin
- 6 – Contents of the pack and other information

#### 1. What Isotretinoin is and what it is used for

Isotretinoin Soft Capsules contain isotretinoin.

- Isotretinoin is related to vitamin A.
- It belongs to a group of medicines called ‘retinoids’.

Isotretinoin is used to treat severe types of acne

- This is acne that can cause scars which do not go away
- These types of acne are also called ‘nodular’ or ‘conglobate’ acne.

Isotretinoin is used when your acne has not got better with any other treatments. This includes antibiotics and skin treatments.

Your treatment must be supervised by a specialist doctor – called a ‘dermatologist’. This is a doctor who specialises in treating skin problems.

#### 2. What you need to know before you take Isotretinoin

##### Do not take Isotretinoin - if:

- You are allergic to peanut or soya or any other ingredient of Isotretinoin. This medicine contains soya oil, as well as isotretinoin. See section 6 (Further information) at the end of this leaflet for a full list of ingredients.

- There is any chance you could become pregnant, you must follow the precautions under “Pregnancy and prevention programme”, see section on “Warnings and precautions”
- You are pregnant or breast-feeding
- You have been diagnosed with liver problems
- You have been diagnosed with very high levels of blood fats (such as high cholesterol or triglycerides)
- You have been diagnosed with very high levels of vitamin A in your body (called ‘hypervitaminosis A’)
- If you are receiving treatment with tetracyclines (a type of antibiotic) at the same time (see “Other medicines and Isotretinoin”)

If any of these apply to you, go back to your doctor and do not take any of this medicine. Talk to your doctor first, before you take it.

### **Use in young people over 12.**

- Do not give to children under 12. Only give to young people over 12 years of age if they have finished all the changes of puberty.

### **Special precautions with Isotretinoin**

Do not take this medicine when you are pregnant.

### **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 gland). 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 breastfeeding. 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 contraceptive 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 intrauterine 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 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.
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- 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  
Your doctor will show you written information on pregnancy and contraception. If you have not seen this information, ask your doctor.

Prescriptions for women who could get pregnant are only for a month at a time. A new prescription is needed for more treatment. You have to take the prescription to the pharmacist/chemist within 7 days – if it is later, the chemist cannot give you the medicine.

### **Advice for men**

The levels of oral retinoid in the semen of men taking Isotretinoin are too low to harm their partner's 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.**

### **Advice for all patients**

#### **Talk to your doctor 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.

- Also tell your doctor if you take medicines for any of these illnesses. This is because your mood may be affected while taking isotretinoin.

#### **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.

**Isotretinoin often increases blood fats**, such as cholesterol or triglycerides. Your doctor will do blood tests before, during and after isotretinoin treatment. It is best that you do not drink alcoholic drinks or that you at least reduce the amount you usually drink while on treatment. Tell your doctor if you already have high blood fats, diabetes, are over-weight, or if you have problems with drinking too

much alcohol. You may need blood tests more often. If your blood fats stay high, your doctor may lower your dose, or take you off this medicine.

- **Isotretinoin may affect your liver**

Your doctor will do blood tests before, during and after isotretinoin treatment to check how your liver is working. If your liver function is affected, your doctor may lower your dose or take you off isotretinoin.

- **Isotretinoin may increase blood sugar levels.** In rare cases, people become diabetic. Your doctor may check blood sugar levels during treatment. This is particularly if you already have diabetes, are over-weight, or if you have problems with drinking too much alcohol.
- **Your skin is likely to get dry** - use a moisturiser and lip balm. To prevent skin irritation it is best not to use things called 'exfoliators' or other anti-acne products.
- **Severe Skin reactions** (e.g. erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) have been reported with the use of this medicine. 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, this medicine may cause severe allergic reactions** some of which can affect skin in the form of eczema, hives (lumpy rash) and bruises or red patches on arms and legs. If you develop an allergic reaction, stop taking this medicine, seek urgent advice from a doctor and tell him that you are taking this medicine.
- **Keep out of the 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 50 or higher).
- **Do not have any cosmetic skin treatments.** Isotretinoin may make your skin more fragile. Do not 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.
- **Isotretinoin has been associated with inflammatory bowel disease.** Your doctor will take you off isotretinoin if you have severe bloody diarrhoea without any history of gastrointestinal disorders.
- **Isotretinoin may cause dry eyes, intolerance to contact lenses and visual difficulties including decreased night vision.** 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.
- **Benign intracranial hypertension has been reported with Isotretinoin** and in some cases where isotretinoin was used together with tetracyclines (a type of antibiotic). Stop taking Isotretinoin 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).
- **Cut down on hard exercise and physical activity.** Isotretinoin can cause muscle and joint pain particularly in young people.
- **Do not take vitamin A supplements** while taking this medicine. Taking both together may increase the risk of side effects.
- **Tell your doctor if you have any kidney problems.** Your doctor may start you on a lower dose of isotretinoin and then increase it to the maximum tolerated dose.
- **You should not donate blood during treatment with this medicine and for 1month after stopping Isotretinoin because an unborn baby could be harmed if a pregnant patient receives your blood.**
- **You must remember not to share your medication with anyone else.** You should return unused capsules at the end of your treatment. Talk to you doctor or pharmacist regarding where to return the capsules.

### **Driving and using machines**

You may experience problems with your eyes and not see as well during your treatment. This can happen suddenly. In rare cases, night vision problems have continued after the treatment has stopped. Drowsiness and dizziness have been reported very rarely. If this happens to you, you should not drive, ride a bike or operate machinery.

### **Taking other medicines**

**Do not take any vitamin A supplements or tetracyclines** (a type of antibiotic), or use any other treatment for acne that will make your skin dry out or peel while you are taking Isotretinoin.

It is fine to use moisturisers and emollients (skin creams or preparations that prevent water loss and have a softening effect on the skin).

Tell your doctor or pharmacist if you are taking any other medicines – including herbal and non-prescription products (including multi-vitamin supplements) and anything else you put on your skin – or if you have taken any recently.

### **Pregnancy, breast-feeding and fertility**

For more information on pregnancy and contraception, see section 2 “Pregnancy and prevention programme”

### **Isotretinoin Soft Capsules contain**

**Soya-bean oil.** If you are allergic to peanuts or soya, do not take this medicinal product.

## **3. How to take Isotretinoin**

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

**The usual starting dose** is 0.5 mg per kilogram (kg) of body weight per day (0.5 mg/kg / day). So, if you weigh 60 kg, your dose will usually start at 30 mg per day.

### **Take the capsules once or twice daily.**

Take them during or after a meal. Swallow them whole, with a drink or a mouthful of food.

**After a few weeks your doctor may adjust your dose.** This depends on how you are getting on with your medicine. For most people the dose will be between 0.5 and 1 mg per kg of body weight per day. If you think that your medicine is too strong or too weak, talk to your doctor or pharmacist.

**If you have severe kidney problems,** you will usually start on a lower dose (such as 10 mg per day) which will be increased up to the highest dose that your body can take. If your body cannot take the recommended dose, you may be prescribed a lower dose. That may mean that you are treated for a longer time and your acne might be more likely to come back.

**A course of treatment usually lasts for 4 to 6 months.** Most people only need one course. Your acne may continue to improve for up to 8 weeks after treatment. Usually you will not start another course until then.

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

### **If you take more Isotretinoin capsules than you should**

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 a dose**

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 two doses at the same time.

#### **4. Possible side effects**

This medicine can have side effects, although not everybody gets them. Some of the side effects associated with the use of isotretinoin are related to the dose. The side effects are generally reversible after changing the dose or stopping treatment, however some may continue after treatment has stopped. Your doctor can help you to deal with them.

**Stop taking this medicine and contact your doctor straight away if you get signs of any of the following side effects.** That may not be enough to stop the side effects. You may need more help, which your doctor can arrange for you.

#### **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.

#### **Mental problems**

**Rare effects** (*may affect up to 1 in every 1,000 people*)

- Depression or related disorders. Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort
- Existing depression getting worse.
- Becoming violent or aggressive.

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

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

**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.

#### **Rash and other skin symptoms**

**Unknown frequency** (*frequency cannot be estimate from the available data*)

- This medicine can cause serious skin rashes, which can be life-threatening, and you will need emergency medical help. They often start as circular patches on your arms, hands, legs or feet, and may have blisters in them. More severe rashes may appear as blisters on your chest and back. You may get other symptoms with it like an eye infection (conjunctivitis), or ulcers in your mouth, throat or nose.
- If a large area of skin starts to peel, this is a danger sign and you need to go to a hospital straight away. Take your medicine with you. Severe forms of rash may lead to widespread peeling of the skin, which can be life threatening. If you get flu-like symptoms (headache, fever, body aches) they may be followed by the serious skin rash, so watch out carefully for this and be ready to act quickly.

**Very common effects** (*may affect more than 1 in every 10 people*)

- Dryness of the skin, especially of the lips and face; red and sore skin, chapped and inflamed lips, rash, mild itching and slight peeling. If you use a moisturising cream from the start of treatment you can reduce the risk of this happening.

- Skin can become more fragile and redder than usual, especially on your face.

**Rare effects** (*may affect up to 1 in every 1,000 people*)

- Hair loss, which is usually only temporary. Your hair should return to normal after the treatment ends.

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

- Your acne can get worse in the first few weeks, but symptoms should improve with time.
- Skin inflamed, swollen, and darker than usual, especially on your face.
- Feeling very sweaty or itchy.
- Increased sensitivity to light.
- Bacterial infections in the nail bed and other nail changes.
- Swellings, discharging, pus.
- Thickened scarring after surgery.
- Increased body hair.

**Allergic reactions**

**Rare effects** (*may affect up to 1 in every 1,000 people*)

- Serious allergic reactions such as difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth. Also sudden swelling of the hands, feet and ankles. If you have any allergic reaction, stop taking isotretinoin and contact your doctor.
- Allergic skin reactions such as rash, itchiness.

**Other problems**

**Very common effects** (*may affect more than 1 in every 10 people*)

- Raised liver enzymes seen in blood tests.

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

- Yellow skin or eyes, and feeling more tired than usual. These can be signs of hepatitis.
- Difficulty urinating (passing water), swollen or puffy eyelids, feeling more tired than usual. These may be signs of kidney problems.
- Severe abdominal (tummy) pain, with or without bloody diarrhoea, feeling sick (nausea) and being sick (vomiting). These can be signs of serious gut conditions.
- Long lasting headache along with feeling sick (nausea), being sick (vomiting) and change in your eyesight including blurred vision. These may be signs of benign cranial hypertension, especially if isotretinoin is taken with antibiotics called tetracycline
- Other sight problems including blurred vision, distorted vision, cloudy surface on the eye (corneal opacity, cataracts).
- Dark or cola-coloured urine
- 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 a breakdown of muscle tissue which can lead to kidney failure ‘rhabdomyolysis’. This may occur if you are doing intensive physical activity while you are on this medicine.

**Stop taking this medicine and contact your doctor straight away if you get signs of any of the above side effects.** That may not be enough to stop the side effects. You may need more help, which your doctor can arrange for you.

**Contact your doctor straight away if you get signs of any of the following side effects.** Your doctor may tell you to stop taking this medicine.

**Very common effects** (*may affect more than 1 in every 10 people*)

- Bruising or bleeding more easily - if the number of blood clotting cells goes down.
- Anaemia – weakness, dizziness, pale skin – if the number of red blood cells goes down.

- More likely to get infections with symptoms like chills, sudden fever, sore throat or flu-like symptoms - if the number of white blood cells (which help protect the body from infection and disease) goes down.
- 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.
- Back pain; muscle pain; joint pain particularly in teenagers. **To avoid making any bone or muscle problems worse**, cut down on intensive physical activity while you are taking isotretinoin.
- Changed levels of fats in the blood (including HDL or triglycerides).

**Common effects** (*may affect up to 1 in every 10 people*)

- Headache
- Inside of the nose becomes dry and crusted, causing mild nosebleeds.
- Sore or inflamed throat and nose.
- More liable to get infections, if the white blood cells are affected.
- Higher levels of cholesterol in the blood.
- Protein or blood in the urine.
- Allergic reactions such as rash, itchiness.

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

- Convulsions, drowsiness, dizziness
- You may see less well at night; have blurred vision or colour blindness and colour vision gets worse
- Sensitivity to light may increase, you may find that you need to wear sunglasses to protect your eyes from too bright sunlight
- Lymph glands (the glands around your neck, in your armpits and groin) may become swollen.
- Dry throat, hoarseness
- Sudden tight chest shortness of breath and wheezing, particularly if you have asthma
- Hearing difficulties.
- Feeling very thirsty; frequent need to urinate; blood tests show an increase in your blood sugar. These can all be signs of diabetes.
- Generally feeling unwell.
- High levels of uric acid showing up in blood tests.
- Bacterial infections.
- Inflammation of blood vessels (sometimes with bruising, red patches)
- Arthritis; bone disorders (delayed growth, extra growth and changes to bone density); growing bones may stop growing.
- Calcium deposits in soft tissue
- Sore tendons,
- Increased levels of creatine phosphokinase showing up in blood tests

**Unknown** (*frequency cannot be estimated from the available data*)

- Problems getting or maintaining an erection
- Lower libido
- Breast swelling with or without tenderness in males

**Contact your doctor straight away if you get signs of any of the above side effects.** Your doctor may tell you to stop taking this medicine.

**To avoid making any bone or muscle problems worse**, you should cut down on intensive physical activity while you are taking this medicine.

**If you notice any side effects that you are worried about**, whether they are listed in this leaflet or not, talk to your doctor.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Isotretinoin

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package and keep the blister in the outer carton in order to protect from light.

Do not use after the expiry EXP stated on the pack and blister. The expiry date refers to the last day of that month

**Return any capsules that you have left over at the end of your treatment, to your pharmacist.** Only keep this medicine if your doctor tells you to.

## 6. Contents of the pack and other information

### What Isotretinoin 5 mg, 10 mg, 20 mg, 40 mg Soft Capsule contains

The active substance is isotretinoin

Each capsule of 5 mg contains 5 mg isotretinoin

Each capsule of 10 mg contains 10 mg isotretinoin

Each capsule of 20 mg contains 20 mg isotretinoin.

Each capsule of 40 mg contains 40 mg isotretinoin.

**The other ingredients are:** soya-bean oil, hydrogenated vegetable oil and beeswax yellow.

**Composition of the capsule shell of 5 mg, 20 mg and 40 mg:** gelatin, glycerol, purified water, red iron oxide (E172), yellow iron oxide (E172), and titanium dioxide (E171).

**Composition of the capsule shell of 10 mg:** gelatin, glycerol, purified water, and red iron oxide (E172).

### What Isotretinoin 5 mg, 10 mg, 20 mg and 40 mg Soft Capsule looks like and contents of the pack

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Each Isotretinoin 5 mg Soft Capsule, has a bi-coloured opaque red/brown and cream gelatin shell, with a bright yellow/orange fill. The oval capsule is printed on one side in black ink with the logo "5".

Each Isotretinoin 10 mg Soft Capsule, has a red/brown gelatin shell, with a bright yellow/orange fill. The oval capsule is printed on one side in black ink with the logo "I 10".

Each Isotretinoin 20 mg Soft Capsule, has a bi-coloured opaque red/brown and cream gelatin shell, with a bright yellow/orange fill. The oval capsule is printed on one side in black ink with the logo "I 20"

Each Isotretinoin 40 mg Soft Capsule, has an opaque orange/brown gelatin shell, with a bright yellow/orange fill. The oval capsule is printed on one side in black ink with the logo "I 40".

Isotretinoin capsules come in blister packs of 30, 50 or 100 capsules. Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:** Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer:

Catalent France Beinheim S.A., 74 rue Principale, 67930 Beinheim, France.

Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany

Catalent Germany Schorndorf GmbH, Steinbeisstrasse 2, D-73614 Schorndorf, Germany

**You can find out more about this medicine from your doctor or pharmacist.**

This leaflet was last revised in March 2019