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PACKAGE LEAFLET:
INFORMATION FOR THE USER

Isotretinoin 20 mg soft capsules

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 20 mg is and what it is used for
- What you need to know before you take Isotretinoin 20 mg
- How to take Isotretinoin 20 mg
- Possible side effects
- How to store Isotretinoin 20 mg
- Contents of the pack and other information

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOTRETINOIN 20 MG (continued...)

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 20 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take vitamin A supplements or tetracyclines (a type of antibiotic) during therapy with Isotretinoin 20 mg because the risk of getting side effects may increase.

Do not use any skin treatments for acne during treatment with Isotretinoin 20 mg because local irritation may increase. 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 during treatment with Isotretinoin 20 mg.

Pregnancy and breast-feeding

Pregnancy

Isotretinoin 20 mg must not be taken during pregnancy, as Isotretinoin the active compound of Isotretinoin 20 mg is highly teratogenic. If pregnancy does occur in spite of the described precautions (Pregnancy prevention programme) during treatment in the month following, there is a great risk of very severe and serious damage to the unborn baby.

The foetal deformities associated with exposure to isotretinoin include central nervous system abnormalities (hydrocephalus, cerebellar malformation), abnormalities, microcephaly, facial

1. WHAT ISOTRETINOIN 20 MG IS AND WHAT IT IS USED FOR

Isotretinoin 20 mg soft capsules contains the active ingredient isotretinoin. This is a vitamin A derivative, belonging to the retinoid class of medicines. Isotretinoin 20 mg 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).

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 risks of treatment outweigh the risks (see under Section 2, 'Children and adolescents' below).

2. WHAT YOU NEED TO TAKE ISOTRETINOIN 20 MG

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 20 mg. Additionally, you should receive information materials from your doctor. If not, ask your doctor for this information. If your doctor has not explained the necessary measures or you have not understood them, please contact your doctor before you start taking Isotretinoin 20 mg.

Do not take Isotretinoin 20 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 2.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOTRETINOIN 20 MG (continued...)

dysmorphia, cleft palate, external ear abnormalities (absence of external ear, small or absent external auditory canals), eye abnormalities (microphthalmia), cardiovascular abnormalities such as tetralogy of Fallot, transposition of great vessels, septal defects), thymus gland abnormalities, and parathyroid gland abnormalities. There is also an increased incidence of spontaneous abortion.

If pregnancy occurs or might be likely in a woman treated with isotretinoin, treatment must be stopped immediately and the patient should contact her doctor without delay.

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

Breast-feeding

You should not take Isotretinoin 20 mg if you are breast-feeding, because isotretinoin is likely to pass into the milk and may harm the baby.

Driving and using machines

Your night vision may get worse during your treatment. This can happen suddenly. In rare cases this has continued after the treatment has stopped. You should therefore be cautious when driving or operating machines.

Drowsiness, dizziness and visual disturbances have been reported very rarely. If you experience any of these effects, you should not drive, operate machinery or take part in any other activities where these symptoms could put either yourself or others at risk.

Isotretinoin 20 mg contains soya oil, sorbitol and Ponceau 4R (E124).

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

This medicine contains 17 mg calcium 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.

section on "Warnings and precautions".

- If you are allergic to isotretinoin, soya, peanut or any of the 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)
- If you are taking tetracyclines (a type of antibiotic medicine). Due to the high risk that a child with congenital defects will result if pregnancy occurs you should only take Isotretinoin 20 mg 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 20 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 20 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 20mg. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Isotretinoin 20mg 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 20 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 20 mg is taken only for a short time during pregnancy.

- You must not take Isotretinoin 20 mg if you are pregnant or if you think you might be pregnant.
- You must not take Isotretinoin 20 mg if you are breast-feeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take Isotretinoin 20 mg 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 20 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 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 20 mg.

Women must use effective contraception before, during and after taking Isotretinoin 20 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 20 mg, 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 20 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 20 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 20 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 20 mg, 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.

Some of the side effects associated with the use of isotretinoin are dose-related. The side effects are generally reversible after altering the dose or discontinuation of treatment; however some may persist after treatment has stopped.

Go to a doctor straight away and stop taking Isotretinoin 20mg if any of the following side effects occur.

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

- Serous skin rashes (erythema multiforme, Stevens-Johnson 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.

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 20 mg than you should

The following symptoms are possible: severe headache, nausea or vomiting, somnolence, irritability and blurred vision. 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 20 mg

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 to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

Pregnacy tests

Your doctor will provide you with information brochures that you must read carefully and may refer you to a gynaecologist, who will explain about contraception and recommend the contraceptive methods suitable for you.

Contraception

Your doctor or gynaecologist will carry out a medically supervised pregnancy test before you start to use the contraception (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 one 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 a new prescription for Isotretinoin 20 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.

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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.

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

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

One month after the end of treatment with Isotretinoin 20 mg another medically supervised pregnancy test must be carried out.

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 20 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 20 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.

The following symptoms are the most commonly reported undesirable effects with isotretinoin: dryness of the skin, dryness of the mucosa e.g. of the lips, the nasal mucosa, and the eyes.

Also the following side effects may occur:

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

- Liver inflammation
- Dryness of the skin, dryness of the mucosa e.g. of the lips, the nasal mucosa, and the eyes.

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

- Inflammation of the eyelid area
- Eye inflammation
- Dry eye
- Eye irritation
- Blood levels of fat like substances (triglyceride) increased
- HDL-cholesterol (high density lipoprotein) decreased
- Decreased night vision
- Red blood cell sedimentation rate increased
- Inflammation of the skin
- Number of blood plates increased or decreased
- Inflammation of lips
- Inflammation of the skin
- Crysis of skin
- Localised shedding of layers of skin
- Itching
- Rash with redness
- Skin fragility (risk of frictional trauma)
- Joint pain
- Muscle pain
- Back pain (particularly in children and adolescent patients)
- Increase in the level of liver enzymes (see Section 2, Before you take Isotretinoin 20mg).

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

- Headache
- Neutrophilic leucocytes decreased
- Redness of the eye (conjunctivitis)
- Nosebleed
- Nasal dryness
- Inflammation of the nasal mucosa, respectively pharyngeal mucosa
- Blood cholesterol increased
- Blood sugar levels (blood glucose) increased
- Blood in the urine
- Excretion of protein in the urine.

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

- 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.

Very rare (may affect up to 1 in every 1000 people)

- Loss of hair.

Other precautions

Isotretinoin 20 mg 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 20 mg 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 20 mg may increase your liver enzyme levels. Your doctor will do some blood tests before, during and at the end of your Isotretinoin 20 mg treatment to check your liver values. In cases where liver enzyme values remain high your doctor may reduce your dose or stop your Isotretinoin 20 mg therapy.

Isotretinoin 20 mg may increase your blood sugar levels and in some cases 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 20 mg therapy.

Contact your doctor

If you have any kind of mental problems, or if you think you have signs of depression while taking Isotretinoin 20 mg 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 for appropriate treatment if necessary. Stopping therapy with Isotretinoin 20 mg 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.

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. 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).

If you suffer from kidney failure. In this case therapy has to begin with a lower dose.

Isotretinoin 20 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. Always be cautious when driving or operating machinery at night because these symptoms may be confused with those of alcohol. 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 any difficulties with your eyes. You should be asked to stop taking Isotretinoin 20 mg.

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 20 mg 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

Unknown frequency (frequency cannot be estimated from available data)

- Dark or cola-coloured urine
- Problems getting or maintaining an erection
- Lower libido
- Breast swelling with or without tenderness in male
- Weight gain
- Sacroiliitis, a type of inflammatory back pain causing pain in your buttocks or lower back
- Inflammation of the urethra.
- Difficulties having an orgasm
- Reduced sensation in the genitals

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the Yellow Card Scheme at: 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 20 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 container. Keep the container stored in the outer carton.

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.

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20 mg has on very rare occasions been associated with inflammatory bowel disease.

What to avoid when taking Isotretinoin 20 mg

Avoid too much sun and do not use a sun-lamp or sun-bed. Your skin may become more sensitive to sunlight during Isotretinoin 20 mg 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 20 mg may make your skin more fragile and this could cause scarring or irritation of the skin.

Reduce intensive physical activity during Isotretinoin 20 mg therapy, because muscle and joint pain have been observed during Isotretinoin 20 mg treatment.

Do not donate blood either during or for one month after Isotretinoin 20 mg 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 during treatment.

Children and adolescents

The use of Isotretinoin 20 mg in children under the age of 12 is not recommended. This is because it is not known if it is safe or effective in this age group. Use in adolescents over 12 years of age only after puberty.

These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Isotretinoin 20 mg contains

The active substance is isotretinoin. Each capsule contains 20 mg of isotretinoin.

The other ingredients are Soya-bean oil (see section 2), DL-alpha-tocopherol, disodium edetate, butylhydroxyanisole, soya-bean oil (partly) hydrogenated, (see section 2), beeswax, yellow and vegetable oil hydrogenated.

The capsule shell contains gelatin, glycerol, sorbit