PACKAGE LEAFLET: INFORMATION FOR THE USER Isotretinoin 10mg Capsules, soft

WARNING

Isotretinoin

CAN SERIOUSLY HARM AN **UNBORN BABY**

Women must use effective contraception

Do not use if you are pregnant of 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 aet. 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 agair 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
- 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: 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

2. BEFORE YOU TAKE ISOTRETINOIN continued...)

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

For more information on pregnamova 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 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.

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 not sure.

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

1. WHAT ISOTRETINOIN IS AND WHAT IT IS USED

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 antiacne treatments, including oral antibiotics.

Isotretinoin treatment must be supervised by a dermatologist (a doctor specialised in the treatment o 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 risks (see under Section 3. 'Children' below).

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 fulf it 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 precautionary measures or you have not understood them, please contact your doctor before you start taking

Do not take Isotretinoin

sotretinoin.

 If you are pregnant or breast-• If there is any chance you could

become pregnant, you must follow the precautions under "Pregnancy and prevention programme", see

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

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 vour doctor may adjust your dose. This will depend on how you are aettina 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 insufficiencv If you have severe kidney problems. sotretinoin 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 vears of age due to insufficient data on efficacy and safety. Use in childern over 12 years 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.

Patients with intolerance If you cannot tolerate the

ecommended dose, your doctor may continue your treatment at a ower dose with the consequence of a longer therapy duration and a nigher risk of relapse

precautions". if you are allergic (hypersensitive) to isotretinoin soya, peanut or any of the

section on "Warnings and

if you have liver disease if you have very high levels of lipids (cholesterol, triglycerides) in vour blood

if you have very high levels of vitamin A in your body (hypervitaminosis A) if vou 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 ake 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 lsotretinoin.

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

Talk to your doctor if you experience persistent pain in your lower back or outtocks during treatment with sotretinoin 10mg. These symptoms may be signs of sacroiliitis, a type of nflammatory back pain. Your doctor may discontinue treatment with sofreting 10mg and refer you to a specialist for treatment of inflammatory back pain Eurther 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 gland). It also

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 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

4. POSSIBLE SIDE EFFECTS

doctor or pharmacist.

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 Frequency not known (frequency

cannot be estimated from available • Serious 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

data)

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for a month before taking

You must use contraceptio

sexually active (unless your

doctor decides this is not

even if you do not have

periods or you are not

necessary).

Isotretinoin

month.

asks vou.

Women must agree to

pregnancy testing before, during and after taking

You must agree to regular

You must agree to have

regular pregnancy tests.

ideally every month during

treatment and, because some

medicine may still be left in

stopping Isotretinoin (unless

vour doctor decides this is not

pregnancy tests if your doctor

your body, 1 month after

necessary in your case).

You must not get pregnant

month afterwards because

Your doctor will discuss all

some medicine may still be

these points with you, using a

parent/guardian) to sign it.

and that you will follow the

If you get pregnant while taking

contact your doctor. Your docto

may send you to a specialist for

Isotretinoin, stop taking the

medicine straight away, and

Also, if you become pregnant

within one month after you stop

contact your doctor. Your doctor

may send you to a specialist for

Written information on this

subject is available from your

this material please contact

vour doctor.

and ankles.

mmediatelv

vour doctor.

doctor. If you haven't received

Very rare effects (may affect up to

Sudden tight chest, shortness of

breath and wheezing, particularly

If vou have a serious reaction, get

If you have any allergic reaction,

stop taking Isotretinoin and contact

Frequency not known (frequency

cannot be estimated from available

Muscle weakness which can be

arms or leas, painful, swollen.

bruised areas of the body, dark

urine output, confusion or

activity while you're on

Liver and kidney problems

1 in every 10,000 people)

hepatitis. Stop taking

contact your doctor

Difficulty urinating (passing

may be signs of kidney

contact your doctor.

inflammation. Stop taking

Nervous system problems

Lasting headache, along with

intracranial hypertension

1 in every 10,000 people)

Very rare effects (may affect up to

Yellow skin or eves, and feeling

Isotretinoin straight away and

water), swollen and puffy eyelids,

feeling excessively tired. These

Isotretinoin straight away and

Very rare effects (may affect up to

feeling sick (nausea), being sick

eyesight including blurred vision.

(vomiting) and change in your

These may be signs of *benign*

especially if Isotretinoin is taken

with antibiotics called tetracycline.

tired. These can be signs of

Isotretinoin.

coloured urine, reduced or no

dehydration. These are signs of

rhabdomvolvsis, a breakdown of

muscle tissue which can lead to

kidnev failure. This may occur if

vou are doing intensive physical

potentially life-threatening, may

be associated with trouble moving

in every 10,000 people)

if you have asthma.

Bones and muscles

emergency medical help

taking Isotretinoin, you should

This form confirms that you

have been told about the risks

checklist and will ask you (or a

during treatment or for a

left in your body.

rules above.

You must agree to extra

follow-up visits, ideally every

- 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
- 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

- 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 vou 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 verv 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.

- 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 (flulike symptoms). 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
- Depression or related disorders Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort.
- Existing depression aetting 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

- Prescriptions are limited to 30 You must use contraception days treatment for women of childbearing potential. Isotretinoin, during treatmen Continuation of treatment requires a and for a month afterwards
 - new prescription, and each prescription is only valid for seven
 - Pregnancy tests Your doctor will provide you with nformation 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. 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 documen the date and result of this pregnancy

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 s negative, your doctor will issue your first prescription for Isotretinoir 0 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 treatmen

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

throat, face, lips and mouth. Also **Stop taking Isotretinoin straight** sudden swelling of the hands, feet away and contact your doctor

- Gut and stomach problem **Verv rare effects** (may affect up to 1 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

top taking Isotretinoin straight away and contact your doctor.

Eve disorders Very rare effects (may affect up to 1 in every 10,000 people) Blurred vision.

f 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) Drvness of the skin, especially of the lips and face: inflamed skin. 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 usual, especially the
- 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 evelid area: eves feel drv 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 trialvcerides)
- Bruising, bleeding or clotting more easily -if clotting cells are affected
- Anaemia weakness, dizziness, pale skin - if red blood cells are affected.

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 davs (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 anvone.

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

Mental health problems

You may not notice some changes ir 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 **vour blood.** Your doctor will do some blood tests in order to monitor these levels before, during

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

- 10 people) Headache
- Higher levels of cholesterol in the 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

Very rare side effects with Isotretinoin: (may affect up to 1 in

treatment ends.

- 10.000 people) You may see less well at night; colour blindness and colour
- vision gets worse Sensitivity to light may increase you may find that you need to wear sunglasses to protect your eves from too bright sunlight
- Other sight problems including blurred vision, distorted vision. cloudy surface on the eve (corneal opacity, cataracts)
- Excessive thirst: frequent need to urinate: blood tests show an increase in your blood sugar These can all be signs of diabetes
- www.mhra.gov.uk/vellowcard or Acne can get worse in the first search for MHRA Yellow Card in the few weeks, but symptoms should Google Play or Apple App Store, By improve with time reporting side effects you can help Skin inflamed, swollen, and provide more information on the safety of this medicine.
- darker than usual, especially on the face Excess sweating or itching
- Arthritis; bone disorders (delayed growth, extra growth and changes to bone density); growing bones may stop growing
- 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

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 o 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 vour 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 for 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 n 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 drv eves 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
- Swellings, discharging, pus
- Thickened scarring after surgery Increased body hair Convulsions, drowsiness,
- dizziness Lymph glands may become
- Drv throat, hoarseness
- Hearing difficulties Generally feeling unwell High levels of uric acid in the
- Bacterial infections Inflammation of the blood vessels (sometimes with
- bruising, red patches). **Unknown frequency:** (frequency
- cannot be estimated from the available data)
- Dark or cola-coloured urine Problems getting or maintaining an erection
- Lower libido Breast swelling with or without
- tenderness in males Vaginal dryness.
- 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

5. HOW TO STORE

last day of that month.

children.

ISOTRETINOIN

Keep out of the sight and reach of

Do not use Isotretinoin after the

expiry date which is stated on the

carton. The expiry date refers to the

beeswax. vellow genitals Capsule shell Gelatin Reporting of side effects: alvcerol If you get any side effects, talk to sorbitol solution 70%, liquid (nonour doctor, pharmacist or nurse crystallising) (E420) This includes any possible side effects not listed in this leaflet. You

purified water titanium dioxide (E171) can also report side effects directly via the Yellow Card Scheme at: The soft capsules also contain erythrosine colourant soluble (E127) and black iron oxide (E172).

What Isotretinoin looks like and contents of the pack Isotretinion 10 mg soft gelatin capsules are light violet coloured. oval, with no markings.

The capsules come in blister packs of 28, 30, 56 or 60 capsules. [Not all pack sizes may be marketed.]



suddenly. Tell your doctor if you have any of these symptoms. You doctor may ask you to use lubricating eve ointment or tea 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

Stop treatment immediately and contact your doctor as soon as

asked to stop taking Isotretinoin.

possible

hypertension.

bowel disease.

least SPF 15

irritation of the skin.

doctor tells you to.

the environment.

isotretinoin.

INFORMATION

hydrogenated vegetable oil.

Isotretinoin

If you experience severe

 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 verv rarely associated with a condition called benign intracranial

haemorrhagic diarrhoea (e.g. blood in your stool). Isotretinoi has on verv rare occasions been associated with inflammatory

What to avoid when taking Avoid too much sun and do not use a sun-lamp or sun-bed. Your skin may become more sensitive to sunlight during Isotretingin therapy. Before going out in the

sun apply a sun-protection product with a high protection factor of at 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 Reduce intensive physical activity during Isotretinoin therapy, because muscle and joint

pain have been observed during 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

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect

6. CONTENTS OF THE PACK AND OTHER

What Isotretinoin contains Each capsule contains 10mg of

The other ingredients are Capsule Soya-bean oil, refined, All-rac-αtocopherol disodium edetate. butylhydroxyanisole (E320), sovabean oil partly hydrogenated

 Isotretinoin has been associated with sexual problems. These include problems getting or maintaining an erection, lower libido, vaginal dryness, orgasm difficulties and educed sensation in the genitals There have been reports of longlasting 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 sotretinoin 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 pregnan 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 sotretinoin, 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 ar unborn baby (in medical language is teratogenic). It also increases the risk of miscarriage.

Marketing Authorisation Holder and Manufacturer nogen Healthcare Limited Unit G4, Riverside Industrial Estate Riverside Way, Dartford, DA1 5BS, IIK

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

Innogen Healthcare