

PATIENT INFORMATION LEAFLET – ORAL ISOTRETINOIN

Isotretinoin is an oral treatment for severe types of acne. Although isotretinoin is an effective treatment for severe acne, it has important side effects and should not be used by some people, particularly by women who might be pregnant or are considering becoming pregnant. The issue of isotretinoin in pregnancy is discussed in further detail below.

The following information summarises the main advice for use of, and side effects associated with isotretinoin. **This is not a complete list and anyone prescribed isotretinoin should read carefully the patient information leaflet, which accompanies the medicine.** Anyone with concerns about acne or its treatment should discuss them with their dermatologist.

Isotretinoin is an anti-inflammatory agent derived from vitamin A. A course of treatment usually lasts between 4 and 6 months, and at least 8 weeks should pass before another course is given.

The following people should not receive treatment with isotretinoin:

- Children aged 12 years or younger
- Women who are, or who might be, pregnant (see below)
- Women who are breast-feeding
- People with impaired liver function
- People with high levels of fat in their blood
- People with hypervitaminosis A (presence of too much vitamin A in the body)
- People who are allergic to peanuts, soya, or the sugar sorbitol: isotretinoin contains these ingredients
- Isotretinoin should be used with caution in people with: a history of depression (see below); diabetes; dry-eye syndrome; and impaired kidney function

Please do not take any medicine alongside isotretinoin treatment

BLOOD TESTS

Before starting isotretinoin you will need to have a blood test to check that your lipids (cholesterol and triglyceride) and liver function is normal. The test should be done after fasting from midnight the night before and have nothing to eat or drink except water until after the test has been performed.

Advice for people who have been prescribed isotretinoin:

- Attend all appointments scheduled for you, which should be about once a month. This ensures that the specialist can check the medicine is working safely for you
- An improvement in the appearance of the skin may not be seen for until a few months of treatment. There may also be a slight worsening of acne on starting treatment, which usually subsides in 7-10 days
- Some side effects of isotretinoin are dose-related; some are generally reversible after changing the dose or stopping treatment; and some may persist after treatment has stopped
- Lip balm, moisturisers, and eye ointment may help alleviate any drying of the skin
- Avoid the sun and exposure to ultraviolet light (i.e. avoid the use of tanning beds); use sunscreen (sun protection factor, SPF, 15) from the start of treatment
- Avoid waxing, surgical dermabrasion, or laser surgery of the skin during treatment and for at least 6 months after stopping. This will help prevent any stripping, scarring, or pigmentation of the skin
- Do not donate blood while you are taking isotretinoin and for at least one month after stopping. This will help prevent transmission of the drug to those who should not receive it
- Do not give your medication to anyone else. Return any unused capsules to the pharmacy

Effects on the skin

Some side effects of isotretinoin on the skin are very common, such as inflammation and cracking of the lips, dermatitis (inflammation of the skin), dry skin, itching, red rash and fragile skin (easy bruising). These effects vary in severity, frequency, and duration between patients. Use of a skin moisturiser cream or ointment, and use of a lip balm, may help relieve dryness of the skin and lips. Occasionally patients develop nosebleed, using Vaseline to moisturise the inside of your nose twice daily helps.

Psychiatric side-effects

Depression, aggravation of existing depression, aggressive tendencies, anxiety, and changes in mood have been reported rarely in patients taking isotretinoin. Abnormal behaviour, psychotic disorder, suicidal ideation, suicide attempt, and suicide have been reported very rarely (ie, in one in every 10,000 patients or fewer). Before starting treatment patients should inform their doctor if they have, or have ever had, depression. During treatment, family and friends may be able to help the patient monitor their mood, and the doctor will ask about any changes in mood during follow up appointments. If a patient receiving isotretinoin develops symptoms of depression or mood changes it may be necessary for isotretinoin treatment to stop. Some patients may want to continue treatment and can be offered support while treatment is ongoing. Side effects are generally reversible after stopping treatment; however, some may persist after treatment stops.

Pregnancy

Isotretinoin is a teratogen - that is, if taken by pregnant women, it may cause serious harm to the developing baby, even if taken only for a short period. The possibility of pregnancy must be excluded before a woman of child-bearing potential can begin isotretinoin, and measures must be taken to ensure women taking isotretinoin, or who have recently stopped isotretinoin, do not become pregnant. Your isotretinoin

capsules would also put a female friend or relative in danger of a deformed baby if you shared them. Treatment with isotretinoin during pregnancy is not allowed under any circumstances.

Important information for FEMALE patients

- You must not take isotretinoin if you are pregnant.
- You must not become pregnant while taking isotretinoin, or for 1 month after you stop taking isotretinoin.
- Severe birth defects have occurred in babies of women taking isotretinoin in any amount –even for short periods - during pregnancy. There is an extremely high risk that your baby will be born deformed if you are pregnant or become pregnant while taking isotretinoin. There is also an increased risk of losing the baby before it is born (miscarriage).
- Your doctor will ask you to read and sign a form to show that you understand some of the serious risks associated with isotretinoin.
- You will not get your first prescription for isotretinoin until you have had at least one negative medically supervised pregnancy test or if you are not at risk of becoming pregnant.
- If you are at risk of becoming pregnant you will have a pregnancy assessment every month during your isotretinoin therapy, and a final pregnancy test needs to be done 5 weeks after your isotretinoin treatment has finished. You can only get a prescription each month by returning to your specialist or doctor to have a pregnancy assessment.
- You will need to discuss effective contraception with a doctor or nurse. If you are at risk of becoming pregnant you must use at least one, and preferably two, effective forms of contraception at the same time for at least one month before beginning treatment, during treatment, and for one month after isotretinoin treatment has stopped. Any contraceptive method can fail, including oral contraceptives (the pill) and injectable/implantable contraceptive devices – therefore it is strongly recommended that you use two forms of contraception at the same time, and that one of the two methods is a barrier method such as a male condom.
- Stop taking isotretinoin and contact your doctor immediately, if you have unprotected sex, miss your period or become pregnant while you are taking isotretinoin or in the month after you have stopped isotretinoin treatment.
- Treatment with isotretinoin does not affect your fertility. One month after you have stopped treatment, isotretinoin will no longer be present in your body, and will have no effect on your ability to have healthy children in the future.
- Talk to your doctor if you plan to take other medicines or herbal products. This is especially important for women using contraceptive pills and other types of hormonal contraceptives. Certain medicines and herbal supplements such as St John's wort may make contraceptives less effective. You should therefore avoid taking St John's wort during treatment with isotretinoin.
- Do not breast feed during isotretinoin treatment or for one month after you have stopped taking isotretinoin. It is likely that isotretinoin can pass into breast milk and may harm the baby.
- It is important that you do not share this medicine with anyone else, particularly other females, even if they have the same condition as you.
- Do not give blood during isotretinoin treatment or for one month after you have

stopped. If someone who is pregnant receives your donated blood, her baby may be born with serious birth defects.

- If you have any left-over isotretinoin capsules, you must not give these to anyone else. Doing so can cause birth defects and other serious health problems. Take any left-over capsules to your pharmacy for safe disposal.
- Please use your prescription to collect your supply of isotretinoin within seven days from the date written on the prescription. The pharmacy will not dispense your prescription beyond this seven-day deadline.

Important information for MALE patients

- Studies have shown that isotretinoin therapy does not influence the formation and quality of sperm. Isotretinoin and its metabolites are present at very low levels in your semen. These levels are considered too low to harm the unborn baby of your female partner.
- It is important that you do not share this medicine with anyone else, particularly females, even if they have the same condition as you.
- Do not give blood during isotretinoin treatment or for one month after you have stopped. If someone who is pregnant receives your donated blood, her baby may be born with serious birth defects.
- If you have any left-over isotretinoin capsules, you must not give these to anyone else. Doing so can cause birth defects and other serious health problems. Take any left-over capsules to your pharmacy for safe disposal.