



Isotretinoin 5mg Capsules (Isotretinoin)

Isotretinoin 20mg Soft Capsules (Isotretinoin)

Pregnancy Prevention Programme

Patient Information Brochure

ABOUT THIS BROCHURE

This brochure contains important information about your treatment with Isotretinoin in relation to minimising the risks of possible birth defects with this medicine. You will need to read this brochure carefully before you start taking Isotretinoin.

This brochure describes some of the important facts about Isotretinoin that you need to be aware of, however, it does not replace the advice given to you by a healthcare professional such as your dermatologist or pharmacist. Further very important information about Isotretinoin including how to take it, special warnings and side effects are included in the patient information leaflet which is supplied in each package of Isotretinoin Capsules. Please remember to read the patient information leaflet very carefully.

If you have any further questions or concerns about taking Isotretinoin after you have read this brochure, you should talk to your dermatologist or doctor.

ISOTRETINOIN AND BIRTH DEFECTS

No medicine is completely free from adverse effects. One of the most serious side effects you risk with Isotretinoin is severe and serious birth defects if you 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. If an unborn child is exposed to Isotretinoin this can result in severe and serious defects (malformations) in the child.

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 Isotretinoin 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 Capsules 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 Isotretinoin 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.

Malta ADR Reporting Website :
www.medicinesauthority.gov.mt/adrportal

▼ This medicinal product is subject to additional monitoring.

Date of preparation: Feb 2014

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