

Acitretin

10mg and 25mg Capsules

Patient guide when using acitretin

Pregnancy and Foetal
Exposure Prevention

MORNINGSIDE
HEALTHCARE

What this brochure is for

This brochure contains important information, especially for women of child-bearing age, as the risk of birth defects is high if Acitretin Capsules are taken during pregnancy or for a period after treatment has finished. Please read this brochure carefully before you start taking Acitretin Capsules.

Severe birth defects have occurred in babies of women taking acitretin in any amount – even for short periods – during pregnancy. These include serious central nervous system and heart defects; hearing and visual impairment; malformed ears; facial abnormalities such as high palate; malformations of bones and abnormalities of the thymus. There is also an increased risk of miscarriage.

Important information for women taking Acitretin Capsules

Acitretin Capsules contain the active ingredient acitretin, which causes severe birth defects in pregnancy and is also slowly removed from the body. **Therefore if you are a woman of childbearing age, you must not be or become pregnant during treatment or for 3 years after stopping treatment.**

Adequate contraception is essential

- **Discuss suitable, effective and ongoing contraception with your doctor.**
- **Any contraceptive method can fail – therefore you must use two effective forms of contraception at the same time. At least one of the methods must be a primary method**
 - **Primary methods include:** intrauterine devices, injectable/implantable/insertable hormonal contraceptive products, oral contraceptives (the pill) and contraceptive patches when used carefully, tubal ligation, partner's vasectomy.
 - **Barrier methods include:** male condom, diaphragm/cap with spermicide.
- **Low-dose progesterone-only contraceptives (“minipills”) are not recommended.**
- **You must have been using contraceptives at least 4 weeks before starting treatment with Acitretin Capsules.**
- **Use your contraception continuously. Do not stop using contraceptives at any point during treatment with Acitretin Capsules.**
- **You must not get pregnant for three years after stopping treatment. Therefore, you must continue to use the recommended contraceptives for 3 years after you have finished treatment with Acitretin Capsules.**

Regular pregnancy testing

To make sure you are not pregnant during treatment, your doctor will carry out a pregnancy test before treatment starts with Acitretin Capsules.

As Acitretin Capsules treatment should be started on the second or third day after a normal menstrual cycle the pregnancy test should not be done earlier than 3 days before start of treatment.

Before each month renewal of Acitretin Capsules prescription, your doctor will also want you to have a pregnancy test.

After completion of treatment, you will need to have a pregnancy test every 1-3 months for a period of 3 years.

If you become pregnant during or after treatment

If you have unprotected sex or miss your period while you are taking Acitretin Capsules or in the 3 years after you have stopped treatment, stop taking Acitretin Capsules (if treatment is still ongoing) and contact your doctor immediately.

If despite precautions, you become pregnant during treatment or within the 3 years after stopping Acitretin Capsules, the risk of extremely severe foetal malformations in the unborn baby is high. If you become pregnant during treatment stop taking Acitretin Capsules immediately. Contact your prescribing doctor or your nearest healthcare centre without delay for support and advice.

Do not breast-feed during Acitretin Capsules treatment

Do not take Acitretin Capsules if you are breast-feeding. Acitretin Capsules can pass into breast milk and may harm the baby.

Avoid alcohol

If alcohol is taken during treatment with Acitretin Capsules, a compound called etretinate can form which is removed very slowly from the body and can make the risk of birth defects last longer than 3 years. Therefore women of child-bearing age must not consume alcohol and should avoid all products containing alcohol (drinks, foods, and medicines) during treatment and for 2 months after stopping treatment.

Prescription is only valid for 7 days

Please use your prescription to collect your supply of Acitretin Capsules within seven days from the date written on the prescription. The pharmacy will not dispense your prescription beyond this seven-day deadline.

All of the above mentioned precautions must be followed, even if you are not sexually active, have amenorrhoea (you do not have menstrual periods) or are infertile (except in cases when the uterus has been removed (hysterectomy)).

Acknowledgement form

Your doctor will ask you to read and sign an 'Acknowledgement Form for Female Patients' to show that you understand the serious risks associated with acitretin and the preventive measures that need to be taken.

Important information for men taking Acitretin Capsules

Studies have shown that acitretin therapy does not influence the formation and quality of sperm. Acitretin 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.

Important information for both women and men taking Acitretin Capsules

Giving blood during Acitretin Capsules treatment

Acitretin is carried in the blood. Acitretin in blood transfusions might harm unborn babies if given to pregnant women. Therefore both women and men treated with Acitretin Capsules must not give blood during treatment and for three years after completion of treatment.

Other medicines or herbal products

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 may make contraceptives less effective.

This medicine has been prescribed only for your personal use

You should never give this medicine to anyone else. Doing so can cause harm to unborn babies or other serious health problems. You should return any unused or expired medicines to the pharmacy for disposal.

Acknowledgement form

Your doctor will ask you to read and sign an acknowledgement form to show that you understand the serious risks associated with acitretin and the preventive measures that need to be taken.

Other information

While this brochure gives important facts about Acitretin Capsules that you need to be aware of, it does not replace the advice given to you by your dermatologist, doctor or pharmacist.

Further information (such as how to take Acitretin Capsules, special warnings and possible side effects) is included in the patient information leaflet, which is supplied in each pack of Acitretin Capsules.

Please read this leaflet carefully

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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Adverse events should be reported.

Reporting forms and information can be found at www.yellowcard.gov.uk.

Adverse events should also be reported to Morningside Healthcare Ltd.'s Medical Information Department on Tel: 0345 459 2137. Email: medicalenquiry@Morningsidehealthcare.com

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