

# Acitretin

10mg and 25mg Capsules

## *Pharmacist's guide to dispensing acitretin*

Pregnancy and Foetal Exposure Prevention



## Introduction

Acitretin Capsules contain the active substance acitretin, which is highly teratogenic.

- There is a very high risk that foetal exposure to acitretin will result in life threatening congenital abnormalities (e.g. craniofacial defects, cardiovascular or CNS malformations, skeletal and thymic defects) and spontaneous abortions.
- There is a risk that acitretin (half-life approximately 50 hours) can be transformed to etretinate which is also teratogenic and has a very long half-life of approximately 120 days.
- There is a high risk of severe malformation of the foetus should women become pregnant during treatment, or within a 3 year period after cessation of treatment.
- Concurrent ingestion of acitretin and alcohol has been associated with the formation of etretinate which is also highly teratogenic. Women of childbearing potential must therefore not consume alcohol (in drinks, food or medicine) during treatment with acitretin and for 2 months following discontinuation of treatment.
- Women of childbearing potential must not receive blood from patients being treated with acitretin. Therefore donation of blood by a patient being treated with acitretin is prohibited during and for 3 years after completion of treatment with acitretin.

The acitretin **Pregnancy and Foetal Exposure Prevention Programme** has therefore been developed to ensure that female patients are not pregnant when starting acitretin and do not become pregnant during acitretin therapy or for at least 3 years after stopping acitretin treatment. The programme also describes measures for other patient groups to decrease the risk of foetal exposure.

This brochure provides a guide to dispensing Acitretin Capsules in accordance with the Pregnancy and Foetal Exposure Prevention Programme.

This guide only provides a summary of the Pregnancy and Foetal Exposure Prevention Programme. For full details and other prescribing information (including details of undesirable effects), please refer to the currently approved Summary of Product Characteristics (SmPC) for Acitretin Capsules.

### The teratogenic risks of acitretin

If pregnancy occurs either during treatment with acitretin or in three years following the end of treatment, there is a great risk of very severe and serious foetal malformations.

There is also an increased risk of spontaneous abortion.

**The Acitretin Capsules Pregnancy and Foetal Exposure Prevention Programme should be followed for all female patients at risk of pregnancy.**

### The programme consists of 3 parts:

- Educational programme
- Therapy management
- Distribution control

### Educational program

The purpose of the educational programme is to:

- enhance the understanding of the teratogenic risks of acitretin by both patients and physicians
- enhance female patient information awareness and acknowledgement

As part of the educational programme the following brochures/forms are provided:

- Doctor's guide to prescribing acitretin
- Doctor's checklist for prescribing to female patients
- Pharmacist's guide to dispensing acitretin (this document)
- Acknowledgement form for female patients
- General acknowledgement form for patients
- Patient Guide when using acitretin

### **Therapy Management**

The therapy management is based upon:

- provision of educational material to patients
- pregnancy testing (with a minimum sensitivity of 25mIU/mL) before, during and for 3 years after end of treatment
- use of two effective methods of contraception simultaneously. The patient must use two complementary forms of contraception for at least one month before initiating therapy, continuing throughout the treatment period, and then for at least 3 years after stopping therapy. At least one of the methods must be a primary method (see examples below).

### **Distribution control**

Distribution control involves that the prescription of acitretin for women should be limited to a 30 day supply and the prescription will only be valid for 7 days.

## *Conditions of prescribing acitretin in female patients at risk of pregnancy*

Acitretin Capsules should only be prescribed by physicians experienced in the use of systemic retinoids.

Acitretin is contraindicated in women of childbearing potential unless all of the following conditions of the Pregnancy Prevention Programme are met:

- She is suffering from a severe disorder of keratinisation which is resistant to standard therapies.
- She understands the teratogenic risk.
- She understands the need for rigorous follow-up, on a monthly basis.
- She understands and accepts the need for effective contraception, without interruption, 1 month before starting treatment, throughout the duration of treatment and for 3 years after the end of treatment. Two complementary forms of contraception must be used simultaneously, at least one of which must be a primary form.

Primary contraceptive methods include: intrauterine devices, injectable/implantable/insertable hormonal contraceptive products, combination oral contraceptives and contraceptive patches when used carefully, tubal ligation, partner's vasectomy. Low dose progesterone-only products (minipills) are not recommended due to indications of possible interference with their contraceptive effect.

Barrier methods include: male condom, diaphragm/cap with spermicide.

- Even if she has amenorrhoea she must follow all of the advice on effective contraception.
- She should be capable of complying with effective contraceptive measures.
- She is informed and understands the potential consequences of pregnancy and the need to rapidly inform of any omission of contraception, unprotected intercourse or suspected pregnancy.
- She understands the need and accepts to undergo pregnancy testing before, during and for 3 years after the end of treatment.
- She has been counselled that she must avoid alcohol consumption (drink, food, medicines) during treatment with acitretin and for 2 months following discontinuation of treatment. Concomitant use of acitretin and alcohol has been found to lead to formation of the highly teratogenic etretinate, which eliminates more slowly from the body than acitretin.
- She has acknowledged that she has understood the hazards and necessary precautions associated with the use of acitretin.

These conditions also concern women who are not currently sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

The prescriber, must ensure that:

- The patient complies with the conditions for pregnancy prevention as listed above, including confirmation that she has an adequate level of understanding.
- The patient has acknowledged the aforementioned conditions.
- The patient has used two methods of effective contraception simultaneously for at least 1 month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least 3 years after cessation of treatment.
- Negative pregnancy test results have been obtained before, during and for 3 years after the end of treatment. The dates and results of pregnancy tests should be documented.

## *Additional precautions*

### **Female patients not at risk of pregnancy**

It is important that female patients not at risk of pregnancy are warned of the teratogenic risks of acitretin. The importance of contraception should also be discussed with these patients as a woman not at risk of pregnancy at the start of acitretin therapy may have a change in circumstances. All women should sign the acknowledgement form for female patients to confirm that they have been informed of the risks of teratogenicity with acitretin. Full patient information about the teratogenic risk of acitretin and the strict pregnancy prevention measures should be given to female patients not at risk of pregnancy.

### **Male patients**

The available data suggest that the level of maternal exposure from the semen of male patients receiving acitretin is not of a sufficient magnitude to be associated with the teratogenic effects of acitretin.

However, male patients should be reminded that they must not share their medication with anyone, particularly not females. Full patient information about the teratogenic risk of acitretin and the strict pregnancy prevention measures should be given to male patients.

### **All patients**

Patients should be instructed never to give acitretin to another person and to return any unused capsules to their pharmacist at the end of treatment. All patients should sign the acknowledgement form and be told not to donate blood during therapy and for 3 years following discontinuation of acitretin because of the potential risk to the foetus of a pregnant transfusion recipient.

## *Dispensing restrictions for acitretin*

**Under the Pregnancy and Foetal Exposure Prevention Programme the following dispensing restrictions apply to acitretin prescriptions:**

1. Prescriptions of acitretin for women should be limited to 30 days of treatment and the prescription is only valid for 7 days.
  - Under the Pregnancy and Foetal Exposure Prevention Programme prescriptions presented more than 7 days after the prescription date should be considered expired and the patient should be told to get a new prescription from their prescriber. For some female patients this may require a further negative pregnancy test.
  - If a prescription for more than 30 days treatment is received for a female patient, the prescriber should be contacted to confirm whether or not the patient is in the Pregnancy and Foetal Exposure Prevention Programme. If the patient is not being treated under the Pregnancy and Foetal Exposure Prevention Programme the acitretin can be dispensed.
  - If in doubt check with the prescriber.



2. Prescriptions for male patients do not have a limit on the duration of treatment to be dispensed or restriction on the period the prescription is considered valid.
3. Ideally, pregnancy testing, issuing a prescription and dispensing acitretin should occur on the same day.
4. Do not accept:
  - Telephone-transmitted prescriptions for acitretin
  - Repeat prescriptions
  - Free sample distribution
5. All patients should be instructed:
  - Never to give this medicine to another person
  - To return any unused capsules to their pharmacist at the end of treatment.
  - Not to donate blood during therapy and for 3 years following discontinuation of acitretin because of the potential risk to the foetus of a pregnant transfusion recipient.

## *Further information*

For further information about the Acitretin Capsules Pregnancy and Foetal Exposure Prevention Programme, please contact Morningside Healthcare Ltd., Telephone: 0345 459 2137  
Email: [medicalenquiry@Morningsidehealthcare.com](mailto:medicalenquiry@Morningsidehealthcare.com)

### **Further supplies of the Acitretin Capsules Pregnancy and Foetal Exposure Prevention Brochures and Forms**

Pregnancies occurring during treatment and within 3 years following discontinuation of treatment should be reported.

Health professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme (Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)).

**Adverse events should be reported.**

**Reporting forms and information can be found at [www.yellowcard.gov.uk](http://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](mailto:medicalenquiry@Morningsidehealthcare.com)**

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