Pharmacist's guide to dispensing isotretinoin

Isotretinoin Actavis (isotretinoin)

10 mg and 20 mg soft capsules

Pregnancy and Foetal Exposure Prevention

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Actavis

Introduction

Isotretinoin Actavis contains the active substance isotretinoin, which is highly teratogenic.

There is an extremely high risk that foetal exposure to isotretinoin will result in life threatening congenital abnormalities. The isotretinoin **Pregnancy and Foetal Exposure Prevention Programme** has therefore been developed to ensure that female patients are not pregnant when starting isotretinoin and do not become pregnant during isotretinoin therapy or for at least one month after stopping isotretinoin treatment. The programme also describes measures for other patient groups to decrease the risk of foetal exposure.

This brochure provides a guide to dispensing Isotretinoin Actavis 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 Isotretinoin Actavis.

The teratogenic risks of isotretinoin

If pregnancy occurs either during treatment with isotretinoin or in the month following the end of treatment with isotretinoin there is a great risk of very severe and serious foetal malformations. There is also an increased risk of spontaneous abortion.

The Isotretinoin Actavis 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 isotretinoin by both patients and physicians
- enhance female patient information, awareness and acknowledgement.

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

- Doctor's guide to prescribing isotretinoin
- Doctor's checklist for prescribing to female patients
- Pharmacist's guide to dispensing isotretinoin (this document)
- Acknowledgement form for female patients
- General acknowledgement form for patients
- Patient information brochure

Therapy management

The therapy management is based upon:

- provision of educational material to patients
- medically supervised pregnancy testing before, during and 5 weeks after end of treatment
- use of at least one effective method of contraception. Preferably the patient should use two complementary forms of contraception including a barrier method for at least one month before initiating therapy, continuing throughout the treatment period, and then for at least one month after stopping therapy.

Distribution control

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

Conditions of prescribing isotretinoin in female patients at risk of pregnancy

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

- She has severe acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy
- 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 1 month after the end of treatment. At least one and preferably two complementary forms of contraception including a barrier method should be used.
- Even if she has amenorrhea 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 consult if there is a risk of pregnancy.
- She understands the need and accepts to undergo pregnancy testing before, during and 5 weeks after the end of treatment.
- She has acknowledged that she has understood the hazards and necessary precautions associated with the use of isotretinoin.

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 at least one and preferably two methods of effective contraception including a barrier method for at least 1 month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least 1 month after cessation of treatment.
- Negative pregnancy test results have been obtained before, during and 5 weeks 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 isotretinoin. The importance of contraception should also be discussed with these patients as a woman not at risk of pregnancy at the start of isotretinoin therapy may have a change in circumstances. All women should sign the acknowledgement for female patients form to confirm that they have been informed of the risks of teratogenicity with isotretinoin. Full patient information about the teratogenic risk of isotretinoin 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 isotretinoin is not of a sufficient magnitude to be associated with the teratogenic effects of isotretinoin.

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 isotretinoin and the strict pregnancy prevention measures should be given to male patients.

All patients

Patients should be instructed never to give isotretinoin 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 1 month following discontinuation of isotretinoin because of the potential risk to the foetus of a pregnant transfusion recipient.

Dispensing restrictions for isotretinoin

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

1. Prescriptions of isotretinoin 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 isotretinoin 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 isotretinoin should occur on the same day.

4. Do not accept:
   - Telephone-transmitted prescriptions for isotretinoin
   - 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 1 month following discontinuation of isotretinoin because of the potential risk to the foetus of a pregnant transfusion recipient.

Further information

For further information about the Isotretinoin Actavis Pregnancy and Foetal Exposure Prevention Programme, please contact <[To be completed nationally]>.

Further supplies of the Isotretinoin Actavis Pregnancy and Foetal Exposure Prevention Brochures

To obtain further supplies of the Isotretinoin Actavis Pregnancy and Foetal Exposure Prevention Programme educational materials, please contact <[To be completed nationally]>.

Date of preparation: <[To be completed nationally]>

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