



Isotretinoin 5mg Capsules (Isotretinoin)

Isotretinoin 20mg Soft Capsules (Isotretinoin)

Pregnancy Prevention Programme

Physician's guide to prescribing Isotretinoin

INTRODUCTION

Isotretinoin is highly teratogenic. There is an extremely high risk that foetal exposure to Isotretinoin will result in life threatening congenital abnormalities. The Isotretinoin Pregnancy Prevention Programme (PPP) 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.

This guide provides a summary of the Pregnancy Prevention Programme. For full details of the Pregnancy Prevention Programme please refer to the Isotretinoin Summary of Product Characteristics (SPC) under section 4.4 Special warnings and special precautions for use.

This brochure should be used in conjunction with the Physician's checklist for prescribing to female patients.

PLEASE NOTE THAT THIS GUIDE PROVIDES INFORMATION RELATING TO ISOTRETINOIN PREGNANCY PREVENTION ONLY – FOR FULL PRESCRIBING INFORMATION INCLUDING DETAILS OF ADVERSE REACTIONS, PLEASE REFER TO THE ISOTRETINOIN SPC.

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 malformation of the foetus.

The foetal malformations associated with exposure to Isotretinoin include:

- Central nervous system abnormalities (hydrocephalus, cerebellar malformation & abnormalities, microcephaly)
- Facial dysmorphism
- Cleft palate
- External ear abnormalities (absence of external ear, small or absent external auditory canals)
- Eye abnormalities (microphthalmia)
- Cardiovascular abnormalities (conotruncal malformations such as tetralogy of Fallot, transposition of great vessels, septal defects)
- Thymus gland abnormality and parathyroid gland abnormalities.

There is also an increased incidence of spontaneous abortion.

ISOTRETINOIN PREGNANCY PREVENTION PROGRAMME

The Pregnancy Prevention Programme should be followed for *all female patients at risk of pregnancy*.

The Pregnancy Prevention Programme consists of 3 parts:

- Educational programme
- Therapy management
- Distribution control

Educational programme

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 available:

- Physician's guide to prescribing Isotretinoin
- Physician's checklist for prescribing to female patients
- Pharmacist's Guide to Dispensing
- Acknowledgement form for female patients
- Patient information brochure
- Brochure on contraception

Therapy management

The basic components of therapy management in the Isotretinoin Pregnancy Prevention Programme are:

- provision of educational material to patients.
- medically supervised pregnancy testing before, during and 5 weeks after end of treatment with Isotretinoin.
- use of at least one method of contraception and preferably 2 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

Under the Pregnancy Prevention Programme the prescription of Isotretinoin Capsules should be limited to a 30 day supply. In addition the prescription for Isotretinoin Capsules is only 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, one month before starting treatment, throughout the duration of treatment and one 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 one month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least one 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 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 be told not to donate blood during therapy and for one 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 Pregnancy Prevention Programme, please contact:

Dr. Andrew Burbage (QPPV)
QPPV
Callisto Consulting Limited
Iron Farm
7 Grimesgate, Diseworth
Leicestershire
DE74 2QD
Mob: 07764 673 805
Fax: 01332 853 950
Email: andrew@callisto-consulting.co.uk

Further supplies of the Isotretinoin Pregnancy Prevention Programme Educational Materials

To obtain further supplies of the Educational materials, please contact:

Mr. Bhavin Kalola
Ennogen Healthcare Ltd
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford
DA1 5BS

Tel: 01322 629 220
Fax: 01322 311 897
Email: bhavin@ennogen.com

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

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▼ This [medicinal product](#) is subject to additional monitoring.