Roaccutane Pregnancy Prevention Programme Checklist for Prescribing to Female Patients

Roaccutane is highly teratogenic. There is an extremely high risk that a deformed infant will result if a female patient becomes pregnant while taking Roaccutane in any amount even for short periods. Potentially all exposed foetuses can be affected. Roaccutane is therefore contraindicated in women who are pregnant or who may become pregnant while undergoing treatment.

Before initiating (or continuing) Roaccutane therapy in a female patient of childbearing potential, the prescribing physician must ensure that all the criteria below are fulfilled:

- The patient 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.

- The patient has received both verbal and written information and understands the teratogenic risk of taking Roaccutane during pregnancy and of exposing a foetus to the drug.

- The patient understands the need for rigorous follow-up, on a monthly basis.

- The patient has received both verbal and written information, accepts and understands 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 the patient has amenorrhoea she understands that she must follow all of the advice on effective contraception.

- The patient is capable of complying with effective contraceptive measures.

- The patient is informed and understands the potential consequences of pregnancy and the need to rapidly consult her doctor if there is a risk of pregnancy.

- The patient understands the need and accepts that she will have to undergo pregnancy testing before, during and 5 weeks after treatment.

- The patient has had a negative pregnancy test prior to starting treatment (during the first 3 days of the menstrual cycle), during treatment according to local practice, and 5 weeks after the end of treatment.

- The patient is encouraged to ask questions about anything concerning her therapy with Roaccutane or the pregnancy prevention instructions that may be unclear to her.

- The patient understands and has acknowledged her understanding of these warnings and precautions associated with the use of Roaccutane and is willing to sign the Acknowledgement Form for Female Patients (if locally required).
Conditions for Prescribing

Prescribing and Dispensing Restrictions

Prescription to women of childbearing potential is limited to 30 days of treatment and continuation of treatment requires a new prescription also limited to a 30 day supply. Ideally, pregnancy testing, issuing a prescription and dispensing of isotretinoin should occur on the same day. Dispensing of isotretinoin should occur within a maximum of 7 days of the prescription.

Contraception

Female patients must be provided with all the available pregnancy prevention information and should be referred for contraceptive advice if they are not using effective contraception.

As a minimum requirement, female patients at potential risk of pregnancy must use at least one effective method of contraception. Preferably the patient should use two complementary forms of contraception including a barrier method. Contraception should be continued for at least 1 month after stopping treatment with isotretinoin, even in patients with amenorrhea.

To assist the prescribing physician in preventing foetal exposure to Roaccutane, and as a reinforcement of the warnings to avoid pregnancy, all female patients of childbearing potential should be provided with the following material:

- Patient information brochure
- Brochure on contraception
- Acknowledgement form for female patients (if locally required)

The brochures and acknowledgement form should be given to all female patients before starting therapy.

Pregnancy Testing

Prior to starting therapy:

- Medically supervised pregnancy test prior to starting contraception to exclude the possibility of pregnancy. The date and result of the test should be recorded.
- Referred for contraceptive advice if not using effective contraception.
- Prescriber should educate the patient about contraception.
- In patients without regular menses, the timing of the pregnancy test should reflect sexual activity of the patient and should be undertaken approximately 3 weeks after the patient last had unprotected sexual intercourse.

Medically supervised pregnancy test should also be performed during the consultation when isotretinoin is prescribed or in the 3 days prior to the visit to the prescriber and should have been delayed until the patient has been using effective contraception for at least 1 month. This test should ensure the patient is not pregnant when she starts treatment with isotretinoin.

Follow-up visit(s):

- Follow-up visits should be arranged at 28 day intervals.
- The need for repeated medically supervised pregnancy tests every month should be determined according to local practice including consideration of the patient’s sexual activity and recent menstrual history.
- Where indicated, follow-up pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.

End of treatment:

- Contraception must be continued for at least 1 month after stopping treatment with Roaccutane.
- Five weeks after stopping treatment, women should undergo a final pregnancy test to exclude pregnancy.