Isotretinoin 5mg Capsules (Isotretinoin)

Isotretinoin 20mg Soft Capsules (Isotretinoin)

Pregnancy Prevention Programme

Checklist for Prescribing to Female Patients

INTRODUCTION

Isotretinoin is highly teratogenic. There is an extremely high risk that foetal exposure to Isotretinoin will result in life threatening congenital abnormalities. Every action should be taken to ensure that the risks and consequences are fully understood by all female patients being considered for treatment.

Before initiating Isotretinoin therapy in a female patient of childbearing potential the following checklist should be completed. This checklist also includes a section for monitoring follow-up visits in patients at risk of pregnancy.

The checklist consists of 3 parts:

This checklist should be used in conjunction with the following brochures:

- 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

PART A

TO BE COMPLETED FOR ALL PATIENTS

Patient Name:	
Date of Birth:	
Hospital Number:	

A current sexual history in all females of childbearing potential should be taken. No assumptions should be made on the basis of age, race or religious beliefs, although clinicians should be sensitive to such issues. It may be necessary to conduct some of this enquiry with the patient alone, in the absence of parents and partners. It should be determined whether the patient is at risk of pregnancy:

1.	**Is the patient at risk of pregnancy?**	**Yes**	**No**

If yes, the patient is at risk of pregnancy, please proceed to part B.

If no, the patient is not at risk of pregnancy, please proceed to part C.

PART B

PATIENTS AT RISK OF PREGNANCY

The Pregnancy Prevention Programme should be followed in all patients at risk of pregnancy. Please note that patients with irregular menses present a difficult management problem that may require specialist advice.

Criteria for prescribing Isotretinoin in patients at risk of pregnancy

When considering prescribing Isotretinoin in patients at risk of pregnancy it is important to ensure that the following criteria are fulfilled.

1.	Does the patient have 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?	Yes	No
2.	Does the patient understand the teratogenic risk of Isotretinoin?	Yes	No
3.	Does the patient understand the need for rigorous follow-up, on a monthly basis?	Yes	No
4.	Does the patient understand and accept 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?	Yes	No
5.	Does the patient understand that at least one and preferably two complementary forms of contraception including a barrier method should be used?	Yes	No
6.	Is the patient capable of complying with effective contraceptive measures?	Yes	No
7.	If the patient has amenorrhoea, does she understand that she must follow all of the advice on effective contraception?	Yes	No
8.	Has the patient been informed and does she understand the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy?	Yes	No
9.	Does the patient understand the need and accepts to undergo pregnancy testing before, during and 5 weeks after the end of treatment?	Yes	No
10.	Has the patient acknowledged that she has understood the hazards and necessary precautions associated with the use of Isotretinoin?	Yes	No

Provision of information to patients at risk of pregnancy

Patients at risk of pregnancy should be provided with the Patient Information Brochure and the Brochure on Contraception.

11.	Has the patient received the Patient Information Brochure?	Yes	No
12.	Has the patient received the Brochure on Contraception?	Yes	No

Contraception in patients at risk of pregnancy

An appropriately trained healthcare professional should give advice on adequate contraception: this will not necessarily be the dermatologist. As a minimum requirement, female patients at potential risk of pregnancy must use at least one effective method of contraception.

The most highly effective methods include contraceptive injections, implants, intra-uterine devices with copper or hormone, combined contraceptive pills and patches when used carefully.

Preferably all patients should use two complementary forms of contraception including a barrier method. Barrier methods on their own are not recommended. Contraception should be continued for at least 1 month after stopping treatment with Isotretinoin, even in patients with amenorrhoea.

13.	Has the patient received advice on adequate contraception?	Yes	No
14.	Has the patient used effective contraception without interruption for at least one month?	Yes	No

Acknowledgement form

All female patients who are at risk of pregnancy should sign a form indicating that they fully understand the risks of pregnancy, that they are not currently pregnant and have been using appropriate contraception for one month before starting treatment, and that the responsibilities of the patient and physician have been discussed. This should include the responsibility of the patient to consult their GP, dermatologist or pharmacist if they have knowingly had unprotected intercourse so that the possibility of using emergency contraception can be considered.

15.	Has the patient signed the acknowledgment form?	Yes	No

Pregnancy testing in patients at risk of pregnancy

Either urine or blood pregnancy tests may be used, as long as they have a minimum sensitivity of 25mIU/mL.

Prior to starting Isotretinoin therapy:

All female patients at risk of pregnancy should have a medically supervised pregnancy test during the consultation when Isotretinoin is prescribed or in the 3 days prior to the visit to the prescriber, and this should have been delayed until the patient had been using effective contraception for at least 1 month. This test should ensure the patient is not pregnant when she starts treatment with Isotretinoin.

16.	Is the pregnancy test prior to starting Isotretinoin therapy positive? Date of pregnancy test …….	Yes*	No

**** If the pregnancy test is positive Isotretinoin should not be started.***

Starting Isotretinoin therapy

Treatment should begin on the day Isotretinoin is received which should be within 7 days of visiting the prescriber and having a negative pregnancy test. Prescriptions of Isotretinoin should be limited to 30 days of treatment and continuation of treatment requires a new prescription. 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.

Follow-up visits

Follow-up visits should be arranged at 28 day intervals. Medically supervised pregnancy testing should be repeated where necessary after consideration of the patient's sexual activity and recent menstrual history (abnormal menses, missed periods or amenorrhoea). 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.

17.	Record of pregnancy testing on follow up visits where necessary			
	Follow up visit 1: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 2: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 3: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 4: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 5: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 6: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 7: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 8: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 9: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No
	Follow up visit 10: Is the pregnancy test positive? Date of pregnancy test	Not done	Yes* ……	No

Records of pregnancy tests at any additional follow up visits should also be recorded

**** If pregnancy occurs in a woman treated with Isotretinoin, treatment must be stopped and the patient should be referred to a physician specialised or experienced in teratology for advice.***

End of treatment

Five weeks after stopping treatment, women should undergo a final pregnancy test to exclude pregnancy.

18.	Is the pregnancy test 5 weeks after stopping Isotretinoin therapy positive? Date of pregnancy test …….	Yes*	No

**** If pregnancy occurs in a woman within 5 weeks of stopping Isotretinoin treatment the patient should be referred to a physician specialised or experienced in teratology for advice.***

PART C.

PATIENTS NOT AT RISK OF PREGNANCY

A patient's sexual behaviour may change during therapy, so a discussion of the risks of teratogenicity should not be limited to those who are sexually active before treatment starts.

1.	Does the patient understand the teratogenic risk of Isotretinoin?	Yes	No

Provision of information to patients not at risk of pregnancy

Patients not at risk of pregnancy should be provided with the Patient Information Brochure and the Brochure on Contraception.

2.	Has the patient received the Patient Information Brochure?	Yes	No
3.	Has the patient received the Brochure on contraception?	Yes	No

Acknowledgement form

All female patients even those not at risk of pregnancy should sign a form indicating that they fully understand the risks of pregnancy and that they are not currently pregnant, and that the responsibilities of the patient and physician have been discussed. This should include the responsibility of the patient to consult their GP, dermatologist or pharmacist if they have knowingly had unprotected intercourse so that the possibility of using emergency contraception can be considered.

4.	Has the patient signed the acknowledgement form?	Yes	No

▼ This medicinal product is subject to additional monitoring.

Malta ADR Reporting Website :
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Date of preparation: Feb 2014

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