**Physician Checklist /Acknowledgement Form for Prescribing to Female Patients**

The potential for pregnancy must be assessed for all female patients prescribed A-CNOTREN (isotretinoin)

Is the patient a woman of childbearing potential? Yes/No

| |
|---|
| A woman has a potential for pregnancy if one of the following applies:<br>Is a sexually mature woman who:<br>1) has not had a hysterectomy or bilateral oophorectomy<br>2) is not in a natural post-menopause for a minimum of 24 consecutive months (i.e., menstruated at a certain point in the last 24 consecutive months). |

This checklist is to be completed by the Physician for all female patients prescribed A-CNOTREN (isotretinoin) and kept with patient notes to document compliance with the A-CNOTREN (isotretinoin) Pregnancy Prevention Programme. After completion a copy of this document should be given to the patient.

A-CNOTREN (isotretinoin) belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to A-CNOTREN (isotretinoin), even for short periods, presents a high risk of congenital malformations. A-CNOTREN (isotretinoin) is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the A-CNOTREN (isotretinoin) Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, you must make sure that the risk of serious harm from drug exposed pregnancy is fully understood by all female patients before treating them with A-CNOTREN (isotretinoin) .

Before initiating A-CNOTREN (isotretinoin) therapy in a female patient, the following checklist must be completed and stored in the patient's notes. This checklist should also be used in all follow-up visits with women of childbearing potential.

Please use the patient reminder card to support your discussion with the patient.

**Women with childbearing potential**
Review the below statements, explain them to the patient and record confirmation of this and acknowledgment from the patient in this form. If the answer to any of these questions is **NO**, A-CNOTREN (isotretinoin) must not be prescribed.

| | Doctor confirm:<br>I have explained this to my patient<br>[YES/NO] | Patient confirm:<br>I have understood this<br>[YES/NO] |
|---|---|---|
| Is the patient suffering from a severe form of acne, severe form of psoriasis or severe disorder of keratinisation which is resistant to standard therapies? | | |
| **Teratogenicity** | | |
| The patient understands that A-CNOTREN belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. A-CNOTREN (isotretinoin) also increases the risk of miscarriage when taken during pregnancy. | | |
| **Contraception** | | |
| The patient understands that she must consistently and correctly use at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary methods of birth control (i.e. user-dependent forms such as oral contraceptive and barrier method) before and during treatment. | | |
| The patient understands that the risk persists even after the medication is stopped and that she must not get pregnant within 1 month after stopping treatment. [3 years for acitretin] | | |
| The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period. | | |
| The patient is aware of the risk of contraceptive failure. | | |
| **Pregnancy Testing & Monthly Prescriptions** | | |
| The first prescription for A-CNOTREN (isotretinoin) can only be given after the patient has had one negative medically supervised pregnancy test. This is to make sure she is not already | | |

| | | |
|---|---|---|
| pregnant before starting treatment. | | |
| Patient understands that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription should be limited to 30 days. | | |
| Patient understands the need for and agrees to pregnancy testing before, during and after treatment. | | |
| Patient understands the need to do a pregnancy test 1 month after stopping treatment because the drug stays in the body for 1 month after the last dose and can damage an unborn baby if pregnancy occurs. | | |
| The contraceptive methods and pregnancy test results were recorded in the patient's appointment table (included in patient reminder card). | | |
| The patient has received a copy of the educational package. | | |
| The patient knows to contact their doctor if they have unprotected sex, miss their period, become pregnant, or suspect that they have become pregnant during the risk period. | | |
| If pregnancy occurs, treatment must be stopped and the patient should be referred to an expert physician specialised or experienced in teratology for advice. | | |
| **Other Precautions** | | |
| Patient understands that A-CNOTREN (isotretinoin) has been prescribed to her only and must not be shared with others. | | |
| Patient understands that she must not donate blood during treatment with A-CNOTREN (isotretinoin) and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient. | | |
| Signature | | |
| Date | | |

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MAH at Neofarma Pharmaceuticals Ltd, 42-46 Mill Street, Qormi 3105 email: info@neofarma.com.mt, tel: 20109494, who will follow up with you to record the pregnancy outcome.

Signature of parent or legal guardian is necessary if the patient is under the age of 18 years.

***Call for reporting***

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with retinoid containing medicines in accordance with the national spontaneous reporting system. Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt

***Company contact point***

Alternatively, suspected adverse reaction may also be reported to the marketing authorisation holders using the details provided below.

| Company/ MAH | Product name | Email | Phone |
|---|---|---|---|
| Neofarma Pharmaceuticals | A-Cnotren 10mg Isotretinoin Capsule 20mg | info@neofarma.com.mt | +356 2010 9494 |
| Neofarma Pharmaceuticals | A-Cnotren 20mg Isotretinoin Capsule 20mg | info@neofarma.com.mt | +356 2010 9494 |