This document is approved by The Executive Directorate of Pharmacovigilance at SFDA

Acknowledgement of Risk Form for **Ruatine®** (Isotretinoin)

Patient Details

Name of patient:	
Date of birth:	
Phone number:	
Dermatologist name and address:	

2.0 – Mar 2025

Information for Patients

All medicines have benefits and risks. Isotretinoin works well to treat severe acne, but it can cause side effects. For example, Your acne may worsen before improving, your lips could become very dry, Your skin may burn more easily in the sun, even if you don't normally burn easily.. Some side effects may continue even after stopping isotretinoin. It's unclear how often this happens or how long the side effects can last.

Isotretinoin can seriously harm an unborn baby. This is why patients **must not** become pregnant during treatment with isotretinoin and for 1 month after isotretinoin is stopped. Patients of childbearing potential must enter the Pregnancy Prevention Programme.

This **Isotretinoin Acknowledgement of Risk Form** is to make sure you know about the side effects and possible risks which have been associated with isotretinoin. If you are under 18 years old, then this form is also to record that your healthcare professional (HCP) has agreed that Ruatine® (Isotretinoin) is a suitable medicine for you to take.

Your prescriber will go through this form with you. Please read each part of it carefully. You need to agree to all applicable points to receive isotretinoin. You will receive a copy of your completed form before starting isotretinoin treatment - please keep the copy safe.

Information for Healthcare Professionals (HCPs)

The Prescriber must complete this form for **all patients** treated with isotretinoin.

The Prescriber and patient (and usually a parent or guardian if under 18 years old) should go through the form together. The patient must be given a copy of the completed form.

This form is divided into 3 sections:

1. **Isotretinoin risks:** a checklist of the risks of isotretinoin, including possible risks to mental health and sexual function.

2. **Pregnancy Prevention Programme:** all patients of childbearing potential must enter the Pregnancy Prevention Programme in order to be fully informed of the risks to an unborn baby and to prevent harm to an unborn baby from exposure to isotretinoin.

3. **Acknowledgement of risk:**
   - **All patients** (and usually a parent or guardian if under 18 years old) must sign to confirm they are aware of the risks of isotretinoin.
   - The Prescriber must sign to confirm they have explained the risks to the patient.

1. Isotretinoin risks:

The Prescriber and patient must go through every point in this checklist and tick once completed. All patients must complete this section.

	Prescriber explained	Patient acknowledges
I have discussed my treatment options for acne with my prescriber.	☐	☐
I have read the relevant patient information on isotretinoin. I understand there are a range of possible side effects associated with taking isotretinoin. I understand that some side effects may continue after treatment. I agree to read the patient information leaflet that comes with the medicine before starting Ruatine® (Isotretinoin).	☐	☐
I understand that isotretinoin may be linked with possible mental health and sexual function side effects. Possible mental health side effects include low mood, depression, anxiety, agitation, aggression, self-harm, suicidal thoughts/attempts, and psychosis (loss of touch with reality).	☐	☐
I have had blood tests for my liver and blood fat levels before treatment.	☐	☐
I agree to attend regular clinic appointments during my treatment for monitoring.	☐	☐
I understand I must not donate blood during treatment with isotretinoin and for 1 month afterward.	☐	☐
I will not share my Ruatine® (Isotretinoin) capsules with anyone else.	☐	☐
I will inform my family and/or friends that I am taking isotretinoin. I will tell them about possible side effects to look out for. I will ask them to tell me to contact my prescriber if needed	☐	☐
If I have thoughts of harming myself or if there are serious concerns about my mental health, I will stop taking isotretinoin and immediately seek medical help.	☐	☐
I have been given information on how to get in contact with my prescriber. I will contact my prescriber if I have concerns about the side effects of isotretinoin or if I stop treatment (see section 3.3 of this form).	☐	☐

Please continue to section 2: Pregnancy Prevention Programme

2. Pregnancy Prevention Programme

Does the patient have childbearing potential?

A female with childbearing potential unless they:

a. Have undergone surgical sterilization (tubal ligation), confirmed by a healthcare professional.
b. Are post-menopausal, confirmed by a healthcare professional.

If 'No' go to section 3: Acknowledgment of risk

All patients with childbearing potential (anyone who may be able to get pregnant) must be entered into the Pregnancy Prevention Programme.

	Prescriber explained	Patient acknowledges
I understand that isotretinoin can seriously harm an unborn baby and increase the risk of miscarriage when taken during pregnancy. I know that I must not get pregnant whilst taking isotretinoin and for 1 month after stopping treatment.	☐	☐
Use of contraception - complete 1. OR 2. as applies		
1. I have been using contraception for the last 4 weeks. I agree to pregnancy testing during treatment. I understand and agree to use the following contraception during treatment and for 1 month afterward (either a or b): a. A hormonal contraceptive pill or contraceptive injection plus a barrier method (i.e. a condom, female condom, vaginal cap). b. The coil (IUD), intra-uterine system (IUS), or contraceptive implant (highly effective user-independent forms of contraception) which have been in place for at least 4 weeks.	☐ ☐	☐ ☐
2. The prescriber and I agree I do not need to use contraception because there is expected to be **no risk of pregnancy** during treatment and for 1 month after treatment. If my situation changes, I will let my prescriber know and take/use appropriate contraception to avoid pregnancy. **Prescriber to document here the agreed reason that no contraception is needed. Go to the "Pregnancy" section.**	☐	☐
I am aware that any contraception can fail. I know there is a very small chance of getting pregnant even if I am on contraception.	☐	☐

Hormonal contraception can be less effective in some situations. I understand I may need to use extra contraception if: • I am starting new medications, including antibiotics or herbal preparations such as St John's Wort • I have diarrhoea and vomiting • I have missed taking my contraception	☐	☐
I understand the first prescription for isotretinoin can only be given after I have had one negative pregnancy test checked by the prescriber.	☐	☐
I understand I need a pregnancy test 1 month after stopping treatment because the risks to an unborn baby last for 1 month after the last dose.	☐	☐
The contraceptive methods and pregnancy test results have been recorded in my medical records.	☐	☐
Pregnancy		
I will stop my isotretinoin immediately, inform my dermatologist, and seek medical advice if I miss my period, become pregnant, or suspect that I have become pregnant. This applies during isotretinoin treatment and for 1 month after stopping.	☐	☐

Please continue to section 3: Acknowledgment of risk

3. Acknowledgment of risk

3.1. Patients

All patients

The patient (and if applicable their parent or guardian) must sign to confirm that they understand the possible risks of isotretinoin.

I confirm I understand the possible risks of isotretinoin	**Yes** ☐	**No** ☐

Name of patient:	**Signature of patient:**	**Date of signature:**
Name of parent or guardian (if applicable):	**Signature of parent or guardian (if applicable):**	**Date of signature:**

Patients with childbearing potential (tick A, B or C as appropriate).

☐ **A. I confirm** do not require contraception because there is no risk of pregnancy during treatment and for 1 month after treatment. I do not require pregnancy testing. I will let my prescriber know if my situation changes. ☐ **B. I confirm** I have been using the contraceptive implant or have had a coil (IUD) or intra-uterine system (IUS) for at least 4 weeks. I agree to pregnancy testing before follow-up appointments. I may choose to do monthly pregnancy tests at home because no contraception is 100% effective. I will let my prescriber know if my situation changes. ☐ **C. I confirm** I have been using a hormonal contraceptive pill or hormonal injection **plus** I agree to use a barrier method (i.e. a condom, female condom, vaginal cap). I agree to pregnancy testing every 30 days during treatment.	
Signature of patient:	Date of signature:

3.2. Prescriber

I confirm that the possible risks of isotretinoin have been explained to the patient.

Pregnancy Prevention Programme status: (tick 'Not applicable', A, B, or C, as appropriate). For patients in groups 'Not applicable', A and B, once stable on isotretinoin (after the first 1-3 months) the prescription may be for longer than 30 days (up to 12 weeks).

Not applicable (no childbearing potential)	Group A	Group B	Group C
☐	☐	☐	☐

Name of Prescriber:	Role and unique identifier:
Signature of Prescriber:	Date of signature:

Once completed, a copy of this form should be given to the patient, or their parent(s) or guardian(s) and this form should be stored in their medical notes and shared with all healthcare professionals if needed.

Remember:

Talk to your dermatologist about your treatment or if you have any concerns. You should stop taking isotretinoin and contact your dermatologist for further advice if you have serious concerns about your mental health or thoughts of harming yourself or other serious side effects.

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to follow up and record the pregnancy outcome.

Call For Reporting:

Any suspected adverse reactions should be reported immediately to MS Pharma Saudi or to the National Pharmacovigilance and Drug Safety Centre.

- **Pharmacovigilance department at MS Pharma:**
  - Email: pharmacovigilance@mspharma.com
  - Website: www.mspharma.com
  - Phone No: + 966112790122 Ext. 6013

- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
  - Email: npc.drug@sfda.gov.sa
  - Call Center: 19999
  - Website: https://ade.sfda.gov.sa/
  - QR Code: