Physician Checklist/Acknowledgement Form for Prescribing Isotretinoin Rowex (isotretinoin) to Female Patients

▼ **This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See box on back cover for details on how to report.**

The potential for pregnancy must be assessed for all girls and women of childbearing potential treated with Isotretinoin Rowex

Is the patient a girl or woman of childbearing potential? yes ☐ no ☐

A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant.

This form is to be completed by the physician and patient at initial and follow-up visits for all female patients prescribed Isotretinoin Rowex. The signed document should be kept with the patient notes to document compliance with the Isotretinoin Rowex Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Isotretinoin Rowex belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Isotretinoin Rowex, even for short periods, presents a great risk of very severe and serious congenital malformations. Isotretinoin Rowex is therefore strictly contraindicated during pregnancy and in women of childbearing potential unless all the conditions of the Isotretinoin Rowex Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, you must ensure that the teratogenic risk and necessary precautions are fully understood and acknowledged by all female patients before treating them with Isotretinoin Rowex.

Please refer to the patient reminder card in the pack to support your discussion with the patient.

Review the below statements, discuss them with your patient and ensure that she understands and acknowledges the risks and necessary precautions related to the use of Isotretinoin Rowex. Record confirmation of this on the form. If the answer to any of these questions is NO, Isotretinoin Rowex must not be prescribed.

PART A: To be completed by the physician

I confirm that the patient is prescribed Isotretinoin Rowex because she is suffering from a severe form of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy.		no
I confirm that I have discussed the following information with my patient:		
Teratogenicity		
Isotretinoin Rowex belongs to a class of drugs (retinoids) known to cause severe and serious foetal malformations, including central nervous system abnormalities, facial dysmorphia, cleft palate, external ear abnormalities, eye abnormalities, cardiovascular abnormalities, thymus gland abnormality and parathyroid gland abnormalities.	yes	no
Isotretinoin Rowex increases the risk of spontaneous abortion when taken during pregnancy.	yes	no
Isotretinoin Rowex must not be used in pregnancy.	yes	no
Contraception		
The need for consistent and correct use, without interruption, of 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 user-dependent methods of contraception (e.g. oral contraceptive and barrier method).	yes	no
The need for contraception, as described above, for at least 1 month before treatment, throughout the entire duration of treatment and for at least 1 month after stopping treatment as the risk persists until the product is completely eliminated, which is within 1 month following the end of treatment.	yes	no
I have provided advice on contraception which is appropriate for the patient, or I have referred her for contraception services as appropriate.	yes	no

Pregnancy Testing & Monthly Prescriptions		
The need for a medically supervised pregnancy test at least 1 month after the patient has started using contraception and shortly (preferably a few days) prior to the first prescription for Isotretinoin Rowex to ensure that the patient is not pregnant when she starts treatment.	yes	no
The need for prescriptions to ideally be limited to 30 days, in order to support regular follow up, including pregnancy testing and monitoring.	yes	no
The need for pregnancy testing during (ideally monthly) and 1 month after stopping treatment, as the risk of severe and serious foetal malformations persists until the product is completely eliminated.	yes	no
The need to contact her doctor immediately in case of suspected or inadvertent pregnancy during treatment or within 1 month after stopping treatment.	yes	no
The need to stop treatment immediately in case of suspected or inadvertent pregnancy and need for patient referral to an expert physician specialised or experienced in teratology for advice (in case of pregnancy).	yes	no
I have referred the patient to the patient reminder card included in the pack.	yes	no
Other Precautions		
Isotretinoin Rowex must not be shared with others.	yes	no
The patient must not donate blood during treatment with Isotretinoin Rowex and for 1 month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	yes	no

Doctor Name: Doctor Signature: Date:

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to The Pharmacovigilance Department, Rowex Ltd., Bantry, Co. Cork, P75V009, Ireland. Tel: 02750077, email: pv@rowa-pharma.ie who will follow up with you to record the pregnancy outcome.

PART B: To be completed by the patient

The doctor has explained the following information to me and I confirm that I have understood this:		
Why I have been prescribed Isotretinoin Rowex	yes	no
Teratogenicity		
That Isotretinoin Rowex belongs to a group of medicines called *retinoids* (for treatment of acne) and can seriously harm an unborn baby (the medicine is said to be 'teratogenic'). It can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland).	yes	no
That Isotretinoin Rowex also makes a miscarriage more likely even if only taken for a short time during pregnancy.	yes	no
That I must not get pregnant whilst taking Isotretinoin Rowex or for 1 month after stopping this treatment as some medicine may still be left in my body.	yes	no
That I must not take Isotretinoin Rowex if I am pregnant or think I might be pregnant.	yes	no
Contraception		
That I must use at least 1 very reliable method of contraception (for example an intra uterine device or contraceptive implant) or 2 effective methods that work in different ways (for example a hormonal contraceptive pill and a condom).	yes	no
That I must use contraception as described above for 1 month before taking Isotretinoin Rowex during treatment and for 1 month after stopping treatment, as some medicine may still be left in my body after stopping treatment.	yes	no
We discussed the possibilities of effective contraception, or we planned a consultation with a professional experienced in advising on effective contraception.	yes	no
Pregnancy Testing & Monthly Prescriptions		

That my doctor will ask me to take a pregnancy test, before I start treatment. The test must show that I am not pregnant when starting treatment with Isotretinoin Rowex.	yes	no
That the prescription is limited to 30 days in order to support regular follow up, including pregnancy testing and monitoring.	yes	no
The need for pregnancy testing during (ideally monthly) and 1 month after stopping treatment, because some medicine may still be left in my body and could damage an unborn baby if pregnancy occurs.	yes	no
The need to contact my doctor immediately if I have unprotected sex, miss a period, am pregnant, or think that I might be pregnant while taking Isotretinoin Rowex or within 1 month after stopping treatment.	yes	no
The need to stop taking Isotretinoin Rowex straight away if I become pregnant or think I might be pregnant.		no
That my doctor may send me to a specialist for advice.	yes	
I was informed about the copy of the patient reminder card in the pack.		no
	yes	

Other Precautions

That I must not share this medicine with others.	yes	no
That I must not donate blood during treatment with Isotretinoin Rowex and for 1 month after stopping treatment because an unborn baby could be harmed if a pregnant patient receives my blood.	yes	no

Patient Name: Patient Signature: Date:

Parent/Legal Guardian (if patient is under the age of 16): Parent/Legal Guardian Signature: Date:

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to The Pharmacovigilance Department, Rowex Ltd., Bantry, Co. Cork, P75V009, Ireland. Tel: 02750077, email: pv@rowa-pharma.ie 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 16.

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to the Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 :

postlicensing.medicinesauthority@gov.mt

Further Information

For additional electronic copies of this risk minimisation material, refer to www.medicinesauthority.gov.mt and download the required material (enter 'isotretinoin RMM' in the search box and click on). Alternatively, if you would like hard copies, please contact Prohealth Limited, Mdina Road Zebbug, ZBG9019 Tel 23385000; email pharmacovigilance@prohealth.com.mt

For further information about Isotretinoin Rowex, please contact Medical Information at Rowex Ltd. by telephone (02750077) or email (pv@rowa-pharma.ie) or Prohealth Limited Malta on 23385000, email pharmacovigilance@prohealth.com.mt