Physician materials

Physician Checklist/Acknowledgement Form for Prescribing to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed retinoids (acitretin, alitretinoin and isotretinoin)

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

A woman has a potential for pregnancy if one of the following applies:
Is a sexually mature woman who:
1) Has not had a hysterectomy or bilateral oophorectomy
2) Is not in a natural postmenopausal 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 retinoids and kept with patient notes to document compliance with the retinoids Pregnancy Prevention Programme. After completion a copy of this document should be given to the patient.

The Pharmaceutical products belong to the retinoid class of drugs that cause severe birth defects. Foetal exposure to retinoids, even for short periods, presents a high risk of congenital malformations. Retinoids is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the retinoids 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 retinoids.

Before initiating retinoids 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**, retinoids must not be prescribed.

	Doctor confirm: I have explained this to my patient [YES/NO]	Patient confirm: I have understood this [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?		
The patient understands that the pharmaceutical product belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. Retinoids 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 retinoids 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 7-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. Specifically for acitretin: Patient understands the need for periodic pregnancy tests with 1-3 monthly intervals throughout treatment and also for a period of 3 years after stopping treatment. This is because the drug can stay in the body for 3 years 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 retinoids has been prescribed to her only and must not be shared with others.		
Patient understands that she must not donate blood during treatment with retinoids and for one month [for acitretin 3 years] 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 [3 years for acitretin] following discontinuation of treatment should be reported to the MAH, 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.

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
Actavis Group PTC ehf	Decutan 10mg soft capsules Decutan 20mg soft capsules Neotigason 10 mg Capsule Neotigason 20 mg Capsule	PHVMALTA@actavis.com	+30 2118805156
Genus Pharmaceuticals Ltd.	Acitretin 25mg Capsules	dso@britannia-pharm.com	+44 1189209500
Neofarma Pharmaceuticals	Isotretinoin Capsule 10mg Isotretinoin Capsule 20mg	info@neofarma.com.mt	+356 20109494