Prescriber Checklist / Acknowledgement Form for Prescribing Alitretinoin to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed alitretinoin capsules.

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 postmenopause 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 alitretinoin capsules and kept with patient notes to document compliance with the alitretinoin capsules Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Alitretinoin capsules belong to the retinoid class of drugs that cause severe birth defects. Foetal exposure to alitretinoin capsules, even for short periods, presents a high risk of congenital malformations. Alitretinoin capsules are therefore strictly contraindicated in women of childbearing potential, unless all conditions in the alitretinoin capsules 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 alitretinoin capsules.

Before initiating alitretinoin 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.

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MHRA and the company listed in the patient information leaflet who will follow up with you to record the pregnancy outcome.

Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported to the MHRA and the company listed in the patient information leaflet. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can call on 0800 731 6789.

A signature of the parent or legal guardian is necessary if the patient is under the age of 16.

Is the patient a woman of childbearing potential? Yes/No (If No, go to section 4) **Women of 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**, alitretinoin capsules 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 severe chronic hand eczema unresponsive to potent topical corticosteroids?		
1. Teratogenicity		
The patient understands that alitretinoin capsules belong to a class of drugs (retinoids) known to cause severe birth defects and that she must not get pregnant whilst taking it. Alitretinoin capsules also increases the risk of miscarriage when taken during pregnancy.		
2. 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.		
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.		
3. Pregnancy Testing & Monthly Prescriptions		
The first prescription for alitretinoin capsules 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 patient has received a copy of the educational package.		
The patient knows to contact her doctor if she has unprotected sex, misses her period, becomes pregnant, or suspects that she has 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.		
4. Other Precautions		
Patient understands that alitretinoin capsules have been prescribed to her only and must not be shared with others.		
Patient understands that she must not donate blood during treatment with alitretinoin capsules and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.		
Doctor signature ..... Patient (or guardian if under 16) signature ..... Date.....		

Signature of parent or legal guardian may be provided as required.

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