

Dear Healthcare Professional,

### Toctino (alitretinoin): Important Information on the Pregnancy Prevention Programme

Toctino (alitretinoin oral, 10mg or 30mg) is indicated for use in adults who have severe chronic hand eczema, unresponsive to treatment with potent topical corticosteroids.

Like other retinoids, Toctino is a teratogen. Treatment with Toctino during pregnancy is contraindicated and special precautions must be taken when treating women of childbearing potential. Stringent contraception measures must be followed one month before patients receive Toctino treatment, while patients are receiving treatment and for one month after stopping Toctino treatment. No special contraception requirement is indicated for male patients taking Toctino. Please ensure that you have reviewed the Summary of Product Characteristics (SmPC) and the 'Checklist for Prescribing to Female Patients', detailing actions required for prescribing Toctino.

A Pregnancy Prevention Programme (PPP) has been developed to assist you in fulfilling the requirements for Toctino treatment. It is important to note that Toctino is strictly contraindicated in women of childbearing potential unless all the requirements of the PPP are fulfilled. The PPP is supported by the following documents:

- 'Guidance for Doctors and Pharmacists'
- 'Patient Information Brochure'
- 'Information About Contraception'
- 'Checklist for Prescribing to Female Patients'
- 'Acknowledgement Form for Female Patients'

These documents should enhance the awareness and understanding of the teratogenic risks associated with the use of Toctino.

### When prescribing Toctino, consider the following:

- The patient has to be informed and fully understand the term teratogenicity and the potential risks of using the product during pregnancy
- The patient must sign the 'Acknowledgement Form for Female Patients,' or similar patient information/consent form that contains warnings about the risk of potential birth defects if the foetus is exposed to alitretinoin
- Check the patient understands the requirement to use effective contraception for one month before starting treatment, during treatment and for one month after stopping treatment with Toctino, using at least one and preferably two effective methods of contraception
- The need to conduct pregnancy testing before, and during the treatment as determined according to local practice and 5 weeks following the end of treatment with Toctino
- Mandatory reporting of all pregnancy cases to the applicable Health Authorities and to Stiefel, a GSK Company.

### In addition there are controls on the distribution of Toctino:

- Prescriptions for female patients prescribed under the PPP must be limited to 30 days of treatment
- Prescriptions are only valid for 7 days

Further copies of the materials contained in this pack are available and can be downloaded from the website [www.toctino.co.uk](http://www.toctino.co.uk)

We will continue to inform you of important developments and changes. If you have any questions about Toctino, please contact Stiefel, a GSK Company, Stockley Park West, Uxbridge, UB11 1BT, Tel: 0800 221 441.

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Stiefel, a GSK Company on 0800 221 441.**