Ireland
Teva Pharmaceuticals Ireland

Actavis

Pharmacist Checklist

Guidance for dispensing Neotigason▼ (acitretin)

Neotigason belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Neotigason, even for short periods of time, presents a high risk of severe and serious congenital malformations and an increased risk of spontaneous abortion.

Neotigason is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions of the Neotigason Pregnancy Prevention Programme are fulfilled.

If you are aware that a pregnancy has occurred in a woman treated with Neotigason, treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within 3 years of stopping Neotigason she should be referred to her prescribing doctor.

Patient Reminder Card: Counsel **all** patients (male and female) on the patient reminder card which is included in the product packaging*. In the event that broken bulk dispensing cannot be avoided, the patient should be provided with a copy of the package leaflet and patient reminder card.

In the interim period until the product packaging is updated to include the patient reminder card, please ensure that a copy of the patient reminder card is provided to all patients when dispensing this medicine.

As a pharmacist, you should only dispense Neotigason after checking the following information:

For women of child-bearing potential:	**Pharmacist confirm [Yes/No]**
• In order to support regular follow up, including pregnancy testing and monitoring, the prescription for Neotigason should ideally be limited to a 30-day supply.	YES ☐ NO ☐
• Ideally, pregnancy testing, issuing a prescription and dispensing of Neotigason should occur on the same day.	YES ☐ NO ☐
• Dispensing of Neotigason should occur within a maximum of 7 days of the prescription.	YES ☐ NO ☐
All patients should be instructed:	
• Never to give Neotigason to another person.	YES ☐ NO ☐
• To return any unused capsules to their pharmacist at the end of treatment.	YES ☐ NO ☐
• Not to donate blood during Neotigason therapy and for 3 years after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	YES ☐ NO ☐

Reporting suspected adverse events or reactions

▼ 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. Reporting forms and information can be found at www.hpra.ie.

Adverse events should also be reported to Teva by telephone (00442075407117) or email (safety.ireland@teva.ie).

- **For additional hard copies of this risk minimisation material** please contact our Teva Ireland Customer Service number on Freephone 1800-201-700.
- **For additional electronic copies of this risk minimisation material,** refer to www.hpra.ie and download the required material (enter 'Neotigason' or 'acitretin' in the search box and click on 'EdM' next to any of the medicines that appear).

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