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Thalidomide 50mg hard capsules: Pregnancy Prevention Programme to minimise the risk of teratogenicity

Dear Healthcare Professional,

Accord-UK Ltd will be launching Thalidomide 50mg Capsules in the UK and in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), we are writing to inform you about the Accord-UK Pregnancy Prevention Programme (PPP) which is being introduced to minimise the risk of teratogenicity with thalidomide.

Summary

- Thalidomide is a powerful human teratogen that can cause severe and life-threatening birth defects and must not be used during pregnancy.
- Pregnancy prevention measures are required for women of childbearing potential and for male patients since thalidomide is found in semen. Full details of these measures can be found in the product information.
- Pharmacies who wish to dispense thalidomide must be registered with Accord-UK, as part of a controlled distribution system.
- A Prescription Authorisation Form (PAF), which is completed by the prescriber and dispensing pharmacist, must accompany each prescription of thalidomide. Pharmacies will have to agree to return a copy of all completed PAFs to Accord-UK to allow assessment of the effectiveness of the PPP and monitor off label use.

Background on the Pregnancy Prevention Programme

Thalidomide is used in combination with melphalan and prednisone as first line treatment of patients with untreated multiple myeloma, aged ≥ 65 years or ineligible for high dose chemotherapy.

In accordance with the Summary of Product Characteristics (SmPC), female patients who are of child-bearing potential must use one form of effective contraception (please refer to the SmPC for further information) starting at least 4 weeks before treatment, during treatment (including during dose interruptions) and continuing for at least 4 weeks after stopping treatment unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. In addition, for women of childbearing potential a medically supervised pregnancy test must be performed prior to starting treatment and repeated every 4 weeks (including 4 weeks after the end of treatment) to confirm that the patient is not pregnant, except in the case of confirmed tubal sterilisation. Male patients, including those who have

had a vasectomy, must use a condom during treatment with thalidomide, during any interruptions in treatment and for at least 7 days after stopping thalidomide if their partner is pregnant or is of childbearing potential and not using effective contraception.

During treatment (including during dose interruptions) and for at least 7 days after stopping treatment, male patients must not donate semen or sperm, and all patients must not donate blood.

For women of childbearing potential, prescriptions of thalidomide should be limited to a maximum of 4 weeks of treatment. For all other patients, prescriptions of thalidomide should be limited to a maximum of 12 weeks of treatment.

For further details about how to minimise the risk of teratogenicity as well as information about other risks associated with thalidomide please refer to the SmPC, which can be found on the electronic medicines compendium (emc) website: www.medicines.org.uk.

A requirement of the PPP is for Accord-UK to have a controlled distribution system. This requires all pharmacies to register with Accord-UK Medical Information using the pharmacy registration form; no stock can be supplied until this registration is complete. You can obtain the Accord PPP materials, including the pharmacy registration form, by completing the enclosed form and sending it back to Accord using the stamped addressed envelope. The PPP materials include:

- Healthcare Professional information brochure
- Patient information brochure
- Pharmacy registration forms
- Treatment initiation forms
- Prescription authorisation forms (PAFs)
- Patient card
- Pregnancy exposure forms

For each prescription, a PAF must be completed by the prescriber and pharmacist. A copy of each PAF must be sent to Accord so that the effectiveness of the PPP can be assessed.

To facilitate the implementation of the PPP during the coronavirus (COVID-19) pandemic, temporary pregnancy prevention guidance for immunomodulatory drugs (including thalidomide) has been published by the MHRA:
https://www.gov.uk/guidance/immunomodulatory-drugs-temporary-pregnancy-prevention-guidance-during-coronavirus-covid-19

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report suspected side effects electronically via:

- the Yellow Card website
- the free Yellow Card app; download now from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.
Adverse reactions and reports of pregnancies associated with the use of thalidomide may also be reported to Accord-UK Medical Information at the contact details stated below.

Company contact point

Accord-UK Medical Information department can be reached directly on 01271 385257 or by email on rmpteam@accord-healthcare.com
This is the contact point for all enquiries relating to the use of thalidomide and for further details on the Pregnancy Prevention Programme.

Yours faithfully

Mr Peter Kelly
Managing Director, UK
Accord-UK Ltd

Enc:

- Form of Intent to prescribe or dispense thalidomide
- Stamped Addressed Envelope (SAE)