

Frequently Asked Questions

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Frequently Asked Questions (FAQs)

Where can I get further copies of the Lenalidomide Healthcare Professional's Information Pack or the patient materials?

If you would like further copies of the Lenalidomide Healthcare Professional's Information Pack or any other materials for healthcare professionals or patients, please telephone or email Glenmark Pharmaceuticals Europe Ltd. using the contact details below.

Tel: 0800 458 0383

Email: UKPV@glenmarkpharma.com

Fax: +441923396600

Materials can also be printed from the electronic medicines compendium (emc) website:
www.medicines.org.uk/emc

What must I do prior to ordering or dispensing lenalidomide?

All pharmacies must register with Glenmark Pharmaceuticals Europe Ltd. prior to ordering or dispensing lenalidomide. You will need to register the dispensing pharmacy using the Pharmacy Registration Form. This form is contained within this pack. Completed Pharmacy Registration Forms should be sent via email UKPV@glenmarkpharma.com or fax to +441923396600. Once you have returned a completed Pharmacy Registration Form, we will inform the distributors who will place you on the registered list.

Do I need a registration number to order lenalidomide?

No, you just need to register with Glenmark Pharmaceuticals Europe Ltd. by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered and can receive lenalidomide.

Where do I order lenalidomide?

Once registered, to order lenalidomide please contact Glenmark Customer Services. You must have returned the Pharmacy Registration Form to Glenmark before you can place an order. You will need to fax or email your order to the distributors (all orders must be received in writing).

Distributor: Glenmark Customer Services

Tel: +441923 202 950

Email: Orders.UK@glenmarkpharma.com

How should I report an Adverse Event or suspected pregnancy?

Adverse events and suspected pregnancies should be reported to Glenmark Pharmaceuticals Europe Ltd. Medical Information. Adverse event reporting forms, pregnancy reporting forms and pregnancy outcome forms are included in this Healthcare Professional's Information Pack. Completed forms should be forwarded to Glenmark Pharmaceuticals Europe Ltd. Medical Information using the contact details below:

Tel: 0800 458 0383

Email: medical_information@glenmarkpharma.com

Adverse events can also be reported online via the Yellow Card website <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Frequently Asked Questions (FAQs) (continued)

What are the contact details for Glenmark Pharmaceuticals Europe Ltd. Medical Information?

To contact Glenmark Pharmaceuticals Europe Ltd. Medical Information, please telephone or email using the contact details below:

Tel: 0800 458 0383

Email: medical_information@glenmarkpharma.com

How will Glenmark Pharmaceuticals Europe Ltd. audit pharmacies registered for the Lenalidomide Pregnancy Prevention Programme?

Glenmark Pharmaceuticals Europe Ltd. audits will be performed remotely as an ongoing process, using the information supplied on the Prescription Authorisation Forms, and the collated results will be shared with the MHRA and the EMA. Glenmark Pharmaceuticals Europe Ltd. will contact the pharmacy in cases where there are irregularities or queries on Prescription Authorisation Forms so that any potential problems or errors can be dealt with as they arise.

The Prescription Authorisation Forms must be sent to Glenmark Pharmaceuticals Europe Ltd. for every cycle of lenalidomide treatment for all patients, to allow audit obligations (which were agreed by the Chief Pharmacist when they signed the Pharmacy Registration Form) to be effectively fulfilled by Glenmark Pharmaceuticals Europe Ltd. collating the data from the Prescription Authorisation Forms you have supplied. It is therefore critical that Prescription Authorisation Forms are completed fully and accurately.

All the information will be provided, in an anonymised and aggregated format within the annual audit reports, to the Medicines and Healthcare Regulatory Agency (MHRA) and the European Medicines Agency (EMA).

Where do I send my Prescription Authorisation Forms?

Please contact the Risk Management Team on the following contact details:

Tel: 0800 458 0383

Email: UKPV@glenmarkpharma.com

Fax: +441923396600

If you wish to use email, please scan the completed form and email it as an attachment.

Please keep a copy of the Prescription Authorisation Forms for your records.