

# If you become pregnant during treatment or within 1 week of stopping treatment with Ponvory



If you become pregnant, suspect pregnancy or decide to become pregnant, treatment with Ponvory must be stopped.

If you become pregnant during treatment or within 1 week following discontinuation of treatment, please report it to your doctor immediately.

Janssen has put in place a Pregnancy Outcomes Enhanced Monitoring (POEM) programme to collect information about pregnancy in patients exposed to Ponvory immediately before and during pregnancy, and on infant outcomes post-delivery.

## Reporting of side effects

Ponvory is a new medicine and its safety is being closely monitored. Contact your doctor, pharmacist or nurse if you experience side effects with any medication you are taking. This includes any side effects that are not listed on the information leaflet that comes with this medication.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to:  
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000  
E: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)  
Alternatively, to report Suspected Adverse Drug Reactions, contact Janssen's Local Representative, AM Mangion, on the following:  
Phone (24/7): 00356 2397 6333  
Email: [pv@ammangion.com](mailto:pv@ammangion.com)  
Address: AM Mangion Ltd, Mangion Building, N/S Off Valletta Road, Luqa, LQA 6000, MALTA

For further information, please contact Janssen's Local Representative, AM Mangion Medical Information by using one of the following methods:

**Phone:** 00356 2397 6888

**Email:** [medicalaffairs@ammangion.com](mailto:medicalaffairs@ammangion.com)

**Website:** [www.ammangion.com.mt](http://www.ammangion.com.mt)

PONVORY® (ponesimod)

## PREGNANCY REMINDER CARD

Information for female patients of childbearing potential

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. For more information, see the section on reporting of side effects.

## Before starting Ponvory



### **Do not use Ponvory if you are pregnant, breastfeeding or could become pregnant and are not using effective contraception.**

- A pregnancy test must be conducted, and negative results must be verified by your doctor before starting treatment with Ponvory
- Your doctor will explain before treatment initiation, and regularly thereafter, the potential harmful effects of Ponvory to the unborn baby if you become pregnant during treatment and the actions required to minimise this risk
- Talk with your doctor about reliable methods of contraception that you should use during treatment and for at least 1 week after you stop Ponvory treatment

## While you are taking Ponvory



While taking Ponvory you must not become pregnant. A pregnancy test should be repeated at suitable times during Ponvory treatment

- You must use effective contraception during treatment with Ponvory and for at least 1 week after treatment ends
- Ponvory must be stopped at least 1 week before you attempt to conceive; contact your doctor, pharmacist or nurse for further medical advice regarding the risk of harmful effects to the unborn baby
- If you become pregnant, suspect pregnancy or decide to become pregnant, you should tell your doctor straight away. Treatment with Ponvory must be stopped immediately and a follow-up appointment should be scheduled with your doctor. See information below regarding reporting pregnancy while taking Ponvory
- You should not breastfeed while taking Ponvory

## After stopping Ponvory



- If you stop taking Ponvory due to pregnancy or attempting to conceive, your multiple sclerosis symptoms may return, get worse or new symptoms may appear. Tell your doctor immediately if you experience this after stopping treatment with Ponvory
- You should not attempt to conceive for at least 1 week after stopping Ponvory treatment; effective methods of contraception should be continued for at least 1 week
- If you become pregnant within 1 week of stopping treatment with Ponvory, you should tell your doctor immediately. See following information regarding reporting pregnancy while taking or within 1 week of stopping Ponvory treatment