PONVORY®▼ (ponesimod)
PREGNANCY REMINDER CARD

Information for female patients of childbearing potential

Adverse events should be reported. ▼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. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in the package leaflet. You can also report side effects via HPRA Pharmacovigilance, Website www.hpra.ie

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Marketing authorisation holder: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

janssen Neuroscience
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Before starting PONVORY®

Read this card containing important information which is essential to ensure safe and effective use of PONVORY® and appropriately manage selective risks. Read this card and the patient information leaflet which is inside your PONVORY medication package before you start your treatment.

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

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.

You are encouraged to enrol in the the POEM programme. Ask your doctor for more information or please contact Janssen-Cilag Limited on 1800 709 122 or at medinfo@its.jnj.com

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.

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For further information, please contact
Janssen Medical Information on:
Tel: 1800 709 122
Email: medinfo@its.jnj.com

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Reference: PONVORY® (ponesimod) patient information leaflet available from www.medicines.ie