Multiple sclerosis medicine Gilenya not to be used during pregnancy. Update of restrictions

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Information on Gilenya

- Gilenya (fingolimod) is a 'disease-modifying therapy' medicine used to treat adults and children over 10 years of age with highly active relapsing-remitting multiple sclerosis (MS), a disease in which inflammation destroys the protective sheath surrounding the nerve cells. 'Relapsing-remitting' means that the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).
- Gilenya is used when MS remains active despite appropriate treatment with at least one other disease-modifying therapy or is severe and getting worse rapidly.

In Malta the following product is authorised through centralised licensing procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Fingolimod	Gilenya	Hard Capsules	POM	EU/1/11/677/001-008	Novartis Europharm Limited

Information from the EMA about the updated restriction on Gilenya

The review on Gilenya was started following post-marketing reports suggesting an association between Gilenya and birth defects. The review suggested risk of major congenital malformations twice as high in infants who have been exposed to Gilenya during pregnancy when compared to the 2 to 3% risk of birth defects in normal population (EUROCAT - the European network of population-based registries for the epidemiological surveillance of congenital anomalies[1]). The most frequently reported birth defects in infants exposed to Gilenya (fingolimod) *in utero* are congenital heart diseases (such as atrial and ventricular septal defects, tetralogy of Fallot), renal abnormalities and musculoskeletal abnormalities.

Following the review, the EMA's recommendations are:

- Pregnant women and women able to have children who are not using effective contraception must not use Gilenya
- Gilenya must be stopped if a woman becomes pregnant and pregnancy must be closely monitored
- A pregnancy test must be performed starting treatment with Gilenya to ensure women are not pregnant

[1] http://www.eurocat-network.eu

- Women using Gilenya must use effective contraception during treatment and for two months after stopping the medicine.

Updated educational materials to help counsel patients about the risk of reproductive toxicity will be made available and will include a physician's checklist, a guide for patients, parents and caregivers and a pregnancy-specific patient reminder card.

A European Commission binding decision on this opinion will be issued in due course.

In Malta

For Healthcare Professionals

- Gilenya (fingolimod) is now contraindicated in pregnant women and in women of childbearing potential not using effective contraception, due to the risk of congenital malformations in foetuses exposed *in utero*
- For women of childbearing potential, ensure that:
  - Patients are informed of the risk of harmful effects to the foetus associated with fingolimod treatment
  - A negative pregnancy test result is available before treatment initiation
  - Effective contraception is used during treatment and for 2 months after treatment discontinuation
  - Fingolimod treatment is stopped 2 months before planning a pregnancy
- If a woman becomes pregnant during treatment, Gilenya must be discontinued and the patient should be given medical advice about the risk of harmful effects to the fetus. The pregnancy should be closely monitored, and ultrasonography examinations should be performed.

A DHPC letter about the safety concern has been disseminated to HCPs in Malta. Archived DHPC letters are available online at http://www.medicinesauthority.gov.mt/dhpc

Advice for Patients

- If you are pregnant or able to have children but are not using effective contraception, you must avoid taking Gilenya, a multiple sclerosis medicine
- If you are a female patient able to have children and just starting treatment with Gilenya, you will first need to have a pregnancy test to make sure that you are not pregnant
- Gilenya may harm the unborn child if taken during pregnancy, exposing the child to higher risk of birth defects, in particular those affecting the heart, kidneys, bones and muscles
- While taking Gilenya, you must use effective contraception. If you are planning to have a baby and you are taking Gilenya, talk to your doctor. Before trying for a baby, you must stop taking Gilenya and wait for at least two months. During these two months, you must still use contraception
- If you do become pregnant while taking Gilenya, tell your doctor straight away. Your doctor will stop your Gilenya treatment and carry out extra tests to monitor your pregnancy

- Your doctor will talk to you about this risk before starting and during treatment with Gilenya, and will give you a card with information on why you should not become pregnant while taking Gilenya, and what you should do to avoid becoming pregnant while you are taking this medicine
- If you have any questions about Gilenya or the risks it poses to the unborn child, talk to your doctor, nurse or pharmacist.

For more information please see the European Medicines Agency's press release on Gilenya

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Gilenya (fingolimod). Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

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