Direct Healthcare Professional Communication

08-Aug-2019

Gilenya (fingolimod) – New contraindication in pregnant women and in women of childbearing potential not using effective contraception

Dear healthcare professional,

In agreement with Saudi Food and Drug Authority (SFDA), Novartis would like to inform you of the following:

Summary

- **Due to the risk of congenital malformations in fetuses exposed to fingolimod (Gilenya), fingolimod is now contraindicated in:**
    - **pregnant women**
    - **women of childbearing potential not using effective contraception**

- Post-marketing data suggest that infants born to mothers who have been exposed to fingolimod during pregnancy have a two-fold increased risk for congenital malformations compared with the rate observed in the general population (2-3 %; EUROCAT).

- **For women of childbearing potential, ensure before treatment initiation and during the treatment that:**
    - the patient is informed on the risk of harmful effects to the foetus associated with fingolimod treatment,
    - a negative pregnancy test result is available before any 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:**
    - fingolimod must be discontinued,
    - medical advice should be given to the patient regarding the risk of harmful effects to the foetus,
    - the pregnancy should be closely monitored, and ultrasonography examinations should be performed.

Background

Gilenya is indicated as disease-modifying therapy in highly active relapsing-remitting multiple sclerosis for the following groups of adults and children aged 10 years and older:

- patients with highly active disease despite a full and adequate course of treatment with at least one disease-modifying therapy , or
- patients with rapidly evolving severe relapsing-remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

The receptor affected by fingolimod (sphingosine1-phosphate receptor) is involved in vascular formation during embryogenesis. Animal studies have shown reproductive toxicity in rats.

Based on human experience, post-marketing data suggest that use of fingolimod is associated with a 2 fold increased risk of major congenital malformations when administered during pregnancy compared with the rate observed in the general population (2-3 %; EUROCAT[1]).

The most frequently reported major malformations are:
- congenital heart disease such as atrial and ventricular septal defects, tetralogy of Fallot;
- renal abnormalities;
- musculoskeletal abnormalities.

Information is provided in the "Physician Information Pack," which includes 3 educational materials to facilitate the regular counselling of patients regarding the risk of reproductive toxicity[2]:

- Physician's checklist

- Patient / Parent / Caregiver guide

- Pregnancy-specific patient reminder card

[1] EUROCAT: European surveillance of congenital anomalies (http://www.eurocat-network.eu)
[2] The current educational materials will be updated.

Call for reporting

Physicians are encouraged to continue reporting on pregnant patients who may have been exposed to fingolimod at any time during pregnancy (from 8 weeks prior to last menstrual period onward) to Novartis by dialling Novartis Saudi toll free number: 8001240078 or visiting www.report.novartis.com. Physicians may also enroll a pregnant MS patient under their care in the fingolimod pregnancy registry by dialling the toll free number: 8001240078 or visiting www.report.novartis.com.

Gilenya is subject to additional monitoring to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Please report any suspected adverse reactions associated with the use of fingolimod in accordance with the national requirements via the national spontaneous reporting system, to:

Novartis Consulting AG, Patient Safety Department:
Phone: +996112658100
Toll free number: 8001240078
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com
Website: www.report.novartis.com

National Pharmacovigilance Center (SFDA):
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Yours faithfully,

Malak Alowais
Patient Safety Manager (QPPV)
Novartis Saudi Arabia

Alowais Malak

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