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Our ref : ١٧١٩..

Date : 25/12/2017

اشارتنا : ١٧-١٢-١٣٧٨

التاريخ : ٠٧ / ربيع الثاني /١٤٣٩هـ

Direct Healthcare Professional Communication

25-12-2017

Fingolimod (Gilenya) – contraindications in patients with cardiac conditions

Dear Healthcare professional,

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

Summary

Warnings against the use of fingolimod (Gilenya) in patients with underlying cardiac disorders have been strengthened; fingolimod is now contraindicated in:

- Patients with myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attacks, decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months.
- Patients with severe cardiac arrhythmias requiring treatment with class Ia (e.g. quinidine, procainamide, disopyramide) and class III (potassium-channel blockers, e.g. amiodarone, sotalol, ibutilide, dofetilide) anti-arrhythmic drugs.
- Patients with second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick-sinus syndrome, if they do not wear a pacemaker.
- Patients with a baseline QTc interval ≥500 milliseconds.

Background

Gilenya is indicated as a disease modifying therapy for the treatment of patients with relapsing multiple sclerosis to reduce the frequency of relapses and to delay the progression of disability.

The risk of serious cardiac rhythm disturbances with fingolimod, including polymorphic ventricular arrhythmia (PVA), is already described in the product information. However, cases of PVA, including fatalities have been reported. Therefore, to minimise the risk of severe adverse events in patients with cardiac conditions, contraindications are being introduced. The warnings and precautions on the immunosuppressive effect of fingolimod potentially leading to serious infections and cancer are also being updated.

Cases of basal cell carcinoma (BCC) and other cutaneous neoplasms (e.g. melanoma) have been reported in patients receiving Gilenya. Vigilance for BCC and other cutaneous neoplasms is warranted.

Cases of lymphoma have been reported in patients treated with Fingolimod. Therefore monitoring for lymphoma signs and symptoms is advised and extensive evaluation should be performed promptly if lymphoma is suspected.

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
ترخيص وزارة التجارة رقم ٣

الرياض
ص.ب :١٦٠٣٢
الرياض : ١١٤٦٤
تلفون : ٨٨٨٢ ٤٦٥
تليفاكس : ٨١٢٧ ٤٦٤

جدة
ص.ب : ٨٦٤٠
جدة : ٢١٤٩٢
تلفون : ٥٦٦٦ ٦٦٩
تليفاكس: ٣٥٣٤ ٦٦٣

الدمام
ص.ب : ٦٥٠٣
الدمام : ٣١٤٥٢
تلفون :٣١٧٤ ٨٣٤
تليفاكس : ٤٢٠٠ ٨٣٤

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التاريخ :

For complete information on the side effects and risks with fingolimod and the related recommendations for use, please consult the product information (summary of product characteristics (SmPC) and package leaflet).

Call for reporting

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:
Saudi Arabia: P.O. Box 16032, Riyadh 11464, Tel: +966114658882
Phone: +996112658100
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com

National Pharmacovigilance and Drug Safety Center:
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa
Gilenya is subject to additional monitoring to allow quick identification of new safety information.
Healthcare professionals are asked to report any suspected adverse reactions.

Yours sincerely,

Malak Alowais
Patient Safety Head Deputy (QPPV)
Novartis Saudi Arabia

25-12-2017

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ترخيص وزارة التجارة رقم ٣

الرياض	جدة	الدمام
ص.ب :١٦٠٣٢	ص.ب : ٨٦٤٠	ص.ب : ٦٥٠٣
الرياض : ١١٤٦٤	جدة : ٢١٤٩٢	الدمام : ٣١٤٥٢
تلفون : ٨٨٨٢ ٤٦٥	تلفون : ٥٦٦٦ ٦٦٩	تلفون :٣١٧٤ ٨٣٤
تليفاكس : ٨١٢٧ ٤٦٤	تليفاكس: ٣٥٣٤ ٦٦٣	تليفاكس : ٤٢٠٠ ٨٣٤