Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:

Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find enclosed our Circular No.....58..... dated ...05/08/19 regarding updated restrictions for Gilenya.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU.

dg-padc@moh.gov.om ص.ب رقم : ٣٩٣ مسقط - الرمز البريدي : ١٠٠ ، هاتف : ٢٢٣٥٧١١١ ، فاكس : ٢٢٣٥٨٤٨٩، البريد الإلكتروني :
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 58/ 2019

03 -12-1440 H

05 -08-2019

Updated restrictions for Gilenya: multiple sclerosis medicine not to be used in pregnancy

The European Medicines Agency (EMA has recommended that the multiple sclerosis medicine Gilenya (fingolimod) must not be used in pregnant women and in women able to have children who are not using effective contraception. If a woman becomes pregnant while using Gilenya, the medicine must be stopped and the pregnancy will have to be closely monitored. This is because the active substance in Gilenya, fingolimod, can harm the unborn baby and may cause birth defects.

To minimise this risk, women able to have children must have a pregnancy test before starting treatment with Gilenya to ensure they are not pregnant, and must use effective contraception during treatment and for two months after stopping the medicine.

These recommendations follow a review triggered by reports suggesting that the risk of birth defects in infants who have been exposed to Gilenya during pregnancy is twice as high as the 2 to 3% risk observed in the general population. The most frequently reported birth defects in infants exposed to Gilenya were those affecting the heart, kidneys, bones and muscles.

Information for healthcare professionals

- Due to the risk of congenital malformations in fetuses exposed to fingolimod *in utero*, Gilenya is now contraindicated in pregnant women and in women of childbearing potential not using effective contraception.
- For women of childbearing potential, ensure that:
  - patients are informed of the risk of harmful effects to the fetus 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.

dg-padc@moh.gov.om : البريد الإلكتروني ، ٢٢٣٥٨٤٨٩ ، فاكس : ٢٢٣٥٧١١١ ، هاتف : ١٠٠ ، الرمز البريدي : ٣٩٣ مسقط - ص.ب رقم
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These updated recommendations follow a review of available data triggered by post-marketing reports suggesting that infants born to mothers treated with fingolimod during pregnancy have a two-fold increased risk of major congenital malformations compared with the rate observed in the general population (which is 2-3 %, according to EUROCAT - the European network of population-based registries for the epidemiological surveillance of congenital anomalies.

The most frequently reported major malformations in infants exposed to fingolimod *in utero* are congenital heart diseases (such as atrial and ventricular septal defects, tetralogy of Fallot), renal abnormalities and musculoskeletal abnormalities.

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.

More about the medicine

Gilenya is a type of medicine known as a 'disease-modifying therapy' that is 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 the disease remains active despite appropriate treatment with at least one other disease-modifying therapy, or is severe and getting worse rapidly. Gilenya contains the active substance fingolimod.

More information on Gilenya can be found on the EMA website.

Gilenya is registered in Oman.

The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Ph. Hussain Al Ramimmy
ACTG. DIRECTOR GENERAL

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