NOVARTIS

Our ref : 922353

اشارتنا : ص/٦٥٦/ف/س

Date : 02/03/2014

التاريخ :

HEMOPHAGOCYTIC SYNDROME (HPS) REPORTED IN PATIENTS TREATED WITH GILENYA

Dear Health Care Professional

Novartis Pharma Service AG, Saudi Arabia ("Novartis") in collaboration with Saudi Food and Drug Authority would like to inform you on the reporting of two fatal cases of Hemophagocytic Syndrome (HPS) in patients treated with Gilenya (fingolimod) 0.5mg capsules.

Summary

- Two cases of HPS have been reported in patients treated with fingolimod. These cases had a fatal outcome and occurred in the context of an infection. A causal relationship between these two cases and fingolimod has not been established.
- An early diagnosis of HPS is important in order to improve the prognosis by early initiation of treatment of the HPS and/or the underlying condition, e.g. viral infection.
- Symptoms and signs often associated with HPS are:
  - fever, asthenia, hepato-splenomegaly and adenopathy which may be associated with more severe manifestations such as hepatic failure or respiratory distress.
  - progressive cytopenia, markedly elevated serum ferritin levels, hypertriglyceridemia, hypofibrinogenemia, coagulopathy, hepatic cytolysis and hyponatremia.
- The present letter is to raise the awareness of the healthcare professionals regarding the difficulty to diagnose HPS and the importance of an early diagnosis as there is a risk of a worse outcome when the diagnosis and thus the treatment are delayed.

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
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

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التاريخ :

Further information on hemophagocytic syndrome (HPS)

HPS is a very rare and potentially life-threatening hyper-inflammatory syndrome, that has been described in association with infections (primary or reactivation of virus infections e.g. Epstein Barr Virus), malignancies (e.g. lymphoma), immune deficiency and a variety of autoimmune diseases (e.g. lupus, multiple sclerosis).

Clinically, HPS manifests with fever, asthenia, hepato-splenomegaly, adenopathy which may be associated with more severe manifestations such as hepatic failure or respiratory distress. Laboratory findings consist of progressive cytopenia, markedly elevated serum ferritin levels, hypertriglyceridemia, hypofibrinogenemia, coagulopathy, hepatic cytolysis and hyponatremia.

The cytopathological feature of HPS is the activation of well differentiated macrophages with prominent hemophagocytosis in hematopoietic organs or lymph nodes. Diagnosis requires the assessment of all clinical and laboratory findings and should be confirmed by a specialist.

There is no defined standard treatment for HPS to date; diverse chemotherapeutic agents have been described to improve the outcome in some situations. In addition to treatment of the syndrome, it is also important to treat the underlying condition (e.g. viral infection). Early recognition and prompt treatment have been shown to improve prognosis of HPS. The outcome of HPS can be fatal, especially when an appropriate diagnosis and treatment is delayed.

Reporting requirement

To report adverse events potentially associated with Gilenya, please call Novartis Saudi Arabia (01 1465882) Fax: +966 11 4653679 or send it to the National Pharmacovigilance and Drug Safety Center at Fax: +966-11-2057662 or by email to npc.drug@sfda.gov.sa or through online: http://ade.sfda.gov.sa/

Yours sincerely,

Kamel Maged

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تليفاكس : ٤٢٠٠ ٨٣٤