Direct Healthcare Professional Communication

January 2022

Glatiramer Acetate: Rare cases of severe liver damage

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary,

Rare cases of severe liver damage (including liver failure, hepatitis with jaundice and in individual cases liver transplantation) have been reported after the marketing of glatiramer acetate.

Most cases of severe liver damage decreased with discontinuation of treatment.

To reduce the risk of severe liver damage, a recommendation was made to monitor the liver function and a criteria for discontinuing therapy has been created:

Before starting treatment with glatiramer acetate and regularly thereafter (e.g. every 6-12 months) it is recommended to measure the serum aminotransferase or alkaline phosphatase in all patients and determine the total bilitrubin level.

Patients should be monitored for signs of liver damage during treatment. If clinically relevant liver damage is suspected, the treatment with glatiramer acetate should be discontinued.

Please inform your patients:

- How to recognize signs and symptoms that indicate liver damage, such as nausea, loss of appetite, repeated vomiting, diffuse itching, dark colored urine and pale stools, yellowing of the skin or the whites of the eyes, increased tendency to bleed.
- Contact a doctor immediately if one of the above signs and symptoms appeared.

Background information:

Glatiramer acetate is used to treat relapsing multiple sclerosis (MS).

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Glatiramer acetate is a synthetic, complex mixture of polypeptides and acts as a disease-modifying agent which leads to a significant reduction in the number of attacks.

Rare cases became more severe with post-marketing observation and liver damage has been reported. The possible pathomechanism that leads to liver damage is currently not known.

The drug-induced liver injury (DILI) pattern is considered idiosyncratic.

The pattern of reported events was similar for the two dosages 20mg/ml and 40mg/ml. Hepatic events occurred within days to years of treatment with Glatiramer acetate. In these cases, among other things, the following accompanying circumstances are reported: excessive alcohol consumption, existing or known history of liver damage and the use of other potentially hepatotoxic drugs. Most cases of severe liver damage decreased with discontinuation of treatment.

Recommendation for professionals:

The early detection of possible liver damage from the use of Glatiramer acetate is essential so that timely measures can be taken and if so, clinically relevant the treatment can be discontinued. Healthcare professionals should measure before starting treatment with glatiramer acetate and regularly thereafter (for example every 6-12 months) the serum aminotransferase and alkaline phosphatase in all patients.

Determine phosphatase and total bilirubin levels.

Patients should look for signs and symptoms of liver damage during treatment and be trained to see a doctor if symptoms occur.

References

Switzerland

https://www.swissmedic.ch/swissmedic/fr/home/medicaments-a-usage-humain/surveillance-du-marche/health-professional-communication--hpc-/dhpc-glatirameracetat.html

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

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Online reporting: https://primaryreporting.who-umc.org/EG
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Hotline: 15301

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