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Direct Healthcare Professional Communication, refined guidance on when first dose monitoring procedures should be repeated for Gilenya (fingolimod)

Dear Healthcare Professional

Summary

In April 2012, Novartis informed you about enhanced first dose monitoring procedures in relation to the transient decrease in heart rate and atrioventricular conduction delay upon treatment initiation with Gilenya. These recommendations were included in the Summary of Product Characteristics.

The purpose of the present communication is to provide guidance on repeat "first dose cardiovascular monitoring" in case of treatment interruption and for patients requiring pharmacological intervention to treat bradyarrhythmia-related symptoms after first dose.

New advice:

Treatment interruption

The same first dose monitoring as for treatment initiation should be repeated if treatment is interrupted for:

- 1 day or more during the first 2 weeks of treatment.
- more than 7 days during weeks 3 and 4 of treatment.
- more than 2 weeks after one month of treatment.

If the treatment interruption is of shorter duration than the above, the treatment should be continued with the next dose as planned.

Patients requiring pharmacological intervention to treat bradyarrhythmia-related symptoms after first dose

As per the current SmPC, patients requiring pharmacological intervention during the first dose monitoring should be monitored overnight in a medical facility.
In these patients, it is recommended to repeat the first dose monitoring after the second dose of Gilenya.
These recommendations are reflected in a new version of the Summary of Product Characteristics and the Patient Leaflet and are effective immediately for patients treated with Gilenya.

Further information on the safety concern

It is known that the effects of GILENYA on heart rate and atrioventricular conduction may recur on reintroduction of GILENYA treatment following interruption. Further analyses of clinical pharmacology and dose titration data indicate that the risk of occurrence of these effects depends upon the duration of the interruption and time since initiation of GILENYA treatment.

The updated guidance from the Summary of Product Characteristics on the management of the transient decrease in heart rate and atrioventricular conduction delay upon treatment initiation with Gilenya can be found in the Annex.

The content of this letter has been agreed with the Malta Medicines Authority.

Call for Reporting

Healthcare professionals should report any suspected adverse reactions associated with use of fingolimod (See below).

Suspected adverse drug reaction should be reported to the Malta Medicines Authority by use of postlicensing.mru@gov.mt. Alternatively any suspected adverse reactions can also be reported to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA, or at:
http://www.medicinesauthority.gov.mt/pub/adr.doc.

Adverse reactions should also be reported to Novartis on 22983217 / 21222872 or drug_safety.malta@novartis.com.

Yours sincerely,

Graziella Vella

Annex
Extract from the revised Product Information (with changes made visible)

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