NOVARTIS

ספטמבר 2025

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

הנדון: Gilenya 0.5 mg

התכשיר שבנדון רשום בישראל להתוויה הבאה:

Gilenya is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

המרכיב הפעיל: fingolimod (as hydrochloride) 0.5 mg

אנו מודיעים על עדכונים בעלון לרופא.
מפורטים להלן העדכונים המהותיים בלבד:

7. Warnings and Precautions

7.8 Fetal Risk

~~Based on findings from animal studies,~~ GILENYA may cause fetal harm when administered to a pregnant woman. In animal reproduction studies conducted in rats and rabbits, developmental toxicity was observed with administration of fingolimod at doses less than the recommended human dose. Available observational pregnancy registry data suggest that use of GILENYA is associated with an increased prevalence of major birth defects in comparison to the general population.

7.11 Increased Blood Pressure

Increases in blood pressure have been observed in patients treated with GILENYA.
In adult MS controlled clinical trials, patients treated with GILENYA 0.5 mg had an average increase over placebo of approximately 3 mmHg in systolic pressure, and approximately 2 mmHg in diastolic pressure, first detected after approximately 1 month of treatment initiation, and persisting with continued treatment. Hypertension was reported as an adverse reaction in 8% of patients on GILENYA 0.5 mg and in 4% of patients on placebo.
~~Blood pressure should be monitored~~ Monitor blood pressure (BP) in patients during treatment with GILENYA.

10. USE IN SPECIFIC POPULATIONS

10.1 Pregnancy

Risk Summary
Available observational pregnancy registry data suggest that use of GILENYA is associated with an increased prevalence of major birth defects in comparison to the general population. However, limitations in the number of exposed pregnant women and in the study design preclude definitive conclusions (see Data).

Data from prospective reports to the ~~GILENYA~~ Pregnancy Registry ~~(GPR)~~ are currently not sufficient to allow for an adequate assessment of the drug-associated risk for ~~birth defects and~~ miscarriage ~~in humans~~.
Based on findings from animal studies, GILENYA may cause fetal harm when administered to a pregnant woman.

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Data

Human Data

In a prospective observational GILENYA pregnancy registry (GPR) (2011 - 2024), the rate of major birth defects among 147 live births, stillbirths, or terminations of pregnancy due to fetal anomalies from women who were administered fingolimod during the first trimester was 8.2% (95% CI: 4.3-13.8) using the European Registration of Congenital Anomalies and Twin classification and 10.9% (95% CI: 6.4-17.1) using the Metropolitan Atlanta Congenital Defects Program classification. The most frequent major birth defects were congenital heart defects, renal/urinary malformations, and limb/musculoskeletal malformations. Study limitations include no adjustment for confounders, no re-adjudication in case of spontaneous resolution, lack of an internal comparator cohort, and small sample size.

In fingolimod prospective pharmacovigilance data, the most frequent major birth defect types were similar to those reported in the GPR.

The pattern of malformations reported for GILENYA is similar to that observed in the general population. There is no evidence of clustering of specific birth defects with GILENYA.

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פניה לבעל הרישום.

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