

Please read the following materials:

PRESCRIBING
INFORMATION

DEAR HEALTHCARE
PROFESSIONAL
LETTER

DEAR
PROFESSIONAL
SOCIETY LETTER

GUIDE TO
IMPORTANT SAFETY
INFORMATION

GILENYA
PREGNANCY
REGISTRY

Risk Evaluation and Mitigation Strategy (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

In order for Novartis Pharmaceuticals Corporation to communicate certain risks about GILENYA, we have worked with the FDA to develop materials to communicate the risks of:

- Bradyarrhythmia and Atrioventricular (AV) Block
- Infections
- Macular Edema
- Posterior Reversible Encephalopathy Syndrome
- Respiratory Effects
- Liver Injury
- Fetal Risk

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ALICE HUGHES
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