Fingolimod (GILENYA)

FDA notified a rare and serious brain infection (PML) after taking fingolimod in patients diagnosed with multiple sclerosis (MS).


- Fingolimod is used to treat relapsing forms of MS, a nervous system disease that affects the brain and spinal cord.

- This is the first case of progressive multifocal leukoencephalopathy (PML), reported following the administration of fingolimod to a patient who had not previously received Natalizumab (which is associated with a higher risk of PML).

- PML is a rare and serious brain infection caused by JC virus that damages fatty covering of the brain and myelin. PML usually causes death or severe disability.

- Patients should NOT stop taking fingolimod without first discussing any questions or concerns with their treating physician.

- Physicians and patients are encouraged to report adverse events related to the use of fingolimod.