Gilenya[®] (fingolimod): Pregnancy-Specific Patient Reminder Card



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IF USED DURING PREGNANCY, GILENYA® (FINGOLIMOD) CAN HARM YOUR UNBORN BABY.

Gilenya® (fingolimod) should not be used in pregnant women and women of childbearing potential not using effective contraception.

It is important that you use effective contraception while taking Gilenya® (fingolimod) and for 2 months after you stop taking it to avoid becoming pregnant. Your doctor will provide counselling regarding effective contraception.

Beginning Gilenya® (fingolimod) treatment



Gilenya® (fingolimod) is teratogenic (an agent which causes harm or abnormalities in the development of the embryo or fetus following exposure during pregnancy, resulting in birth defects or malformations).



Before you start treatment with Gilenya® (fingolimod) and then regularly during treatment, your doctor will inform you about the risks to the unborn baby and explain what you should do to avoid becoming pregnant while you are taking Gilenya® (fingolimod).



Your doctor will ask you to take a pregnancy test to ensure that you are not pregnant before you start treatment with Gilenya® (fingolimod).



Your doctor will inform you about the need for effective contraception while on treatment and for 2 months after discontinuation. Talk to your doctor about the most effective contraception options available to you.



Please read the Gilenya® Patient, Parent and Caregiver Medication Guide provided by your doctor.

While you are taking Gilenya® (fingolimod)



You should not become pregnant while taking Gilenya® (fingolimod) and for 2 months after stopping treatment.



You should use effective contraception during treatment and for 2 months after discontinuing treatment to avoid becoming pregnant.



Your doctor will verify your pregnancy status at suitable intervals.



Your doctor will provide counselling regularly regarding the risks of Gilenya® (fingolimod) harming an unborn baby if you become pregnant and the required actions to minimize the risk.



Tell your doctor **immediately** if you think you are pregnant or if you want to become pregnant because your doctor will consider stopping your Gilenya® (fingolimod) treatment.



In the event of a pregnancy, your doctor will give you medical advice regarding the harmful effects of Gilenya® (fingolimod) to the fetus and will perform medical follow-up examination. An ultrasonography examination should be performed, and Gilenya® (fingolimod) treatment may be discontinued.

After stopping Gilenya® (fingolimod) treatment



Inform your doctor immediately if you believe your condition of multiple sclerosis is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms after stopping treatment with Gilenya® (fingolimod) due to pregnancy.



Effective contraception is needed for 2 months after stopping Gilenya® (fingolimod) treatment because of the length of time it takes for Gilenya® (fingolimod) to leave the body.



HSA Approved RMP - Gilenya® Pregnancy-Specific Patient **Reminder Card**

This material is also available online.

Please scan this QR code

or visit https://www.medhub.novartis.com.sg/ermp/Gilenya

If you have any questions about the information in this reminder card, please contact your doctor.

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