

EMA warns that Gilenya must not be used during pregnancy

The European Medicines Agency (EMA) has issued a press release recommending that **Gilenya** (fingolimod) must not be taken by pregnant women or by women of childbearing age who are not using an effective form of contraception.

A review of **Gilenya** and **pregnancy** was carried out by the EMA's safety committee following reports which suggested that, babies born to mothers taking Gilenya during pregnancy have a greater risk of birth defects compared with the general population.

The EMA have published the following advice to women taking Gilenya:

- You must not take Gilenya if you are pregnant or if you are able to have children but are not using effective contraception.
- This is because Gilenya may harm the unborn baby if taken during pregnancy. If you take Gilenya during pregnancy, your child could be at higher risk of birth defects, in particular those affecting the heart, kidneys, bones and muscles.
- You must use effective contraception while taking Gilenya. If you are taking Gilenya and are planning to have a baby, talk to your doctor first. Before trying for a baby, you must stop taking Gilenya and wait for at least two months. During these two months, you must still use contraception.
- If you do become pregnant while taking Gilenya, tell your doctor straight away. Your doctor will stop your Gilenya treatment and carry out extra tests to monitor your pregnancy.
- Your doctor will talk to you about this risk before starting and during treatment with Gilenya, and will give you a card with information on why you should not become pregnant while taking Gilenya, and what you should do to avoid becoming pregnant while you are taking this medicine.
- If you are a woman able to have children and just starting treatment with Gilenya, you will first need to have a pregnancy test to make sure that you are not pregnant.
- If you have any questions about Gilenya or the risks it poses to the unborn child, talk to your neurologist, MS nurse or pharmacist.

The EMA press release can be found here: <https://www.ema.europa.eu/en/news/updated-restrictions-gilenya-multiple-sclerosis-medicine-not-be-used-pregnancy>.