Fingolimod:

Pregnancy-Specific Patient Reminder Card

Approved by
MHRA June 2022

VIATRIS

Before starting fingolimod treatment

Fingolimod is contraindicated in pregnant women and women of child-bearing potential (including adolescents) not using effective contraception.

At treatment start and then regularly, your doctor will inform you about the teratogenic risk (causes defects to unborn babies) and required actions to minimise this risk.

A pregnancy test must be conducted and the negative result verified by a doctor before starting treatment.

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 Fingolimod Patient, Parent, Caregiver Guide provided by your doctor.

While you are taking fingolimod

While on treatment women must not become pregnant.

Patients must use effective contraception while taking fingolimod.

Women must not become pregnant during treatment and for 2 months after discontinuing treatment.

Pregnancy tests must be repeated at suitable intervals.

Your doctor will provide regular counselling about fingolimod's serious risks to the foetus.

If you become pregnant or if you want to become pregnant please discuss this with your doctor because fingolimod treatment must be discontinued.

In the event of a pregnancy your doctor will provide counselling.

Your doctor will give you medical advice regarding the harmful effects of fingolimod to the foetus and will provide an evaluation of the potential outcome.

After stopping fingolimod treatment

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

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

Reporting of side effects

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website: www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse reactions/events should also be reported to Viatris at e-mail address: pv.uk@viatris.com or call 01707 853000
(Select Option 5).

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