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Fingolimod patient information

Fingolimod
Pregnancy-Specific Patient Reminder Card

Approved by MHRA October 2022

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 Guide Leaflet 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.

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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.

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Reporting of side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store,

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and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting side effects you can help provide more information on the safety of your medication.

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SANDOZ

For further information please contact Sandoz UK Medical Information Department: 01276 698 101 or Sandozgb@EU.propharmagroup.com

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Date of preparation: October 2022 245706

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