

Sphingolin (Fingolimod)

Pregnancy-Specific Patient Reminder Card

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

Before starting Sphingolin (Fingolimod) treatment

Sphingolin (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 minimize 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 Sphingolin (Fingolimod) Patient Guide Leaflet provided by your doctor.

While you are taking Sphingolin (Fingolimod)

While on treatment women must not become pregnant. Patients must use effective contraception while taking Sphingolin (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 Sphingolin (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 Sphingolin (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 Sphingolin (Fingolimod) to the foetus and will provide an evaluation of the potential outcome.

An ultrasonography examination should be performed, and Sphingolin (Fingolimod) treatment will be discontinued.

After stopping Sphingolin (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 Sphingolin (Fingolimod) due to pregnancy.

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

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.

To Report any Adverse Drug Reaction or Concerns please call:

National Pharmacovigilance & Drug Safety Centre at Saudi Food and Drug Authority (SFDA):

SFDA call centre: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfda.gov.sa>

Marketing Authorization Holder Contact Information:

Saudi AmaroX Industrial Company

Ms. Razan almalki

Pharmacovigilance Specialist

Al Jamiyah Street – Al Malaz – Riyadh Code 12629, Saudi Arabia.

Phone: +966 11 226 8850

Mobile: +966 531215235

Email: r.almalki@amaroxpharma.com