

- If you suffer from depression or anxiety or if you become depressed or anxious while you are taking Fingolimod, let your doctor know. You may need to be monitored more closely.

Other medicines and Fingolimod

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are taking any of the following medicines:

- medicines that suppress or modulate the immune system**, including other medicines used to treat MS, such as beta interferon, glatiramer acetate, natalizumab, mitoxantrone, teriflunomide, dimethyl fumarate or alemtuzumab. You must not use Fingolimod together with such medicines as this could intensify the effect on the immune system (see also "Do not take Fingolimod")
- corticosteroids**, due to a possible added effect on the immune system
- vaccines**. If you need to receive a vaccine, seek your doctor's advice first. During and for up to 2 months after treatment with Fingolimod, you should not receive certain types of vaccine (live attenuated vaccines) as they could trigger the infection that they were supposed to prevent. Other vaccines may not work as well as usual if given during this period
- medicines that slow the heartbeat** (for example beta blockers, such as atenolol): Use of Fingolimod together with such medicines could intensify the effect on heartbeat in the first days after starting Fingolimod
- medicines for irregular heartbeat**, such as quinidine, disopyramide, amiodarone or sotalol. You must not use Fingolimod if you are taking such a medicine because it could intensify the effect on irregular heartbeat (see also "Do not take Fingolimod")
- other medicines:
 - protease inhibitors, anti-infectives such as ketoconazole, azole antifungals, clarithromycin or telithromycin
 - carbamazepine, rifampicine, phenobarbital, phenytoin, efavirenz or St. John's Wort (potential risk of reduced efficacy of Fingolimod).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Do not use Fingolimod during pregnancy, if you are trying to become pregnant or if you are a woman who could become pregnant and you are not using effective contraception. If Fingolimod is used during pregnancy, there is a risk of harm to the unborn baby. The rate of congenital malformations observed in babies exposed to Fingolimod during pregnancy is about 2-times the rate observed in the general population (in whom the rate of congenital malformations is about 2-3%). The most frequently reported malformations included cardiac, renal and musculoskeletal malformations.

Therefore, if you are a woman of childbearing potential:

- before you start treatment with Fingolimod your doctor will inform you about the risk to an unborn baby and ask you to do a pregnancy test in order to ensure that you are not pregnant, and,
- you must use effective contraception while taking Fingolimod and for two months after you stop taking it to avoid becoming pregnant. Talk to your doctor about reliable methods of contraception.

Your doctor will give you a card which explains why you should not become pregnant while taking Fingolimod.

If you do become pregnant while taking Fingolimod, tell your doctor straight away. Your doctor will decide to stop treatment (see "If you stop taking Fingolimod" in section 3, and also section 4, "Possible side effects"). Specialised pre-natal monitoring will be performed.

Breastfeeding

You should not breastfeed while you are taking Fingolimod.

Fingolimod can pass into breast milk and there is a risk of serious side effects for the baby.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles, including a bicycle, and use machines safely. Fingolimod is not expected to have an influence on your ability to drive and use machines.

However, at initiation of treatment you will have to stay at the doctor's surgery or clinic for 6 hours after taking the first dose of Fingolimod. Your ability to drive and use machines may be impaired during and potentially after this time period.

Information on sodium content of Fingolimod

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Fingolimod

Treatment with Fingolimod will be overseen by a doctor who is experienced in the treatment of multiple sclerosis.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is:

Adults:

The dose is one 0.5 mg capsule per day.

Children and adolescents (10 years of age and above):

The dose depends on body weight:

- children and adolescents with body weight equal to or below 40 kg: one 0.25 mg capsule per day
Fingolimod 0.5 mg hard capsules are not suitable for paediatric patients with body weight \leq 40 kg. Other fingolimod-containing medicinal products are available in a lower strength (as 0.25 mg capsules)
- children and adolescents with body weight above 40 kg: one 0.5 mg capsule per day.

Children and adolescents who start on one 0.25 mg capsule per day and later reach a stable body weight above 40 kg will be instructed by their doctor to switch to one 0.5 mg capsule per day. In this case, it is recommended to repeat the first-dose observation period.

Do not exceed the recommended dose.

Fingolimod is for oral use.

Take Fingolimod once a day with a glass of water. Fingolimod capsules should always be swallowed intact, without opening them. Fingolimod can be taken with or without food.

Taking Fingolimod at the same time each day will help you remember when to take your medicine. If you have questions about how long to take Fingolimod, talk to your doctor or your pharmacist.

If you take more Fingolimod than you should

If you have taken too much Fingolimod, call your doctor straight away.

If you forget to take Fingolimod

If you have been taking Fingolimod for less than 1 month and you forget to take 1 dose for a whole day, call your doctor before you take the next dose. Your doctor may decide to keep you under observation at the time you take the next dose.

If you have been taking Fingolimod for at least 1 month and have forgotten to take your treatment for more than 2 weeks, call your doctor before you take the next dose. Your doctor may decide to keep you under observation at the time you take the next dose. However, if you have forgotten to take your treatment for up to 2 weeks, you can take the next dose as planned.

Never take a double dose to make up for a forgotten dose.

If you stop taking Fingolimod

Do not stop taking Fingolimod or change your dose without talking to your doctor first.

Fingolimod will stay in your body for up to 2 months after you stop taking it. Your white blood cell count (lymphocyte count) may also remain low during this time and the side effects described in this leaflet may still occur. After stopping Fingolimod you may have to wait for 6-8 weeks before starting a new MS treatment.

If you have to restart Fingolimod more than 2 weeks after you stop taking it, the effect on heart rate normally seen when treatment is first started may re-occur and you will need to be monitored at the doctor's surgery or clinic for re-initiation of treatment. Do not restart Fingolimod after stopping it for more than two weeks without seeking advice from your doctor.

Your doctor will decide whether and how you need to be monitored after stopping Fingolimod. Tell your doctor straight away if you think your MS is getting worse after you have stopped treatment with Fingolimod. This could be serious.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be or could become serious.

Common (may affect up to 1 in 10 people):

- coughing with phlegm, chest discomfort, fever (signs of lung disorders)
- herpes virus infection (shingles or herpes zoster) with symptoms such as blisters, burning, itching or pain of the skin, typically on the upper body or the face. Other symptoms may be fever and weakness in the early stages of infection, followed by numbness, itching or red patches with severe pain

- slow heartbeat (bradycardia), irregular heart rhythm
- a type of skin cancer called basal cell carcinoma (BCC) which often appears as a pearly nodule, although it can also take other forms
- depression and anxiety are known to occur with increased frequency in the MS population and have also been reported in paediatric patients treated with fingolimod
- weight loss

Uncommon (may affect up to 1 in 100 people):

- pneumonia with symptoms such as fever, cough, difficulty breathing
- macular oedema (swelling in the central vision area of the retina at the back of the eye) with symptoms such as shadows or blind spot in the centre of the vision, blurred vision, problems seeing colours or details
- reduction in blood platelets which increases risk of bleeding or bruising
- malignant melanoma (a type of skin cancer which usually develops from an unusual mole). Possible signs of melanoma include moles which may change size, shape, elevation or colour over time, or new moles. The moles may itch, bleed or ulcerate
- convulsion, fits (more frequent in children and adolescents than in adults)

Rare (may affect up to 1 in 1,000 people):

- a condition called posterior reversible encephalopathy syndrome (PRES). Symptoms may include sudden onset of severe headache, confusion, seizures and/or vision disturbances
- lymphoma (a type of cancer that affects the lymph system)
- squamous cell carcinoma: a type of skin cancer which may present as a firm red nodule, a sore with crust, or a new sore on an existing scar

Very rare (may affect up to 1 in 10,000 people):

- electrocardiogram anomaly (T-wave inversion)
- tumour related to infection with human herpes virus 8 (Kaposi's sarcoma)

Not known (frequency cannot be estimated from the available data):

- allergic reactions, including symptoms of rash or itchy hives, swelling of lips, tongue or face, which are more likely to occur on the day you start Fingolimod treatment
- signs of liver disease (including liver failure), such as yellowing of your skin or the whites of your eyes (jaundice), nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (brown coloured), feeling less hungry than usual, tiredness and abnormal liver function tests. In a very small number of cases, liver failure could lead to liver transplantation
- risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to an MS relapse. Symptoms might also arise that you might not become aware of by yourself, such as changes in mood or behaviour, memory lapses, speech and communication difficulties, which your doctor may need to investigate further to rule out PML. Therefore, if you believe your MS is getting worse or if you or those close to you notice any new or unusual symptoms, it is very important that you speak to your doctor as soon as possible
- cryptococcal infections (a type of fungal infection), including cryptococcal meningitis with symptoms such as headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion
- Merkel cell carcinoma (a type of skin cancer). Possible signs of Merkel cell carcinoma include flesh-coloured or bluish-red, painless nodule, often on the face, head or neck. Merkel cell carcinoma can also present as a firm painless nodule or mass. Long-term exposure to the sun and a weak immune system can affect the risk of developing Merkel cell carcinoma
- after fingolimod treatment is stopped, symptoms of MS can return and may become worse than they were before or during treatment
- autoimmune form of anaemia (decreased amount of red blood cells) where red blood cells are destroyed (autoimmune haemolytic anaemia)

If you experience any of these, **tell your doctor straight away.**

Other side effects

Very common (may affect more than 1 in 10 people):

- infection from flu virus with symptoms such as tiredness, chills, sore throat, aching in the joints or muscles, fever
- feeling of pressure or pain in the cheeks and forehead (sinusitis)
- headache
- diarrhoea
- back pain
- blood testing showing higher levels of liver enzymes
- cough

Common (may affect up to 1 in 10 people):

- ringworm, a fungal infection of the skin (tinea versicolor)
- dizziness
- severe headache often accompanied by nausea, vomiting and sensitivity to light (migraine)
- low level of white blood cells (lymphocytes, leucocytes)
- weakness
- itchy, red, burning rash (eczema)
- itching
- blood fat (triglycerides) level increased
- hair loss
- breathlessness
- depression
- blurred vision (see also the section on macular oedema under "some side effects could be or could become serious")
- hypertension (fingolimod may cause a mild increase in blood pressure)
- muscle pain
- joint pain

Uncommon (may affect up to 1 in 100 people):

- low level of certain white blood cells (neutrophils)
- depressed mood
- nausea

Rare (may affect up to 1 in 1,000 people):

- cancer of the lymphatic system (lymphoma)

Not known (frequency cannot be estimated from the available data):

- peripheral swelling

If any of these affects you severely, tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fingolimod

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the foil after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use any pack that is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fingolimod Capsule contains

The active substance is fingolimod. Each capsule contains 0.5 mg fingolimod (as hydrochloride).

The other ingredients are:

Capsule fill: beta-cyclodextrin, magnesium stearate
Capsule shell: iron oxide yellow (E172), titanium dioxide (E171), gelatine, sodium lauryl sulphate
Printing ink: shellac, black iron oxide (E172), potassium hydroxide.

What Fingolimod Capsule looks like and contents of the pack

Fingolimod 0.5 mg hard capsules are white to off-white hard gelatine capsules, size 3, with dark yellow opaque coloured cap imprinted 'FGM' with black ink and white opaque coloured body with imprinted '0.5 mg' with black ink.

Fingolimod 0.5 mg hard capsules are available in packs containing 7 x 1, 7, 28, 42, 56 or 98 capsules or in multipacks containing 56 (2 x 28) or 84 capsules (3 packs of 28 capsules).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in June 2022.