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Front Page

Package leaflet: Information for the user
Fingolimod Opha 0.5 mg hard capsules
fingolimod

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fingolimod Opha is and what it is used for
2. What you need to know before you take Fingolimod Opha
3. How to take Fingolimod Opha
4. Possible side effects
5. How to store Fingolimod Opha
6. Contents of the pack and other information

1. What Fingolimod Opha is and what it is used for

What Fingolimod Opha is
The active substance of Fingolimod Opha is fingolimod.

What Fingolimod Opha is used for
Fingolimod Opha is used in adults and in children and adolescents (10 years of age and above) to treat relapsing-remitting multiple sclerosis (MS), more specifically in:
- patients who have failed to respond despite treatment with an MS treatment

or
- patients who have rapidly evolving severe MS.

Fingolimod Opha does not cure MS, but it helps to reduce the number of relapses and to slow down the progression of physical disabilities due to MS.

What is multiple sclerosis
MS is a long-term condition that affects the central nervous system (CNS), comprised of the brain and spinal cord. In MS inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the nerves from working properly. This is called demyelination.

Relapsing-remitting MS is characterised by repeated attacks (relapses) of nervous system symptoms that reflect inflammation within the CNS. Symptoms vary from patient to patient but typically involve walking difficulties, numbness, vision problems or disturbed balance. Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain.

How Fingolimod Opha works
Fingolimod Opha helps to protect against attacks on the CNS by the immune system by reducing the ability of some white blood cells (lymphocytes) to move freely within the body and by stopping them from reaching the brain and spinal cord. This limits nerve damage caused by MS. Fingolimod Opha also reduces some of the immune reactions of your body.

2. What you need to know before you take Fingolimod Opha

Do not take Fingolimod Opha
- if you have a **lowered immune response** (due to an immunodeficiency syndrome, a disease or to medicines that suppress the immune system).
- if your doctor suspects you may have a **rare brain infection called progressive multifocal leukoencephalopathy (PML) or if PML has been confirmed**.
- if you have a **severe active infection or active chronic infection** such as hepatitis or tuberculosis.
- if you have an **active cancer**.
- if you have **severe liver problems.**
- **if, in the last 6 months, you have had heart attack, angina, stroke or warning of a stroke or certain types of heart failure.**
- if you have certain types of **irregular or abnormal heartbeat** (arrhythmia), including patients in whom the electrocardiogram (ECG) shows prolonged QT interval before starting Fingolimod Opha.
- **if you are taking or have recently taken medicine for irregular heartbeat** such as quinidine, disopyramide, amiodarone or sotalol.
- if you are **pregnant** or a **woman of childbearing potential not using effective contraception.**
- **if you are allergic** to fingolimod or any of the other ingredients of this medicine (listed in section 6).

If this applies to you or you are unsure, **talk to your doctor before taking Fingolimod Opha.**

Warnings and precautions
Talk to your doctor before taking Fingolimod Opha:
- **if you have severe breathing problems during sleep (severe sleep apnoea).**
- **if you have been told you have an abnormal electrocardiogram.**
- **if you suffer from symptoms of slow heart rate (e.g. dizziness, nausea, or palpitations).**
- **if you are taking or have recently taken medicines that slow your heart rate** (such as beta blockers, verapamil, diltiazem or ivabradine, digoxin, anticholinesterastic agents or pilocarpine).
- **if you have a history of sudden loss of consciousness or fainting (syncope).**
- **if you plan to get vaccinated.**
- **if you have never had chickenpox**.
- **if you have or have had visual disturbances** or other signs of swelling in the central vision area (macula) at the back of the eye (a condition known as macular oedema, see below), inflammation or infection of the eye (uveitis), **or if you have diabetes** (which can cause eye problems).
- **if you have liver problems.**
- if you have **high blood pressure that cannot be controlled by medicines**.
- if you have **severe lung problems** or smoker's cough.

If any of these applies to you or you are unsure, **talk to your doctor before taking Fingolimod Opha.**

Slow heart rate (bradycardia) and irregular heartbeat
At the beginning of treatment or after taking the first dose of 0.5 mg when you switch from a 0.25 mg daily dose, Fingolimod Opha causes the heart rate to slow down. As a result, you may feel dizzy or tired, or be consciously aware of your heartbeat, or your blood pressure may drop. **If these effects are severe, tell your doctor, because you may need treatment right away.** Fingolimod Opha can also cause an irregular heartbeat, especially after the first dose. Irregular heartbeat usually returns to normal in less than one day. Slow heart rate usually returns to normal within one month. During this period, no clinically significant heart rate effects are usually expected.

Your doctor will ask you to stay at the surgery or clinic for at least 6 hours, with hourly pulse and blood pressure measurements, after taking the first dose of Fingolimod Opha or after taking the first dose of 0.5 mg when you switch from a 0.25 mg daily dose, so that appropriate measures can be taken in the event of side effects that occur at the start of treatment. You should have an electrocardiogram performed prior to the first dose of Fingolimod Opha and after the 6-hour monitoring period.
Your doctor may monitor your electrocardiogram continuously during that time. If after the 6-hour period you have a very slow or decreasing heart rate, or if your electrocardiogram shows abnormalities, you may need to be monitored for a longer period (at least 2 more hours and possibly overnight) until these have resolved. The same may apply if you are resuming Fingolimod Opha after a break in treatment, depending on both how long the break was and how long you had been taking Fingolimod Opha before the break.

If you have, or if you are at risk for, an irregular or abnormal heartbeat, if your electrocardiogram is abnormal, or if you have heart disease or heart failure, Fingolimod Opha may not be appropriate for you.

If you have a history of sudden loss of consciousness or decreased heart rate, Fingolimod Opha may not be appropriate for you. You will be evaluated by a cardiologist (heart specialist) to advise how you should start treatment with Fingolimod Opha, including overnight monitoring.

If you are taking medicines that can cause your heart rate to decrease, Fingolimod Opha may not be appropriate for you. You will need to be evaluated by a cardiologist, who will check whether you can be switched to alternative medicine that does not decrease your heart rate in order to allow treatment with Fingolimod Opha. If such a switch is impossible, the cardiologist will advise how you should start treatment with Fingolimod Opha, including overnight monitoring.

If you have never had chickenpox
If you have never had chickenpox, your doctor will check your immunity against the virus that causes it (varicella zoster virus). If you are not protected against the virus, you may need a vaccination before you start treatment with Fingolimod Opha. If this is the case, your doctor will delay the start of treatment with Fingolimod Opha until one month after the full course of vaccination is completed.

Infections
Fingolimod Opha lowers the white blood cell count (particularly the lymphocyte count). White blood cells fight infection. While you are taking Fingolimod Opha (and for up to 2 months after you stop taking it), you may get infections more easily. Any infection that you already have may get worse. Infections could be serious and life-threatening. If you think you have an infection, have fever, feel like you have the flu, have shingles or have a headache accompanied by stiff neck, sensitivity to light, nausea, rash and/or confusion or seizures (fits) (these may be symptoms of meningitis and/or encephalitis caused by a fungal or herpes viral infection), contact your doctor straight away, because it could be serious and life-threatening.

Human papilloma virus (HPV) infection, including papilloma, dysplasia, warts and HPV-related cancer, has been reported in patients treated with Fingolimod Opha. Your doctor will consider whether you need to have a vaccination against HPV before starting treatment. If you are a woman, your doctor will also recommend HPV screening.

PML
PML is a rare brain disorder caused by an infection that may lead to severe disability or death. Your doctor will arrange magnetic resonance imaging (MRI) scans before you start treatment and during treatment to monitor the risk of PML.

If you believe your MS is getting worse or if you notice any new symptoms, for example changes in mood or behaviour, new or worsening weakness on one side of the body, changes in vision, confusion, memory lapses or speech and communication difficulties, talk to your doctor as soon as possible. These may be symptoms of PML. Also speak with your partner or caregivers and inform them about your treatment. Symptoms might arise that you might not become aware of by yourself.

If you get PML it can be treated and your treatment with Fingolimod Opha will be stopped. Some people get an inflammatory reaction as Fingolimod Opha is removed from the body. This reaction (known as immune reconstitution inflammatory syndrome or IRIS) may lead to your condition getting worse, including worsening of brain function.

Macular oedema
Before you start Fingolimod Opha, if you have or have had visual disturbances or other signs of swelling in the central vision area (macula) at the back of the eye, inflammation or infection of the eye (uveitis) or diabetes, your doctor may want you to undergo an eye examination.

Your doctor may want you to undergo an eye examination 3 to 4 months after starting Fingolimod Opha treatment.

The macula is a small area of the retina at the back of the eye which enables you to see shapes, colours, and details clearly and sharply. Fingolimod Opha may cause swelling in the macula, a condition that is known as macular oedema. The swelling usually happens in the first 4 months of Fingolimod Opha treatment.

Your chance of developing macular oedema is higher if you have **diabetes** or have had an inflammation of the eye called uveitis. In these cases, your doctor will want you to undergo regular eye examinations in order to detect macular oedema.

If you have had macular oedema, talk to your doctor before you resume treatment with Fingolimod Opha.

Macular oedema can cause some of the same vision symptoms as an MS attack (optic neuritis). Early on, there may not be any symptoms. Be sure to tell your doctor about any changes in your vision.
Your doctor may want you to undergo an eye examination, especially if:
- the centre of your vision gets blurry or has shadows;
- you develop a blind spot in the centre of your vision;
- you have problems seeing colours or fine detail.

Liver function tests
If you have severe liver problems, you should not take Fingolimod Opha. Fingolimod Opha may affect your liver function. You will probably not notice any symptoms but if you notice yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting, **tell your doctor straight away.**

If you get any of these symptoms after starting Fingolimod Opha, **tell your doctor straight away**.

Before, during and after the treatment your doctor will request blood tests to monitor your liver function. If your liver function is affected you may need to stop taking the medicine and your doctor will decide whether you should resume treatment with Fingolimod Opha.

High blood pressure
As Fingolimod Opha causes a slight elevation of blood pressure, your doctor may want to check your blood pressure regularly.

Lung problems
Fingolimod Opha has a slight effect on the lung function. Patients with severe lung problems or with smoker's cough may have a higher chance of developing side effects.

Blood count
The desired effect of Fingolimod Opha treatment is to reduce the amount of white blood cells in your blood. This will usually go back to normal within 2 months of stopping treatment. If you need to have any blood tests, tell the doctor that you are taking Fingolimod Opha. Otherwise, it may not be possible for the doctor to understand the results of the test, and for certain types of blood test your doctor may need to take more blood than usual.

Before you start Fingolimod Opha, your doctor will confirm whether you have enough white blood cells in your blood and may want to repeat a check regularly. In case you do not have enough white blood cells, you may have to interrupt treatment with Fingolimod Opha.

Posterior reversible encephalopathy syndrome (PRES)
A condition called posterior reversible encephalopathy syndrome (PRES) has been rarely reported in MS patients treated with Fingolimod Opha. Symptoms may include sudden onset of severe headache, confusion, seizures and vision changes. Tell your doctor straight away if you experience any of these symptoms during your treatment with Fingolimod Opha, because it could be serious.

Cancer
Skin cancers have been reported in MS patients treated with Fingolimod Opha. Talk to your doctor straight away if you notice any skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g. unusual moles) with a change in colour, shape or size over time. Before you start Fingolimod Opha, a skin examination is required to check whether you have any skin nodules. Your doctor will also carry out regular skin examinations during your treatment with Fingolimod Opha. If you develop problems with your skin, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you to be seen on a regular basis.

A type of cancer of the lymphatic system (lymphoma) has been reported in MS patients treated with Fingolimod Opha.

Exposure to the sun and protection against the sun
Fingolimod weakens your immune system. This increases your risk of developing cancers, in particular skin cancers. You should limit your exposure to the sun and UV rays by:
- wearing appropriate protective clothing
- regularly applying sunscreen with a high degree of UV protection.

Unusual brain lesions associated with MS relapse
Rare cases of unusually large brain lesions associated with MS relapse have been reported in patients treated with Fingolimod Opha. In case of severe relapse, your doctor will consider performing MRI to evaluate this condition and will decide whether you need to stop taking Fingolimod Opha.

Switch from other treatments to Fingolimod Opha
Your doctor may switch you directly from beta interferon, glatiramer acetate or dimethyl fumarate to Fingolimod Opha if there are no signs of abnormalities caused by your previous treatment. Your doctor may have to do a blood test in order to exclude such abnormalities. After stopping natalizumab you may have to wait for 2-3 months before starting treatment with Fingolimod Opha. To switch from teriflunomide, your doctor may advise you to wait for a certain time to allow for through an accelerated elimination procedure. If you have been treated with alemtuzumab, a thorough evaluation and discussion with your doctor is required to decide if Fingolimod Opha is appropriate for you.

Women of childbearing potential
If used during pregnancy, Fingolimod Opha can harm the unborn baby. Before you start treatment with Fingolimod Opha your doctor will explain the risk to you and ask you to do a pregnancy test in order to ensure that you are not pregnant. Your doctor will give you a card which explains why you should not become pregnant while taking Fingolimod Opha. It also explains what you should do to avoid becoming pregnant while you are taking Fingolimod Opha. You must use effective contraception during treatment and for 2 months after stopping treatment (see section "Pregnancy and breastfeeding").

Worsening of MS after stopping Fingolimod Opha treatment
Do not stop taking Fingolimod Opha or change your dose without talking to your doctor first.

Tell your doctor straight away if you think your MS is getting worse after you have stopped treatment with Fingolimod Opha. This could be serious (see "If you stop taking Fingolimod Opha" in section 3 and also section 4 "Possible side effects").

Elderly
Experience with Fingolimod Opha in elderly patients (over 65 years) is limited. Talk to your doctor if you have any concerns.

Children and adolescents
Fingolimod Opha is not intended for use in children below 10 years old as it has not been studied in MS patients in this age group.

The warnings and precautions listed above also apply to children and adolescents. The following information is particularly important for children and adolescents and their caregivers:
- Before you start Fingolimod Opha, your doctor will check your vaccination status. If you have not had certain vaccinations, it may be necessary for you to be given them before Fingolimod Opha is started.
- The first time you take Fingolimod Opha, or when you switch from a 0.25 mg daily dose to a 0.5 mg daily dose, your doctor will monitor your heart rate and heartbeat (see "Slow heart rate (bradycardia) and irregular heartbeat" above).
- If you experience convulsions or fits before or whilst taking Fingolimod Opha, let your doctor know.
- If you suffer from depression or anxiety or if you become depressed or anxious while you are taking Fingolimod Opha, let your doctor know. You may need to be monitored more closely.

Other medicines and Fingolimod Opha
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 Opha together with such medicines as this could intensify the effect on the immune system (see also "Do not take Fingolimod Opha").
- **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 Opha, 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 Opha together with such medicines could intensify the effect on heartbeat in the first days after starting Fingolimod Opha.
- **Medicines for irregular heartbeat**, such as quinidine, disopyramide, amiodarone or sotalol. You must not use Fingolimod Opha if you are taking such a medicine because it could intensify the effect on irregular heartbeat (see also "Do not take Fingolimod Opha").
- **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 Opha).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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 Opha 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 Opha is used during pregnancy, there is a risk of harm to the unborn baby. The risk of congenital malformations observed in babies exposed to Fingolimod Opha 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 Opha 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 Opha 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 Opha.

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

Breast-feeding
You should not breast-feed while you are taking Fingolimod Opha. Fingolimod Opha 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 Opha 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 Opha. Your ability to drive and use machines may be impaired during and potentially after this time period.

This medicinal product contains less than 1 mmol sodium (23 mg) per hard capsule. That is to say essentially 'sodium-free'.

3. How to take Fingolimod Opha

Treatment with Fingolimod Opha 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.
- 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 Opha is for oral use.

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

Taking Fingolimod Opha 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 Opha, talk to your doctor or your pharmacist.

If you take more Fingolimod Opha than you should
If you have taken too much Fingolimod Opha, call your doctor straight away.

If you forget to take Fingolimod Opha
If you have been taking Fingolimod Opha for less than 1 month and you forgot 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 Opha 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 Opha
Do not stop taking Fingolimod Opha or change your dose without talking to your doctor first.

Fingolimod Opha 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 Opha you may have to wait for 6-8 weeks before starting a new MS treatment.

If you have to restart Fingolimod Opha 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 Opha 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 Opha. Tell your doctor straight away if you think your MS is getting worse after you have stopped treatment with Fingolimod Opha. 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 Opha.
- 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 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 Opha 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.
- Inflammatory disorder after stopping Fingolimod Opha treatment (known as immune reconstitution inflammatory syndrome or IRIS)
- 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 Opha 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 Opha 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 effects 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 at: 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 Opha

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 blister foil after "EXP". The expiry date refers to the last day of that month.

For the PVC/PE/PVDC/aluminium blisters
Store below 30 °C.

For the PVC/PE/PVDC/aluminium blisters
This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Fingolimod Opha contains
- The active substance is fingolimod.

Each capsule contains 0.5 mg fingolimod (as hydrochloride).
- The other ingredients are:

Capsule fill: calcium hydrogen phosphate dihydrate, croscarmellose sodium; hydrocarpropylcellulose; magnesium stearate.
Capsule shell: gelatin; titanium dioxide (E171), yellow iron oxide (E172); printing ink (contains: shellac (E904); propylene glycol, ammonia solution, concentrated; black iron oxide (E172); potassium hydroxide).

What Fingolimod Opha looks like and contents of the pack
Fingolimod Opha 0.5 mg hard capsules are presented as white to off-white granular powder in a yellow cap and white opaque body size 3 hard gelatin capsule with nominal length 15.9 mm, imprinted with "FD 0.5 mg" on the cap with black ink.

PVC/PE/PVDC/aluminium and/or PVC/PE/PVDC/aluminium blisters containing 14 capsules (1 blister), 28 capsules (2 blisters) or 98 capsules (7 blisters) packed in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Opha AS
Rupnicu iela 5,
Ābele, Ābeles novads, LV-2114,
Latvia

Manufacturer
Genepharm S.A.,
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Opha

Back Page