Fingolimod-Teva
fingolimod 500 micrograms

Important information for patients and caregivers about Fingolimod-Teva▼

▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

What is multiple sclerosis (MS)?[1]

MS is the most common acquired chronic neurological disease affecting young adults. It is often diagnosed between the ages of 20 to 40 and, in Australia, affects three times more women than men.

In MS, the body's own immune system mistakenly attacks and damages the fatty material – called myelin – around the nerves. Myelin is important for protecting and insulating nerves so that the electrical messages that the brain sends to the rest of the body travel quickly and efficiently.

As the myelin breaks down during a MS attack – a process called demyelination – patches of nerves become exposed and then scarred, which renders the nerves unable to communicate messages properly and at risk of subsequent degeneration. This means that the brain cannot talk to other parts of the body, resulting in a range of symptoms that can include a loss of motor function (e.g. walking and hand and arm function, loss of sensation, pain, vision changes and changes to thinking and memory).

How does Fingolimod-Teva work?

Fingolimod-Teva contains the active ingredient fingolimod hydrochloride. Fingolimod-Teva belongs to a group of medicines known as sphingosine 1-phosphate (S1-P) receptor modulators.

Fingolimod-Teva helps fight against attacks on myelin by the immune system by affecting the ability of some white blood cells to move freely within the body and by stopping the cells that cause inflammation from reaching the brain. This reduces the nerve damage caused by MS.

Contraindications and Precautions

Fingolimod-Teva should not be used by people who have recently had a stroke or heart attack or those with certain cardiac diseases. It should also be avoided by those taking medicines that are known to decrease the heart rate.

Fingolimod-Teva should not be used by women who are pregnant or of child-bearing potential if they are not using effective contraception. Tell your doctor if you are pregnant or intend to become pregnant.

All women of child-bearing potential (including female adolescents) will be provided with a Pregnancy-Specific Patient Reminder Card.

You should not breast-feed while taking Fingolimod-Teva. Fingolimod-Teva can pass into breast milk and there is a risk of serious side effects for a breast-fed baby.

For paediatric patients, similar precautions will also be taken when the dose is increased from 0.25* mg to 0.5 mg once daily.

Please inform your doctor if you or a family member have a history of epilepsy.

Advise any doctor, dentist or pharmacist you see that you are taking Fingolimod-Teva.

Please read the Consumer Medicine Information Leaflet thoroughly before starting treatment with Fingolimod-Teva. Keep the leaflet handy in case you need to refer to it again during your treatment.

Contact your doctor immediately if you are pregnant or you experience any side effects during treatment with Fingolimod-Teva and for up to two months following discontinuation.

Call your doctor straight away if you think you have an infection, have a fever, or feel like you have the flu during Fingolimod-Teva treatment and for 2 months after the last dose. Infections can be serious and sometimes life threatening.

*0.25 mg strength is available in other brands.

Reference: 1. MS Australia. What is multiple sclerosis (MS)? https://www.msaustralia.org.au/what-is-multiple-sclerosis-ms/ (accessed 31 Jan 2023).

Before starting Fingolimod-Teva treatment

Pregnancy

Fingolimod-Teva is known to be teratogenic (causes defects in unborn babies). Women of child-bearing potential (including adolescents) must have a negative pregnancy test (checked by a healthcare professional), and must take effective contraception before starting treatment with Fingolimod-Teva. Your doctor will inform you about the serious risks Fingolimod-Teva poses to the foetus. Also ask your doctor about appropriate forms of effective contraception.

Human papilloma virus (HPV)-related cancer

Your doctor will assess whether you need to undergo cancer screening (including a Pap test) and if you should have the HPV vaccine.

Liver function

You will have a blood test to check your liver function before and during treatment with Fingolimod-Teva and this will continue for two months after you stop treatment. If liver problems are detected your doctor may decide to discontinue treatment.

Seizures

Inform your doctor if you or a family member have a history of epilepsy.

Blood and vaccination check

Before initiating treatment with fingolimod, a recent complete blood count (ie. Within 6 months or after discontinuation of prior therapy) should be available. The blood test is to check your full blood count, including white blood cells and liver function (including transaminase and bilirubin levels).

Active acute or chronic infections should be resolved prior to starting treatment.

If you don't have any history of chicken pox (varicella zostervirus), your doctor will check your status and may decide to vaccinate against chicken pox.

Paediatric patients should complete a full vaccination schedule before starting fingolimod.

Cardiovascular check

This check includes a discussion of any specific heart conditions you may have and co-medications known to slow heart rate that you may take.

An ECG will be taken to measure the baseline activity of your heart prior to taking your first dose.

Fingolimod-Teva: First dose precaution

For some people, starting Fingolimod-Teva treatment can cause their heart rate to slow. If your heart rate slows down after your first dose, you may feel dizzy or tired or be consciously aware of your heartbeat. If you experience symptoms such as dizziness, nausea, vertigo, or palpitations or feel uncomfortable after taking the first dose of fingolimod, please immediately inform your doctor.

Before taking the first dose, you or the child/adolescent will have

- A baseline electrocardiogram (ECG) to assess the action of your heart.
- A blood pressure measurement.
- A physical development assessment.
- Height and weight measurements taken.

During the 6-hour monitoring

- Pulse and blood pressure will be checked every hour– You or the child/adolescent may be monitored with a continuous ECG during this time
- An ECG will be run at the end of 6 hours
- In some circumstances, extended monitoring or overnight stay may be required

Call your doctor if you have missed any doses of Fingolimod-Teva as the first-dose monitoring may need to be repeated depending on how many doses you have missed and the duration of your Fingolimod-Teva treatment.

If you missed:

- 1 day or more during the first 2 weeks of treatment
- more than 7 days during weeks 3 and 4 of treatment
- more than 2 weeks after one month on treatment, the initial effect on your heart rate may occur again. When Fingolimod-Teva therapy is restarted, the doctor may decide to repeat monitoring your heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you or the child/adolescent overnight.

While you are taking Fingolimod-Teva

Infections

Because Fingolimod-Teva affects the immune system, you are more likely to get infections. Call your doctor straight away if you think you have an infection, if you have a fever or you feel like you have the flu during Fingolimod-Teva treatment and for 2 months after the last dose. Infections can be serious and sometimes life threatening, particularly meningitis and/or encephalitis (headache with stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, confusion or seizures).

Fingolimod-Teva can cause a serious viral infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to those of an MS relapse and can include changes in mental ability or behaviour, unsteadiness, limb or facial weakness and visual changes. Contact your doctor as soon as possible if you think your MS is getting worse or if you notice any new neurological symptoms during Fingolimod-Teva treatment and for 8 weeks after the last dose.

Cancer

The doctor will assess whether anyone taking Fingolimod-Teva needs to undergo cancer screening (including a PAP test), and if they should receive the human papilloma virus (HPV) vaccine.

Skin cancer

Skin cancers have been reported in multiple sclerosis patients treated with Fingolimod-Teva. Inform your doctor immediately 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.

Vaccinations

You should not receive certain types of vaccines during and up to 2 months after ceasing treatment with fingolimod.

Liver function

Fingolimod-Teva can cause abnormal results in liver function tests. You will need a blood test at months 1, 3, 6, 9, and 12 while on Fingolimod-Teva and regularly thereafter. Inform your doctor if you notice any yellowing of the skin or the whites of the eyes, abnormally dark urine, pain on the right side of the stomach area, tiredness, feeling less hungry than usual or unexplained nausea and vomiting, as these can be signs of liver injury.

Visual symptoms

While it is not common, Fingolimod-Teva may cause swelling at the back of the eye, a condition known as macular oedema. Contact your doctor immediately if you experience visual symptoms during and up to 2 months after stopping treatment.

Pregnancy

Women of child-bearing potential (including adolescents) should be provided with regular counselling by their doctor about the serious risks to an unborn baby that are posed by taking Fingolimod-Teva. Women of child-bearing potential (including adolescents) must have a negative pregnancy test before starting treatment with Fingolimod-Teva and must use effective contraception while taking Fingolimod-Teva and for two months after stopping treatment.

In case of a pregnancy (intended or unintended) during treatment, or in the 2 months after stopping treatment with Fingolimod-Teva, your doctor should be informed straight away.

Reference: Fingolimod-Teva Consumer Medicine Information.

For further information please contact Teva Medical Information Department: 1800 288 382 (AU TEVA) or MedInfo.ANZ@tevapharm.com

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Date of preparation: February 2023 Gx Au-AU-NP-00002