

FINGOLIMOD-TEVA

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.
-

1. Why am I using FINGOLIMOD-TEVA?

FINGOLIMOD-TEVA contains the active ingredient fingolimod hydrochloride. FINGOLIMOD-TEVA is used in adults, children and adolescents (10 years of age and above) to treat relapsing forms of multiple sclerosis (MS).

For more information, see Section [1. Why am I using FINGOLIMOD-TEVA?](#) in the full CMI.

2. What should I know before I use FINGOLIMOD-TEVA?

Do not use if you have ever had an allergic reaction to FINGOLIMOD-TEVA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use FINGOLIMOD-TEVA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FINGOLIMOD-TEVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FINGOLIMOD-TEVA?

- The usual dose for adults and children weighing over 40 kg is one capsule per day (0.5 mg of fingolimod).
- The usual dose for children weighing 40 kg or less is one 0.25 mg capsule per day.

More instructions can be found in Section [4. How do I use FINGOLIMOD-TEVA?](#) in the full CMI.

*0.25 mg capsules are available in other brands

5. What should I know while using FINGOLIMOD-TEVA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are
-----------------------------	---

	<p>using FINGOLIMOD-TEVA.</p> <ul style="list-style-type: none"> • Avoid becoming pregnant while taking FINGOLIMOD-TEVA • Tell your doctor about any changes in your vision
Things you should not do	<ul style="list-style-type: none"> • You should not receive certain types of vaccines (live attenuated vaccines) during and for up to 2 months after treatment with this medicine
Driving or using machines	<ul style="list-style-type: none"> • Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. • FINGOLIMOD-TEVA is not expected to have an influence on your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none"> • Store it in a cool dry place where the temperature stays below 25°C and away

	from moisture, heat or sunlight.
--	----------------------------------

For more information, see Section [5. What should I know while using FINGOLIMOD-TEVA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: flu related symptoms (tiredness, chills, sore throat, fever), sinusitis, headache, diarrhoea, back pain, cough, weight loss.

Serious side effects include: slow heartbeat (bradycardia) or irregular heartbeat; pneumonia with symptoms such as fever, cough, difficulty breathing; shadows or blind spot in the centre of your vision, blurred vision, problems seeing colours or details; bleeding or bruising more easily than normal (thrombocytopenia).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

FINGOLIMOD-TEVA

Active ingredient(s): *Fingolimod hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FINGOLIMOD-TEVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FINGOLIMOD-TEVA.**

Where to find information in this leaflet:

- [1. Why am I using FINGOLIMOD-TEVA?](#)
- [2. What should I know before I use FINGOLIMOD-TEVA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FINGOLIMOD-TEVA?](#)
- [5. What should I know while using FINGOLIMOD-TEVA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FINGOLIMOD-TEVA?

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 can alter the way the body's immune system works and is used in adults, children and adolescents (10 years of age and above) to treat relapsing forms of multiple sclerosis (MS).

MS is a long-term condition that affects the central nervous system (CNS), particularly how the brain and spinal cord work. In MS, inflammation destroys the protective cover around the nerves (called myelin) and stops the nerves from working properly.

The cause of MS is unknown but it is thought that an abnormal response by the body's immune system plays an important part in the process which damages the CNS.

This medicine slows down the progression of physical disability and decreases the number of flare-ups (relapses) in patients with relapsing MS.

FINGOLIMOD-TEVA helps to 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 nerve damage caused by MS.

FINGOLIMOD-TEVA may also have a direct and beneficial effect on certain brain cells (neural cells) involved in repairing or slowing down the damage of MS.

Ask your doctor if you have any questions about how FINGOLIMOD-TEVA works or why this medicine has been prescribed for you or your child.

2. What should I know before I use FINGOLIMOD-TEVA?

Warnings

Do not use FINGOLIMOD-TEVA if:

- you are allergic to fingolimod, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- any other similar medicines (such as medicines of the same class or with a similar structure)
- have had a heart attack, unstable angina, stroke or warning stroke or certain types of heart failure in the last 6 months

- have certain types of irregular or abnormal heartbeat (arrhythmia)
- are taking or have recently taken medicine for irregular heartbeat such as quinidine, disopyramide, amiodarone or sotalol (due to a possible added effect on irregular heartbeat).

Check with your doctor if you:

- have allergies to any other medicines, foods, dyes or preservatives. Your doctor will want to know if you are prone to allergies.
- have any of the following medical conditions:
 - heart problems, stroke or warning of a stroke (see [Heart conditions](#))
 - a lowered immune response (due to a disease or medicines that suppress the immune system). See section [3 What if I am taking other medicines?](#) You may get infections more easily or an infection you already have may get worse.
 - problems with your liver. FINGOLIMOD-TEVA may affect your liver function.
 - have an infection. Infections can be serious and sometimes life-threatening. Before you start taking FINGOLIMOD-TEVA, your doctor will confirm whether you have enough white blood cells (these fight infections) in your blood.
- take any medicines for any other condition
- plan to receive a vaccine. You should not receive certain types of vaccines (called "live attenuated vaccines") during and up to 2 months after treatment

with FINGOLIMOD-TEVA (see section [3 What if I am taking other medicines?](#)).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

You should avoid becoming pregnant while taking FINGOLIMOD-TEVA or in the two months after you stop taking it because FINGOLIMOD-TEVA may harm your unborn baby.

If you become pregnant while taking FINGOLIMOD-TEVA, tell your doctor without delay. You and your doctor will decide what is best for you and your baby.

You should not breast-feed while you are taking FINGOLIMOD-TEVA.

FINGOLIMOD-TEVA can pass into breast milk and there is a risk of serious side effects for a breast-fed baby.

Children

FINGOLIMOD-TEVA is used in children and adolescents (10 years of age and above) to treat relapsing-multiple sclerosis.

FINGOLIMOD-TEVA has not been studied in children under 10 years of age.

Elderly

Experience with FINGOLIMOD-TEVA in older people (more than 65 years old) is limited.

Heart conditions

Checking the health of your heart is, important. If any of the following applies to you, your doctor may decide not to use FINGOLIMOD-TEVA:

- irregular or abnormal heartbeat
- severe heart disease
- uncontrolled high blood pressure
- history of stroke or other diseases related to blood vessels in the brain
- severe breathing difficulties when asleep (sleep apnoea that is not treated)
- heart rhythm disturbances (called QTc prolongation or abnormal ECG heart tracing) or the risk of these disturbances
- slow heart rate or if you have a history of sudden loss of consciousness (fainting).

Your doctor may decide not to use FINGOLIMOD-TEVA or may refer you first to a cardiologist for further advice before commencing your first dose of FINGOLIMOD-TEVA.

If your doctor thinks that FINGOLIMOD-TEVA is appropriate for you, he/she may refer you first to a cardiologist (doctor specialised in heart disease). You may also be monitored overnight by a health care

professional after taking the first dose of FINGOLIMOD-TEVA.

Vaccination

Tell your doctor if you have never had chickenpox or have no record of vaccination against chickenpox.

Your doctor will test your status of the antibody against this virus and may decide to vaccinate you (if you do not have antibodies to this virus).

In this case you will start FINGOLIMOD-TEVA treatment one month after the full course of the vaccination is completed.

Children or adolescents (10 years of age and above) need to have completed their vaccination schedule before starting treatment with FINGOLIMOD-TEVA.

Vaccination against human papilloma virus (HPV) is recommended. If you are female, your doctor will also recommend HPV screening.

Monitoring and required tests

You will have a blood test to check your liver function before and during treatment with FINGOLIMOD-TEVA and until two months after stopping treatment. If liver problems are detected your doctor may decide to discontinue treatment.

A skin examination is recommended before you start and at regular intervals during treatment. Your doctor will decide what to do if skin problems are noticed.

An eye examination before you start treatment and at regular intervals afterwards is recommended if you have or have had one of the following conditions:

- visual disturbances or other signs of swelling in the central vision area at the back of the eye (a condition known as macular oedema)
- inflammation or infection of the eye (uveitis)
- diabetes.

If you are female, a pregnancy test is recommended to check if you are pregnant.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with FINGOLIMOD-TEVA and affect how it works. Tell your doctor if you are taking any of the following:

- medicines for an irregular or abnormal heartbeat such as quinidine, procainamide, amiodarone or sotalol (see section [2 Do not use FINGOLIMOD-TEVA if:](#))
- medicines that slow down heartbeat such as atenolol (a beta blocker); verapamil, diltiazem or (calcium channel blockers) or ivabradine or digoxin. Your doctor may decide not to use FINGOLIMOD-TEVA or may refer you first to a cardiologist to switch to medicines that do not slow your heart rate or to decide

how you should be observed after the first dose of FINGOLIMOD-TEVA

- medicines that can cause an abnormal heart rhythm called Torsades de Pointes such as citalopram, chlorpromazine, haloperidol, methadone or erythromycin
- medicines that suppress or modulate the immune system including other medicines used to treat MS such as beta-interferon, glatiramer acetate, natalizumab, mitozantrone, dimethyl fumarate, teriflunomide, alemtuzumab or 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 up to 2 months after treatment with FINGOLIMOD-TEVA, administration of some vaccines containing live virus (live attenuated vaccines) may result in an infection that the vaccination is designed to prevent, while others may not work as well.

You may need to take different amounts of your medicines or to take different medicines while you are taking FINGOLIMOD-TEVA. Your doctor and pharmacist can provide you with more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FINGOLIMOD-TEVA.

4. How do I use FINGOLIMOD-TEVA?

How much to take

- **Adults**

The usual dose is one capsule per day (0.5 mg of fingolimod).

- **Children and adolescents (10 years of age and above)**

- The dose depends on the body weight:
- Children and adolescents who weigh 40 kg or less: one 0.25 mg capsule per day.*
- Children and adolescents with a body weight above 40 kg: one 0.5 mg capsule per day.

*0.25 mg capsules are available in other brands

Children and adolescents who started on one 0.25 mg capsule per day and 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 (see below).

Follow the instructions provided and use FINGOLIMOD-TEVA until your doctor tells you to stop.

When to take FINGOLIMOD-TEVA

- FINGOLIMOD-TEVA should be taken at about the same time each day.

- Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

How to take FINGOLIMOD-TEVA

Swallow the FINGOLIMOD-TEVA capsule with a glass of water.

FINGOLIMOD-TEVA can be taken with or without food.

Continue taking your medicine for as long as your doctor tells you to.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Do not stop taking FINGOLIMOD-TEVA unless your doctor tells you to.

Your symptoms may return or become worse if you stop the treatment. Tell your doctor if you have worsening of MS symptoms after stopping FINGOLIMOD-TEVA.

FINGOLIMOD-TEVA 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.

If you stop taking FINGOLIMOD-TEVA:

- for 1 day or more during the first 2 weeks of treatment,
or

- for more than 7 days during weeks 3 and 4 of treatment, or
- for more than 2 weeks after your first month of FINGOLIMOD-TEVA treatment, the initial effect on your heart rate may occur again.

If you restart FINGOLIMOD-TEVA therapy after a break, your doctor may decide to monitor your heart rate and blood pressure every hour, to run ECGs, or to monitor you overnight.

First Dose Precaution

Because FINGOLIMOD-TEVA may have a short-term effect on your heart rate when you take the first dose (or when children/adolescents switch from the 0.25 mg capsule to the 0.5 mg capsule), you will be required to have the health of your heart checked:

- before your first dose of FINGOLIMOD-TEVA
- 6 hours after taking your first dose of FINGOLIMOD-TEVA, and
- if you start FINGOLIMOD-TEVA again after a break from therapy (depending on how long the break is and how long you have been receiving FINGOLIMOD-TEVA treatment).

You will need to stay at the doctor's office or clinic for 6 hours after taking the first dose of FINGOLIMOD-TEVA (or after taking the first dose of 0.5 mg when your child switches from the 0.25 mg capsule daily dose) so that your heart rate and blood pressure can be checked each hour. Your doctor will also check and record the

electrical activity of your heart (using a test called an ECG), and check your heart rhythm.

Tell your doctor if you feel dizzy, tired, or are conscious of your heartbeat.

At the end of the 6-hour observation period, you will be required to have a second ECG.

In case of unusual ECG or slow heart rate at the end of the 6-hour observation period, you may be observed for longer and overnight if necessary. In this case, the same observation process that took place for your first dose of FINGOLIMOD-TEVA will also apply for your second dose.

At the beginning of treatment, FINGOLIMOD-TEVA can cause the heart rate to slow down in some patients. If your heart rate slows down after your first dose, you may feel dizzy or tired or be consciously aware of your heartbeat. If your heart rate slows down too much or your blood pressure drops, you may need treatment without delay. Slow heart rate usually returns to normal within one month.

FINGOLIMOD-TEVA can also cause an irregular heartbeat in some patients, especially after the first dose. Irregular heartbeat usually returns to normal in less than one day.

If you forget to use FINGOLIMOD-TEVA

FINGOLIMOD-TEVA should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you miss a dose during the first 2 weeks call your doctor right away.

- Your doctor may decide to observe you at the time you take the next dose.
- This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much FINGOLIMOD-TEVA

If you think that you have used too much FINGOLIMOD-TEVA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

- You may need urgent medical attention. Your doctor may decide to observe you with hourly heart rate and blood pressure measurements, run ECGs, and he/she may decide to monitor you overnight.
- Symptoms of an overdose may include:
 - swelling in hands or feet
 - tingling or numbness in hands or feet
 - muscle pain
 - fever.

5. What should I know while using FINGOLIMOD-TEVA?

Things you should do

You should avoid becoming pregnant while taking FINGOLIMOD-TEVA or in the two months after you stop taking it because FINGOLIMOD-TEVA may harm your unborn baby.

Talk to your doctor about the associated risk. Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

If you become pregnant while taking this medicine, tell your doctor immediately.

FINGOLIMOD-TEVA should not be taken if you are pregnant.

Tell your doctor about any changes in your vision, especially if:

- the centre of your vision gets blurry or has shadows
- if you develop a blind spot in the centre of your vision
- if you have problems seeing colours or fine detail.

FINGOLIMOD-TEVA may cause macular oedema uncommonly (swelling of a small area at the back of the eye). When this side effect does occur, it usually happens in the first 4 months of treatment. Your chance of developing macular oedema is higher if you have diabetes or have had an inflammation of the eye called uveitis. It can cause some of the same vision symptoms as an MS attack (optic neuritis).

Your doctor should carry out regular skin examinations during your treatment with FINGOLIMOD-TEVA. Limit your exposure to the sun and UV rays by wearing appropriate protective clothing and regularly applying sunscreen with a high degree of UV protection. This will help minimise your risk of developing skin cancers.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular checks to help prevent you from having side effects from the medicine. This includes blood tests to check your liver function and regular skin checks.

Call your doctor straight away if you:

- think you have an infection, have fever, or feel like you have the flu. You may get infections more easily while you are taking FINGOLIMOD-TEVA and for up to 2 months after you stop taking it. Any infection that you

already have may get worse. Infections can be serious and sometimes life threatening.

- notice any skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks. Skin cancers have been reported in MS patients treated with FINGOLIMOD-TEVA. Symptoms may include abnormal growth or changes of skin tissue (e.g. unusual moles) which may change in colour, shape or size over time.
- notice signs that your MS is getting worse (e.g. weakness or visual change) or if you notice any new or unusual symptoms. These may be the symptoms of a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy (PML) or a condition called tumefactive lesions. Your doctor may organise an MRI scan to decide if you need to stop taking FINGOLIMOD-TEVA.
- think you have an infection; a fever; feel like you
- have the flu, or have a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion, or seizures/fits (these may be symptoms of meningitis and/or encephalitis)
- have sudden onset of severe headache, confusion, seizures and vision changes which are symptoms of a condition called posterior reversible encephalopathy (PRES)
- have swelling in your neck, armpits or groin, persistent tiredness, fever, night sweats, shortness of breath, unexplained weight loss, itchy skin which are symptoms of lymphoma
- have unexplained nausea, vomiting, abdominal pain, tiredness, yellowing of the skin or whites of your eyes,

abnormally dark urine. These may be signs of liver injury.

Remind any doctor, dentist or pharmacist you visit that you are using FINGOLIMOD-TEVA.

Things you should not do

- You should not receive certain types of vaccines (live attenuated vaccines) during and for up to 2 months after treatment with this medicine (see section [3 What if I am taking other medicines?](#)).
- **Do not give this medicine to anyone else, even if their condition seems similar to yours.**
- **Do not use it to treat any other complaints unless your doctor tells you to.**

Driving or using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.

FINGOLIMOD-TEVA is not expected to have an influence on your ability to drive and use machines.

Looking after your medicine

- Store it in a cool dry place where the temperature stays below 25°C

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut - related: <ul style="list-style-type: none">• diarrhoea• weight loss• nausea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<p>Lung - related:</p> <ul style="list-style-type: none"> ● cough ● breathlessness <p>Skin - related:</p> <ul style="list-style-type: none"> ● ringworm, a fungal infection affecting the skin with ring-like red itchy rash ● itchy, red, burning rash (eczema) ● itchy skin <p>Flu symptoms such as:</p> <ul style="list-style-type: none"> ● tiredness ● chills ● sore throat ● joint or muscles aching ● fever <p>Pain - related:</p> <ul style="list-style-type: none"> ● muscle or joint pain ● feeling of pressure or pain in the cheeks and forehead (sinusitis) ● severe headache often together with nausea, vomiting and 	

Less serious side effects	What to do
<p>sensitivity to light (signs of migraine)</p> <ul style="list-style-type: none"> ● headache ● back pain <p>Vision - related:</p> <ul style="list-style-type: none"> ● blurred vision (see also information on macular oedema below) <p>Other:</p> <ul style="list-style-type: none"> ● dizziness ● weakness 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● bronchitis with symptoms such as coughing with phlegm, chest pain, fever ● shingles or herpes zoster symptoms such as blisters, burning, itching or pain of the skin, typically on the upper body or face. Other symptoms may be fever and weakness in the early stages of 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>infection, followed by numbness, itching, and red patches with severe pain.</p> <ul style="list-style-type: none"> ● fever, cough, difficulty breathing, tiredness, aching joints and muscles which are signs of infections. ● slow heartbeat (bradycardia) or irregular heartbeat ● pneumonia with symptoms such as fever, cough, difficulty breathing ● shadows or blind spot in the centre of your vision, blurred vision, problems seeing colours or details which are symptoms of macular oedema (swelling in the central vision area of the retina at the back of the eye) ● moles which may change size, shape, elevation or colour over time, or new moles which may be symptoms 	

Serious side effects	What to do
<p>of melanoma, a type of skin cancer usually developing from an unusual mole (naevus). The moles may itch, bleed or ulcerate.</p> <ul style="list-style-type: none"> ● skin nodules (e.g. shiny pearly nodules), patches or open sores ● skin lesions of unusual colour ● convulsions, fits (more frequent in children and adolescents than in adults) ● bleeding or bruising more easily than normal. This may be due to low level of platelets (thrombocytopenia). ● yellowing of your skin or the whites of your eyes, abnormally dark urine, unexplained nausea, vomiting, pain on the right side of your stomach area, feeling less hungry than usual and tiredness, which 	

Serious side effects	What to do
<p>may be signs of liver injury</p> <ul style="list-style-type: none"> ● worsening of MS symptoms (e.g. weakness or visual changes) which could be signs of a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy. ● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing ● sudden onset of rash or hives ● sudden onset of severe headache, confusion, seizures and/or vision changes, which are symptoms of a condition called posterior reversible encephalopathy (PRES) ● headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion or 	

Serious side effects	What to do
seizures (fits) which are symptoms of a cryptococcal infection (a type of fungal infection), including cryptococcal meningitis, or meningitis/encephalitis (caused by herpes or varicella zoster virus).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Some side effects may not give you any symptoms and can only be found when tests are done. These include:

- hypertension (FINGOLIMOD-TEVA may cause a mild increase in blood pressure)
- higher levels of liver enzymes and/or liver injury
- increased level of blood fat (triglycerides)
- changes to blood cell counts
- abnormal lung function test results starting after one month of treatment, remaining stable after that and reversible after treatment discontinuation.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FINGOLIMOD-TEVA contains

Active ingredient (main ingredient)	Fingolimod hydrochloride
Other ingredients (inactive ingredients)	<u>Capsule Content</u> Pregelatinised maize starch Sodium lauryl sulfate <u>Capsule Shell</u> Iron oxide yellow (E172)

	Titanium dioxide (E171) Gelatin <u>Printing Ink</u> TekPrint™ SW-9008 Black Ink
--	--

Do not take this medicine if you are allergic to any of these ingredients.

What FINGOLIMOD-TEVA looks like

FINGOLIMOD-TEVA is a hard gelatin capsule, size 4, filled with white to off-white powder, imprinted in black, with "TV 7820" on the yellow capsule cap and "TV 7820" on the white opaque capsule body (Aust R 384703).

FINGOLIMOD-TEVA is available in packs of 7, 28, 30 and 84. Not all pack sizes may be marketed.

Who distributes FINGOLIMOD-TEVA

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Ph: 1800 288 382

www.tevapharma.com.au

This leaflet was prepared in January 2023.