

# FYNOD®

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## Consumer Medicine Information (CMI) summary

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

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

## 1. Why am I taking FYNOD?

FYNOD contains the active ingredient fingolimod hydrochloride. FYNOD is used to treat relapsing forms of multiple sclerosis in adults, children and adolescents (10 years of age and above). For more information, see Section [1. Why am I taking FYNOD?](#) in the full CMI.

## 2. What should I know before I take FYNOD?

Do not take if you have ever had an allergic reaction to fingolimod hydrochloride 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

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information, see Section [2. What should I know before I take FYNOD?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FYNOD 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 take FYNOD?

**Adults:** the usual dose is one 0.5 mg capsule taken once a day. **Children and adolescents:** the dose is dependent on body weight. More instructions can be found in Section [4. How do I take FYNOD?](#) in the full CMI.

### 5. What should I know while taking FYNOD?

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| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking FYNOD</li><li>• Tell your doctor about any changes in your vision.</li><li>• Tell your doctor straight away if you think you have an infection, fever,</li></ul> |
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|---|---|
|   | <p>or feel like you have the flu.</p> <ul style="list-style-type: none"> <li>● 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.</li> </ul>  |
| <p><b>Things you should not do</b></p>  | <ul style="list-style-type: none"> <li>● You should not receive certain types of vaccines (live attenuated vaccines) during and for up to 2 months after treatment with this medicine.</li> <li>● Avoid becoming pregnant while taking FYNOD or in the two months after you stop taking it because FYNOD may harm your unborn baby.</li> <li>● Do not give this medicine to anyone else, even if their condition seems similar to yours.</li> </ul> |
| <p><b>Driving or using machines</b></p> | <ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until</li> </ul>  |

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|                                    | <p>you know how FYNOD affects you. Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. FYNOD is not expected to have an influence on your ability to drive or use any machines.</p> |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Store your medicine in a cool dry place where the temperature stays below 25°C.</li> <li>• Keep your medicine in the pack until it is time to take them.</li> </ul>                         |

For more information, see Section [5. What should I know while taking FYNOD?](#) in the full CMI.

## 6. Are there any side effects?

**Common side effects:** flu symptoms, headache, diarrhoea. **Serious side effects:** coughing with phlegm, chest pain, shingles/herpes zoster, slow or irregular heartbeat, blurred vision, skin nodules, difficulty breathing, seizures.

**This is not a complete list of side effects.** 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. 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](http://www.tga.gov.au/reporting-problems).

## FYNOD®

**Active ingredient(s):** *fingolimod hydrochloride*

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### Consumer Medicine Information (CMI)

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

#### Where to find information in this leaflet:

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

## 1. Why am I taking FYNOD?

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

**FYNOD is used to treat adults, children and adolescents (10 years of age and above) with relapsing forms of multiple sclerosis (MS).**

FYNOD can alter the way the body's immune system works and slows the progression of physical disability and decreases the number of flare-ups (relapses) in patients with relapsing 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.

FYNOD 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.

FYNOD 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 FYNOD works or why this medicine has been prescribed for you or your child.**

## **2. What should I know before I take FYNOD?**

### **Warnings**

#### **Do not take FYNOD if:**

- you are allergic to fingolimod, or any other similar medicines (such as medicines of the same class or with a similar structure), or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can take this medicine. Some 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
- you have had heart attack, unstable angina, stroke or warning stroke or certain types of heart failure in the last 6 months
- you have certain types of irregular or abnormal heartbeat (arrhythmia)
- you 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).

Tell your doctor if you have allergies to other medicines, foods, preservatives or dyes. Your doctor may want to know if you are prone to allergies.

## **Check with your doctor if you:**

- **have had heart problems, a stroke or warning of a stroke**

Checking the health of your heart is important. If any of the following applies to you, your doctor may decide not to use FYNOD or may refer you to a cardiologist for further advice before commencing your first dose of FYNOD. You may also be monitored overnight by a healthcare professional after taking your first dose of FYNOD.

- 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)
- a 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).

## **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 FYNOD 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 FYNOD.

- **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 FYNOD (see Section [3. "What if I am taking other medicines?"](#)).

- **have any other medical 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. FYNOD may affect your liver function.

- **have an infection as it may get worse**

Infections can be serious and sometimes life-threatening. Before you start taking FYNOD, your doctor will confirm whether you have enough white blood cells (these fight infections) in your blood.

- **take medicines for any other condition**

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

**Before you start treatment with FYNOD, you will have:**

- a blood test to check your liver function before and during treatment with FYNOD 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
- vaccination against human papilloma virus (HPV) is recommended. If you are female, your doctor will also recommend HPV screening.

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**

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

If you become pregnant while taking FYNOD, 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 FYNOD.**

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

### **Elderly**

Experience with FYNOD in older people (more than 65 years old) is limited.

### **Children under 10 years**

FYNOD has not been studied in children under 10 years of age.

### 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 FYNOD and affect how it works. These include:**

- medicines for an irregular or abnormal heartbeat such as quinidine, procainamide, amiodarone, or sotalol
- 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 FYNOD 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 FYNOD
- 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 FYNOD, 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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

You may need to take different amounts of your medicines or take different medicines while you are taking FYNOD.

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 FYNOD.**

## **4. How do I take FYNOD?**

**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

### **First dose precaution**

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

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

You will need to stay at the doctor's office or clinic for 6 hours after taking the first dose of FYNOD (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 FYNOD will also apply for your second dose.

At the beginning of treatment, FYNOD 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.

FYNOD 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.

## **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.
- 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.

\*0.25 mg strength is available in other brands.

**Do not exceed the recommended dose.**

## **When to take FYNOD**

- FYNOD 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 to take it. It does not matter if you take this medicine before or after food.

## **How to take FYNOD**

- Swallow the FYNOD capsule with a glass of water.
- FYNOD can be taken with or without food.

## **How long to take FYNOD**

- **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 FYNOD 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 FYNOD.

FYNOD 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 FYNOD:

- 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 FYNOD treatment, the initial effect of your heart rate may occur again.

If you restart FYNOD 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.

## **After using FYNOD**

- Tell your doctor straight away, if you believe your MS is getting worse after you have stopped treatment with FYNOD, because it could be serious
- Symptoms of MS can return and may become worse compared to before or during treatment

## **If you forget to take FYNOD**

**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 your 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 take too much FYNOD**

If you think that you or anyone else have taken too much FYNOD, or taken a first dose by mistake, urgent medical attention may be needed.

### **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.**

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 taking FYNOD?

### Things you should do

- **Avoid becoming pregnant while taking FYNOD or in the two months after you stop taking it because FYNOD 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.
- **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.
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FYNOD.**
  - Remind any doctor, dentist or pharmacist you visit that you are using FYNOD.

## **Call your doctor straight away if you:**

- **become pregnant while taking this medicine.**

FYNOD should not be taken if you are pregnant.

- **think you have an infection, fever or feel like you have the flu.**

You may get infections more easily while you are taking FYNOD 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 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.

FYNOD 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).

- **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 FYNOD. Symptoms may include abnormal growth or changes of skin tissue (e.g., unusual moles) which may change in colour, shape or size over time. Your doctor should carry out regular skin examinations during your treatment with FYNOD.

- **notice any of following symptoms or disease while you are taking FYNOD because it could be serious:**
  - 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 FYNOD.
  - if you 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).
  - sudden onset of severe headache, confusion, seizures and vision changes which are symptoms of a condition called posterior reversible encephalopathy (PRES).
  - 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.

- 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.

## **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.
- 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**

**Be careful before you drive or use any machines or tools until you know how FYNOD affects you.**

FYNOD may cause dizziness in some people.

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

## **Drinking alcohol**

Tell your doctor if you drink alcohol.

## **Looking after your medicine**

- Keep your medicine in the pack until it is time to take them.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Heat or dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

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

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

## **6. Are there any side effects?**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FYNOD even if you do not think that it is connected with the medicine.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Less serious side effects**

| <b>Less serious side effects</b>   | <b>What to do</b>   |
|--|---|
| <p><b>General</b></p> <ul style="list-style-type: none"> <li>● headache</li> <li>● dizziness</li> <li>● severe headache often together with nausea, vomiting and sensitivity to light (signs of migraine)</li> <li>● weakness</li> </ul> <p><b>Infection related</b></p> <ul style="list-style-type: none"> <li>● flu symptoms such as tiredness, chills, sore throat, joint or muscle aching, fever</li> <li>● feeling of pressure or pain in the cheeks and forehead (sinusitis)</li> </ul> <p><b>Skin related</b></p> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you or affect you severely.</b></p> <p>This list includes the more common side effects of your medicine.</p> |

| <b>Less serious side effects</b>  | <b>What to do</b> |
|---|-------------------|
| <ul style="list-style-type: none"> <li>● ringworm, a fungal infection affecting the skin with ring-like red itchy rash</li> <li>● itchy, red, burning rash (eczema)</li> <li>● itchy skin</li> </ul> <p><b>Gut or Gastrointestinal related</b></p> <ul style="list-style-type: none"> <li>● diarrhoea</li> <li>● nausea</li> <li>● weight loss</li> </ul> <p><b>Muscles related</b></p> <ul style="list-style-type: none"> <li>● back pain</li> <li>● muscle or joint pain</li> </ul> <p><b>Respiratory related</b></p> <ul style="list-style-type: none"> <li>● cough</li> <li>● breathlessness</li> </ul> <p><b>Eye related</b></p> <ul style="list-style-type: none"> <li>● blurred vision (see also information on macular oedema below)</li> </ul> |                   |

## Serious side effects

| Serious side effects   | What to do   |
|--|--|
| <p><b>Lungs related:</b></p> <ul style="list-style-type: none"><li>• bronchitis with symptoms such as coughing with phlegm, chest pain, fever.</li><li>• pneumonia with symptoms such as fever, cough, difficulty breathing.</li></ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"><li>• shingles or herpes zoster symptoms such as blisters, burning, itching or pain of the skin, typically of the upper body or face. Other symptoms may be fever and weakness in the early stages of infection, followed by numbness, itching and red patches with severe pain.</li><li>• a headache accompanied by stiff neck, sensitivity</li></ul> | <p><b>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.</b></p> |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <p>to light, nausea, and/or confusion or 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).</p> <ul style="list-style-type: none"> <li>● fever, cough, difficulty breathing, tiredness, aching joints and muscles which are signs of infections.</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>● slow heartbeat (bradycardia) or irregular heartbeat.</li> </ul> <p><b>Eyes related:</b></p> <ul style="list-style-type: none"> <li>● 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</li> </ul> |                   |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <p>vision area of the retina at the back of the eye).</p> <p><b>Signs of skin cancer:</b></p> <ul style="list-style-type: none"> <li>● moles which may change size, shape, elevation or colour over time, or new moles which may be symptoms of melanoma, a type of skin cancer usually developing from an unusual mole (naevus). The moles may itch, bleed or ulcerate.</li> <li>● skin nodules (e.g. shiny, pearly nodules), patches or open sores.</li> <li>● skin lesions of unusual colour</li> <li>● convulsions, fits (more frequent in children and adolescents than adults).</li> </ul> <p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>● bleeding or bruising more easily than normal. This may be due to low level of platelets (thrombocytopenia).</li> </ul> |                   |

| <b>Serious side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <p><b>Liver related:</b></p> <ul style="list-style-type: none"> <li>● 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. These may be signs of liver injury.</li> </ul> <p><b>Brain related:</b></p> <ul style="list-style-type: none"> <li>● 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 which can then develop into immune reconstitution inflammatory syndrome.</li> <li>● sudden onset of severe headache, confusion, seizures</li> </ul> |                   |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <p>and/or vision changes, which are symptoms of a condition called posterior reversible encephalopathy (PRES).</p> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing.</li> <li>● sudden onset of rash or hives.</li> </ul> |                   |

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

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

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

- hypertension (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.

## 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](http://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. It is not addictive.

### What FYNOD contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | fingolimod 0.5 mg per capsule   |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>● calcium hydrogen phosphate dihydrate</li><li>● glycine</li><li>● colloidal anhydrous silica</li><li>● magnesium stearate</li><li>● Empty Gelatin Capsule White Op Body/6789</li></ul> |

|                            |  |
|----------------------------|--|
|                            | <p>Orange Op Cap<br/>G3ICCSRA0485 5984 (ID 119839)</p> <ul style="list-style-type: none"> <li>• either TekPrint SW-9008 Black Ink (ID 2328) or TekPrint SW-9009 Black Ink (ID 2343)</li> </ul> |
| <b>Potential allergens</b> | sulfites   |

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

## What FYNOD looks like

FYNOD 0.5 mg capsule: A No. 3, brown-orange opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with “MYLAN” over “FD 0.5” in black ink on both the cap and body (AUST R 325742).

FYNOD 0.5 mg capsules are available in packs of 28 capsules.

## Who distributes FYNOD

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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FYNOD® is a Viartis company trade mark

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