Cenrifki®

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.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking Cenrifki?

Cenrifki contains the active ingredient tolebrutinib. Cenrifki is a treatment for adults with non-relapsing Secondary Progressive Multiple Sclerosis (nrSPMS) and to slow disability accumulation in the absence of relapse activity with Secondary Progressive Multiple Sclerosis (SPMS).

For more information, see Section 1. Why am I taking Cenrifki? in the full CMI.

2. What should I know before I take Cenrifki?

Do not use if you have ever had an allergic reaction to tolebrutinib or any of the ingredients listed at the end of the CMI or have liver problems.

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 take Cenrifki? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cenrifki 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 Cenrifki?

- You take one tablet orally once a day with a meal, preferably at the same time each day.

More instructions can be found in Section 4. How do I take Cenrifki? in the full CMI.

5. What should I know while taking Cenrifki?

Things you should do	• Remind any doctor, nurse, pharmacist or dentist you visit that you are taking Cenrifki. • It is important to keep all appointments so that your doctor can see if Cenrifki works for you. • Tell your doctor or nurse immediately if you have signs that could indicate potential liver problems.
Things you should not do	• Do not stop your treatment with Cenrifki unless your doctor advises you to.
Drinking alcohol	• Check with your doctor if you drink alcohol. • It is not recommended to drink moderate to large amounts of alcohol while taking Cenrifki.
Looking after your medicine	• Store Cenrifki below 30°C.

For more information, see Section 5. What should I know while taking Cenrifki? in the full CMI.

6. Are there any side effects?

Serious side effects may cause your liver to not work properly, and may increase your likelihood of developing infections. Common side effects may include COVID-19, upper respiratory tract infections, influenza, lower respiratory tract and lung infections, spots caused by bleeding into the skin, abdominal pain, increased liver enzymes, bruising, and heavy menstrual bleeding.

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.

WARNING: Cenrifki may cause your liver to not work properly and can cause serious and potentially fatal liver injury. To help reduce your risk of liver problems, your doctor or nurse will perform blood tests to check your liver before you start treatment, then once a week for the first 12 weeks, then once a month from months 4 to 12, then every 6 months onwards.

Cenrifki®

Active ingredient(s): *tolebrutinib*

Consumer Medicine Information (CMI)

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

A Patient Guide is also available to you to provide important safety information while receiving your treatment with Cenrifki.

Where to find information in this leaflet:

1. Why am I taking Cenrifki?
2. What should I know before I take Cenrifki?
3. What if I am taking other medicines?
4. How do I take Cenrifki?
5. What should I know while taking Cenrifki?
6. Are there any side effects?
7. Product details

1. Why am I taking Cenrifki?

Cenrifki contains the active ingredient tolebrutinib.

Tolebrutinib is an immunomodulatory agent that modifies the activity of certain cell types of the immune system.

Cenrifki is used to treat adults with non-relapsing Secondary Progressive Multiple Sclerosis (nrSPMS) and to slow disability accumulation in the absence of relapse activity with Secondary Progressive Multiple Sclerosis (SPMS).

Multiple Sclerosis (MS) affects the central nervous system (CNS), especially the nerves in the brain and spinal cord. In MS, the immune system (the body's defence system) works incorrectly and attacks a protective layer (called myelin sheath) around nerve cells in the brain and causes inflammation. Breakdown of the myelin sheath stops the nerves from working properly.

Symptoms of MS depend on which part of the central nervous system is affected and can include problems with walking and balance, weakness, numbness, double vision and blurring, poor coordination, and bladder problems. In nrSPMS, the symptoms such as those listed above, gradually continue to worsen after an initial relapsing period and gradually worsen the symptoms listed above.

Cenrifki targets specific immune cells called B cells and microglia inside the CNS. Cenrifki aims to reduce immune cell activation and prevent them from causing inflammation and damage which slows the progression of your disease. Cenrifki helps to significantly slow down the progression of the disease and reduce deterioration of your ability to do everyday tasks.

2. What should I know before I take Cenrifki?

Warnings

Do not use Cenrifki if:

- you are allergic to tolebrutinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver problems.
- you have a severely weakened immune system or severe infections that are not under control.

Check with your doctor if :

- you suffer from liver disease.
- you are taking or plan to take other medicines that may affect your liver, especially during the first 12 weeks of Cenrifki treatment. Your doctor may need to consider alternative options for those medicines.
- you are using or plan to use herbal or dietary supplements. Some of these may potentially affect your liver, and you should avoid using them while taking Cenrifki.
- you drink alcohol
- you have a fever or infection, or you are unable to fight infections.
- you are going to have a vaccination.
- you have a bleeding disorder, have recently undergone surgery or have one scheduled, or are taking medicines that may increase your risk of bleeding.
- you have a history of irregular heartbeat particularly atrial fibrillation.
- you have or have had thoughts of harming or killing yourself. You (or your caregiver) should contact your doctor immediately if any such thoughts occur.

Cenrifki may cause your liver to not work properly, particularly in the first 12 weeks. To monitor your liver,

your doctor or nurse will request a blood test to check your liver:

- before you start taking Cenrifki
- then once a week for the first 12 weeks
- then once a month from months 4 to 12
- then every 6 months onwards

If you had to stop taking Cenrifki because of abnormal liver test results, or if there has been a break in your treatment of one year or more, you should begin the blood test schedule outlined above from the start when you restart Cenrifki treatment.

If you miss a scheduled blood test, immediately tell your doctor or nurse and reschedule the blood test to be completed as soon as possible.

Infections

Talk to your doctor before taking Cenrifki if you have an infection or are unable to fight infections. Cenrifki may make you more likely to get infections. If you have an active infection, you must not start taking Cenrifki until the infection has cleared up. Tell your doctor straight away if you develop any signs or symptoms of infection such as cough, fever, blocked or runny nose, sore throat, or headache, during treatment with Cenrifki. Your doctor will evaluate you and may need to stop your treatment temporarily if you develop a serious infection.

Medicines that can weaken your immune system (such as immunosuppressants), may increase your risk of getting infections when used together with Cenrifki. Your doctor will advise you on the most appropriate course of action should you need to take such medicines while on Cenrifki treatment.

Vaccinations

Tell your doctor if you have recently been given any vaccine or are going to get one in the near future. You must avoid vaccinations with live or live attenuated vaccines during treatment with Cenrifki, as it may make you more likely to get infections. If you need a live or live attenuated vaccine, it should be given at least 2 months before you start treatment with Cenrifki. Cenrifki may affect how well non-live vaccines work. Your doctor may advise you to complete all recommended non-live vaccinations before you start treatment with Cenrifki.

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

Check with your doctor if you are pregnant or intend to become pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is not known if Cenrifki will affect your unborn baby. If you are pregnant, you must only take Cenrifki if your doctor has recommended it during your pregnancy.

It is not known whether Cenrifki passes into breast milk. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

Cenrifki has not been studied in patients below 18 years of age.

Alcohol

Check with your doctor if you drink alcohol or intend to drink alcohol while taking Cenrifki.

It is not recommended to drink moderate to large amounts of alcohol while taking Cenrifki as it may damage your liver, especially during the first 12 weeks of treatment.

3. What if I am taking other medicines?

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

Some medicines may interfere with Cenrifki and affect how it works. Cenrifki may also affect the way some other medicines work. Medicines, herbal or dietary supplements that could be harmful to the liver, may increase the chance of liver damage when taken with Cenrifki.

In particular, before taking Cenrifki, tell your doctor if you are taking or have recently taken any of the following medicines.

Medicines that may increase the levels of Cenrifki include:

- Gemfibrozil – a medicine used to lower cholesterol
- Deferasirox – a medicine used to treat iron overload
- Letermovir – a medicine used to prevent viral infections after bone marrow transplant
- Selpercatinib – a medicine used to treat certain types of cancer

Medicines that may decrease the levels of Cenrifki include:

- St John's wort – a herbal product used to treat depression
- Rifampicin – antibiotic used to treat bacterial infections
- Carbamazepine, Phenytoin – medicines used to treat epilepsy and nerve pain
- Efavirenz, Etravirine – medicines used to treat HIV infection
- Bosentan – a medicine used to treat high blood pressure in the lungs

Medicines that may increase your risk of infections include:

- Medicines that can weaken your immune system
    - o immunosuppressants such as mycophenolate mofetil, cyclophosphamide, or azathioprine

- medicines used to treat inflammation such as Disease-Modifying Antirheumatic Drugs (DMARDs) or long-term corticosteroids.

- Live or live attenuated vaccines – such as chickenpox, oral polio, or nasal flu vaccines.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins, herbal or dietary supplements you are taking and if these affect Cenrifki.

4. How do I take Cenrifki?

How much to take

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

- The recommended dose is 60 mg orally once a day with a meal, preferably at the same time each day.
- Swallow tablets whole with water.

If you forget to take Cenrifki

Cenrifki should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember. **Do not take an extra dose to make up for the dose you missed.**

If you take too much Cenrifki

If you think that you have taken too much Cenrifki, 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.

5. What should I know while taking Cenrifki?

Things you should do

Always follow your doctor, nurse or pharmacist instructions carefully.

Keep all your appointments to have your blood tested to check your liver function while taking Cenrifki.

Tell your doctor or nurse immediately if you have signs that could indicate potential liver problems such as:

- tiredness
- nausea
- vomiting
- pain in the abdomen
- fever
- rash or itching of your skin
- loss of appetite or loss of interest in food
- dark urine
- yellowing of skin or eyes

Remind any doctor, nurse, pharmacist or dentist you visit that you are taking Cenrifki.

Things you should not do

- Do not stop using this medicine without checking with your doctor.

Driving or using machines

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

Cenrifki is not expected to affect your ability to drive and use machines. However, if you feel tired, do not drive or use machines before discussing it with your doctor or nurse.

Looking after your medicine

- Store Cenrifki below 30°C

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

Keep it where young children cannot reach it.

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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• General: • COVID-19 • Upper respiratory tract infections • Influenza • Lower respiratory tract infections like bronchitis and pneumonia • Small red or purple spot caused by bleeding into skin • Increased levels of liver enzymes in blood • Increased chance of bruising • Heavy menstrual bleeding	**Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Liver-related: • tiredness • nausea • vomiting • pain in the abdomen • fever • rash or itching of your skin • loss of appetite or loss of interest in food • dark urine • yellowing of skin or eyes **Infection related:** • cough • blocked or runny nose • sore throat • headache	**Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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 nurse before you decide to stop taking any of your medicines.

7. Product details

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

What Cenrifki contains

Active ingredient (main ingredient)	tolebrutinib
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose hypromellose crospovidone magnesium stearate titanium dioxide iron oxide yellow iron oxide red macrogol
Potential allergens	Sugars (as lactose monohydrate)

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

What Cenrifki looks like

Cenrifki is a drop shaped, orange, film-coated tablet debossed with '60' on one side.

Cenrifki is supplied in blister packs of 7 and 28 tablets.

Aust R 496226

Who distributes Cenrifki

Cenrifki is supplied in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Toll Free No: 1800 818 806

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