CLADRITAB™

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.

1. Why am I using CLADRITAB?

CLADRITAB contains the active ingredient, cladribine. CLADRITAB is used to treat a type of multiple sclerosis (MS) known as relapsing remitting MS. In this type of MS, CLADRITAB has been shown to result in fewer relapses and less progression of disability.

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

2. What should I know before I use CLADRITAB?

Do not use if you have ever had an allergic reaction to cladribine or any of the ingredients listed at the end of the CMI, you are HIV positive and/or have a weakened immune system, you have active tuberculosis or hepatitis, you are taking other medicines that weaken your immune system or affect your bone marrow, you have moderate or severe kidney disease, or you are pregnant or breastfeeding. If you are a man, do not take CLADRITAB if you and your partner are trying to have a baby.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before I use CLADRITAB? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLADRITAB 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 CLADRITAB?

- CLADRITAB is administered in two treatment courses over two years.
- Each treatment course consists of two treatment weeks at the start of a 1 year period. For a treatment week, you will be prescribed to take one or two tablets, once a day for 4-5 days.

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

5. What should I know while using CLADRITAB?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CLADRITAB. • Keep all your doctor and blood test appointments so that your progress can be checked. • Tell your doctor if you get symptoms of shingles, if you believe your MS is getting worse or notice any new symptoms, if you or your partner becomes pregnant during or after your treatment with CLADRITAB, or if you think you have an infection. • Stay out of the sun as much as possible. If you need to be in the sun, use a sunscreen and wear a hat and shirt to protect your skin from the sun.
Things you should not do	• Do not stop taking CLADRITAB or change the dose, without first checking with your doctor. • Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CLADRITAB affects you.
Looking after your medicine	• Store below 30°C. Keep your tablets in the pack until it is time to take them. This is important for safety reasons, to protect the tablets and because the labelling includes important information.

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

6. Are there any side effects?

Common side effects include cold sores, skin rash, hair loss, allergic reactions. Serious side effects include infections and liver problems.

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.

CLADRITAB™

Active ingredient(s): *cladribine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CLADRITAB. **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 CLADRITAB.**

Where to find information in this leaflet:

1. Why am I using CLADRITAB?

CLADRITAB contains the active ingredient, cladribine. CLADRITAB acts on cells in your immune system, known as lymphocytes, to reduce inflammation in the nervous system caused by multiple sclerosis (MS).

CLADRITAB is used to treat a type of MS known as relapsing remitting MS. In this type of MS, CLADRITAB has been shown to result in fewer relapses and less progression of disability.

CLADRITAB has been studied for safety and effectiveness when given as 2 treatment courses over 2 years, each treatment course consists of 2 treatment weeks.

Following completion of the 2 treatment courses, no further cladribine treatment is required in years 3 and 4.

Your doctor is the best person to discuss the long term effects of CLADRITAB treatment beyond above.

2. What should I know before I use CLADRITAB?

Warnings

Do not use CLADRITAB if:

- You are allergic to cladribine, 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 are HIV positive and/or have a weakened immune system, e.g. due to a medical condition.
- You have active tuberculosis or hepatitis
- You are taking other medicines that weaken your immune system or affect your bone marrow (e.g. cyclosporin, methotrexate, mitoxantrone, azathioprine, natalizumab, or on-going use of corticosteroids).
- You have moderate or severe kidney disease. If necessary, your doctor can do tests to check your kidney function.
- You are pregnant or breastfeeding

Check with your doctor if you:

- If you might have or have had an infection. Signs of infection may include fever, chills, sore throat, cough, pain when urinating, or urinating more frequently. If you have any of these or any other signs that make you think you might have an infection or could get an infection, call your doctor as soon as possible. Also, tell your doctor if you have had any herpes infections (e.g. a cold sore, chickenpox or shingles) in the past. You may need vaccination prior to starting the treatment. After receiving a treatment course you may be at risk of developing or experiencing infections, which may be serious and severe. It is important you understand these risks and how to monitor for them. Patients treated with CLADRITAB may be at a higher risk for getting an infection. If you are suffering from an infection before the initiation of your CLADRITAB treatment, your doctor will consider delaying the treatment until the infection is under control or resolved.
- If you have or have had cancer. It is not recommended to use CLADRITAB if you currently have cancer. If you had cancer in the past, you should discuss this with your doctor and they can help you decide if CLADRITAB is right for you.
- If you have been vaccinated recently or if you are planning to be vaccinated (e.g. vaccines for shingles/chickenpox, tuberculosis, hepatitis, influenza, typhoid, yellow fever, etc). Your doctor may need to adjust schedule of your CLADRITAB treatment (see also Section 3. What if I am taking other medicines?).
- If you have an intolerance to fructose (a type of sugar). CLADRITAB contains sorbitol powder. It is not recommended for anyone with fructose intolerance.
- If you have liver problems. If necessary, your doctor can do tests to check your liver function. Your doctor will decide whether you can take CLADRITAB under these conditions.
- Take any medicines for any other condition

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

Do not take CLADRITAB if you are pregnant or trying to become pregnant. If you are a man, do not take CLADRITAB if you and your partner are trying to have a baby.

CLADRITAB may harm your baby. You must use reliable methods of contraception to prevent becoming pregnant yourself or making anyone else pregnant.

Your doctor will advise you for how long this is necessary.

Do not breastfeed during treatment and for at least 1 week after your last dose of CLADRITAB. Limited data have shown CLADRITAB to be passed in breast milk.

If your doctor believes that CLADRITAB is essential for you, he/she will advise you to stop breastfeeding.

Use in children

Do not give CLADRITAB to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

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 CLADRITAB and affect how it works.

Do not take CLADRITAB at the same time as any other medicine taken by mouth.

This is because CLADRITAB may interact with other medicines in the stomach. Allow at least 3 hours before and after CLADRITAB when taking other oral medicines.

Tell your doctor if you are or have been treated with:

- Any medicine that weakens your immune system or affects your bone marrow, e.g. cyclosporin, methotrexate, mitoxantrone, azathioprine, natalizumab, or on-going use of corticosteroids. These medicines must not be used together with CLADRITAB (see also Section 2. What should I know before I use CLADRITAB?). If considered necessary by your doctor, short-term treatment with corticosteroids is possible with CLADRITAB.
- Any other MS medicines, e.g. fingolimod, dimethyl fumarate
- Any medicine which may affect the blood, e.g. carbamazepine. Your doctor may need to supervise your condition more closely if you are using any of these medicines.
- Certain medicines used to treat the heart, blood, circulation or inflammation, e.g. dipyridamole, nifedipine, nimodipine, cilostazol, dilazep, reserpine, eltrombopag, sulindac, corticosteroids, rifampicin or St. John's wort
- Planning any vaccinations or have been vaccinated with the last 4-6 weeks. CLADRITAB must not be taken within 4-6 weeks of vaccination with a 'live' vaccine ('live' vaccines contain weakened forms of infectious agents). You may need to delay your treatment with CLADRITAB after vaccination and avoid certain vaccinations when taking CLADRITAB. Your doctor can advise you.

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

4. How do I use CLADRITAB?

How much to take

- CLADRITAB is administered in two treatment courses over two years. Each treatment course consists of two treatment weeks at the start of a 1 year period. For a treatment week, you will be prescribed to take one or two tablets, once a day for 4-5 days. Sometimes the number of tablets will vary from one week to the next.
- The second treatment week will usually start 4 weeks after the start date of the first.
- There is no CLADRITAB treatment between the two courses.
- Your doctor will decide the number of tablets per day (1 or 2) and number of treatment days (4 or 5) depending on your body weight.
- You may need to take the same number of tablets each day or some days you might take 2 tablets and then only 1 tablet on the following days.
- Ask your doctor or pharmacist if you are unclear about how many tablets to take each day.
- If your doctor determines it to be appropriate, you will receive another course of CLADRITAB treatment (typically, 1 year after the first treatment course).
- Follow the instructions provided when CLADRITAB was prescribed.

When to take CLADRITAB

- Take CLADRITAB at about the same time each day. You may take CLADRITAB before or after a meal.

How to take CLADRITAB

- Follow the instruction illustrated on the carton on how to open the child-resistant pack. Your hands should be dry when handling the tablets.
- Swallow the tablet(s) whole with water. Never cut or crush the tablets and do not chew them or allow them to dissolve in your mouth.
- Take the tablet(s) immediately after removal from the blister. Do not leave them exposed on surfaces, e.g. on a table, or handle them longer than necessary.
- If a tablet is left on a surface or if a broken or fragmented tablet is released from the blister, wash the area thoroughly afterwards.
- Wash your hands with soap and water after taking CLADRITAB.
- If you lose a tablet, contact your doctor or pharmacist for advice.

If you forget to use CLADRITAB

CLADRITAB should be used regularly at the same time each day. If you miss your dose at the usual time and you remember on the same day you were supposed to take it, take it on that day.

If you miss a dose and do not remember it until the following day, do not take the missed dose along with the scheduled dose.

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

- If you miss a dose, take the missed dose on the next day and extend the number of days in that treatment course.
- For example: If you forget to take the Day 3 dose and do not remember it until Day 4, take the Day 3 dose on Day 4, and take the Day 4 dose on Day 5. Extend the total number of days in the treatment course by 1 day until the pack is empty.
- If you miss 2 consecutive doses (e.g. both Day 3 and Day 4 doses), extend the treatment course by 2 days. In this case, you will take your Day 3 dose on Day 5 and your Day 4 dose on Day 6.

If you use too much CLADRITAB

If you think that you have used too much CLADRITAB, 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.

If you take too much CLADRITAB your white blood cells will be affected and you may need additional blood tests. It may also be necessary to stop treatment with CLADRITAB. Your doctor will advise you.

5. What should I know while using CLADRITAB?

Things you should do

Your doctor will check your blood before you start CLADRITAB and at intervals during and after treatment, to make sure that your treatment can be started or continued. Make sure that you keep all appointments scheduled for these blood tests.

Keep all your doctor and blood test appointments so that your progress can be checked.

If you are about to be started on any new medicine or plan to have any vaccinations, tell your doctor or pharmacist that you are taking or have taken CLADRITAB. You should not be vaccinated with 'live' or attenuated live vaccines during or after a CLADRITAB treatment, until your white blood cell counts return to normal.

If you are going to have a blood transfusion, tell the medical staff that you are taking this medicine.

Also tell the medical staff if you are undergoing any procedures where a transfusion may be required, e.g. surgery.

Special precautions may be required to prevent an unwanted reaction to the transfusion.

Stay out of the sun as much as possible. If you need to be in the sun, use a sunscreen and wear a hat and shirt to protect your skin from the sun.

Although not known if related to CLADRITAB, single events of cancer including melanomas, have been seen in people after treatment. As a precautionary measure, you should follow standard cancer screening recommendations, as advised by your doctor. Check your skin regularly and have a doctor check your skin annually for new skin spots or changes to existing spots, moles or freckles.

Call your doctor straight away if you:

- If you think you have an infection. Symptoms of infections may include fever; aching, painful muscles; headache; generally feeling unwell; loss of appetite. Your doctor may delay treatment, or interrupt it, until the infection clears up.
- If you get symptoms of shingles. Symptoms of shingles may include a 'band' of severe pain and blistering rash, typically on one side of the upper body or the face; burning, tingling, numbness or itchiness of the skin in the affected area; signs of infection such as fever, headache or generally feeling unwell.
- if you believe your MS is getting worse or if you notice any new symptoms (e.g. changes in mood or behaviour, memory lapses, speech and communication difficulties). These may be the symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML). PML is a serious condition that may lead to severe disability or death. PML has not yet been observed with CLADRITAB.
- If you or your partner becomes pregnant during or after your treatment with CLADRITAB. CLADRITAB may affect the baby if either you or your partner is taking it. Both men and women must use a proven method of birth control while taking and, for as long as your doctor tells you to, after stopping CLADRITAB. Both men and women should use birth control for at least 6 months (6 menstrual cycles) after their last dose of CLADRITAB.

Remind any doctor, dentist or pharmacist you visit that you are using CLADRITAB.

Things you should not do

- Do not stop taking CLADRITAB or change the dose, without first checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.
- Do not use CLADRITAB to treat any other complaints.

Driving or using machines

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

Looking after your medicine

- CLADRITAB tablets are provided to you in a blister that is fixed to a child-resistant carton.
- Keep your tablets in the pack until it is time to take them. This is important for safety reasons, to protect

the tablets and because the labelling includes important information.

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 where the temperature stays below 30°C; 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.

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
Viral infections: • Cold sore **Skin-related:** • Skin rash • Hair loss **Immune-related:** • Allergic reaction. Symptoms include rash, itching, hives on the skin, or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing	**Speak to your doctor if you have any of these less serious side effects.**

Some of the side effects (e.g. decreased neutrophil count) can only be found when your doctor does tests from time to time to check your progress.

Serious side effects

Serious side effects	What to do
Infections: • Fever, chills, muscle weakness, decreased or difficult urination. The most important side effect of CLADRITAB is reduction in number of a type of white blood cell known as lymphocytes. This is very common in patients on CLADRITAB treatment and may be severe. Reduced lymphocytes may increase your risk of getting an infection, particularly viral infections. • Shingles. Symptoms such as localised 'band' of severe pain and blistering rash, typically on one side of the upper body or the face. Other symptoms may be headache, burning, tingling, numbness or itchiness of the skin in the affected area, feeling generally unwell or fever in the early stages of infection. The infection may require treatment, and treatment with CLADRITAB may need to be interrupted until the infection is resolved. **Liver problems:** • nausea, vomiting, abdominal pain, tiredness, loss of appetite, yellowing of the skin or whites of the eyes, dark urine	**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.**

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.

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 CLADRITAB contains

Active ingredient (main ingredient)	cladribine
Other ingredients (inactive ingredients)	Hydroxypropylbetadex, sorbitol, magnesium stearate
Potential allergens	Sorbitol

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

CLADRITAB does NOT contain gluten, tartrazine or other azo dyes.

What CLADRITAB looks like

CLADRITAB tablets are uncoated, white, round, biconvex tablets engraved with 'C' on one side and '10' on the other side.

Each pack contains 1, 4 or 6 tablets in an aluminium-aluminium blister sealed in a cardboard wallet and fixed to a child-resistant carton (Aust R 501426).

Who distributes CLADRITAB

Merck Healthcare Pty Ltd

Suite 1, Level 1

Building B

11 Talavera Road

Macquarie Park NSW 2113

Medical Information: 1800 633 463

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