Cladribine Te Arai

Cladribine

10 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Cladribine Te Arai.

This leaflet answers some common questions about Cladribine Te Arai. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Cladribine Te Arai against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What cladribine is used for

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

Cladribine is used to treat a type of MS known as relapsing remitting MS. In this type of MS, cladribine has been shown to result in fewer relapses, less disease activity in the brain and less progression of disability.

Cladribine 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 cladribine treatment beyond above.

Ask your doctor if you have any questions about why cladribine has been prescribed for you.

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

Before you use cladribine

When you must not use it

Do not use cladribine 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

If you are not sure whether you should start using cladribine, talk to your doctor.

Before you start to use it

Tell your doctor if:

- 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 cladribine may be at a higher risk for getting an infection. If you are suffering from an infection before the initiation of your cladribine 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 cladribine 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 cladribine 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 cladribine treatment (see also Section 3. What if I am taking other medicines?).
- If you have an intolerance to fructose (a type of sugar). Cladribine 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 cladribine 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?

If you have not told your doctor about any of the above, tell them before you start using cladribine.

Pregnancy and breastfeeding

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

Cladribine 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 take cladribine if you are breastfeeding.

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

Use in children

Do not give cladribine to a child or adolescent.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking cladribine.

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

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

Some medicines may interfere with cladribine. 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 cladribine (see

also Section 2. What should I know before I use cladribine?). If considered necessary by your doctor, short-term treatment with corticosteroids is possible with cladribine.

- 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. Cladribine 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 cladribine after vaccination and avoid certain vaccinations when taking cladribine. Your doctor can advise you.

These medicines may be affected by cladribine or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking cladribine.

How to use cladribine

How much to take

- Cladribine 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 cladribine 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 cladribine treatment (typically, 1 year after the first treatment course).
- Follow the instructions provided when cladribine was prescribed.

When to take it

Take cladribine at about the same time each day.

You may take cladribine before or after a meal.

How to take it

- 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 cladribine.
- If you lose a tablet, contact your doctor or pharmacist for advice.

If you forget to take it

- Cladribine 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.

While you are using cladribine

Things you must do

Your doctor will check your blood before you start cladribine 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 cladribine. You should not be vaccinated with 'live' or attenuated live vaccines during or after a cladribine 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 cladribine, 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 cladribine.
- If you or your partner becomes pregnant during or after your treatment with cladribine. Cladribine 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 cladribine. Both men and women

should use birth control for at least 6 months (6 menstrual cycles) after their last dose of cladribine.

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

Things you must not do

Do not give cladribine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not stop taking cladribine or change the dose, without first checking with your doctor.

Do not use cladribine to treat any other complaints.

Things to be careful of

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much cladribine.

Do this even if there are no signs of discomfort or poisoning.

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using cladribine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

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 cladribine is reduction in number of a type of white blood cell known as lymphocytes. This is very common in patients on cladribine 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 cladribine 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.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using cladribine

Storage

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 where the temperature stays below 25°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

Disposal

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.

Product Description

What it looks like

Tablets 10 mg (white to off-white, round, biconvex tablets engraved with '751' on one side and plain on the other) in a blister pack: packs of 6 tablets.

Ingredients

Active ingredient:

Cladribine

Inactive ingredients:

Hydroxypropylbetadex
Sorbitol
Magnesium stearate

Sponsor Details

Cladribine Te Arai is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205
Herne Bay
Auckland, 1147
NEW ZEALAND

0800 Te Arai (83 2724)

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