

MAVENCLAD®

Cladribine tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MAVENCLAD.

It does not contain all of 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 taking MAVENCLAD against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What MAVENCLAD is used for

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

The active substance in MAVENCLAD is cladribine. Cladribine acts on cells in your immune system, known as lymphocytes, to reduce inflammation in the nervous system caused by MS.

MAVENCLAD 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 MAVENCLAD treatment beyond above.

Ask your doctor if you have any questions or concerns about taking MAVENCLAD.

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

MAVENCLAD is not addictive.

Before you take it

When you must not take it

Do not start or continue taking MAVENCLAD if:

- You are allergic to cladribine or any of the other ingredients listed at the end of this leaflet. 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.
- 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.

Do not take MAVENCLAD and talk to your doctor or pharmacist if you are unsure if any of the above applies to you.

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

MAVENCLAD 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 MAVENCLAD if you are breastfeeding.

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

Do not take MAVENCLAD after the expiry date printed on the pack.

The expiry date refers to the last day of that month. If you take it after the expiry date has passed, it may not work well.

Do not take MAVENCLAD if the packaging shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give MAVENCLAD to a child or adolescent.

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

If you are not sure whether you should start taking MAVENCLAD, contact your doctor.

Before you start to take it

Before starting the treatment courses of MAVENCLAD, tell your doctor about all of your health conditions and have your blood tested as directed by your doctor.

In particular, you must tell your doctor:

- **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. It is important you understand these risks and how to monitor for them.

Patients treated with MAVENCLAD may be at a higher risk for getting an infection. If you are suffering from an infection before the initiation of your MAVENCLAD 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 MAVENCLAD 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 MAVENCLAD 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 MAVENCLAD treatment. (see also 'Using other medicines' below).

- **If you have an intolerance to fructose (a type of sugar)**

MAVENCLAD 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 MAVENCLAD under these conditions.

- **If you are taking any other medication (see also 'Using other medicines' below).**

If you have not told your doctor about any of the above, tell them before you start or continue taking MAVENCLAD.

Also tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Using other medicines

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

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

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

MAVENCLAD 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 MAVENCLAD (see also 'When you must not take it' above). If considered necessary by your doctor, short-term treatment with corticosteroids is possible with MAVENCLAD.
- 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, diltiazem, reserpine, eltrombopag, sulindac, corticosteroids, rifampicin or St. John's wort

These medicines may affect MAVENCLAD. Your doctor can advise you.

Tell your doctor if you have been vaccinated within the last 4-6 weeks or if you are planning any vaccinations.

MAVENCLAD 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 MAVENCLAD after vaccination and avoid certain vaccinations when taking MAVENCLAD. Your doctor can advise you.

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

Ask your doctor or pharmacist if you have any questions.

How to take it

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

They may differ from the information contained in this leaflet.

Your doctor will check your blood before you start MAVENCLAD 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.

How much to take

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

There is no MAVENCLAD 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.

How long to take it

Treatment Courses

A treatment course refers to the two treatment weeks at the start of a 1 year period.

A treatment week involves taking one or two tablets each 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.

Subsequent Treatment Course

If your doctor determines it to be appropriate, you will receive another course of MAVENCLAD treatment (typically, 1 year after the first treatment course).

How to take it

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 MAVENCLAD.

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

When to take it

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

If you forget to take it

If you miss a dose 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.

In this case, 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.

Never take a double dose on the same day to make up for the dose that you missed.

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 hints.

If you take too much

Immediately contact your doctor or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much MAVENCLAD.

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

You may need medical attention.

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

While you are taking MAVENCLAD

Things you must do

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

Tell your doctor 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.

Tell your doctor immediately 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

Tell your doctor as soon as possible 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 MAVENCLAD.

Tell your doctor immediately if you or your partner becomes pregnant during or after your treatment with MAVENCLAD.

MAVENCLAD 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 MAVENCLAD.

Both men and women should use birth control for at least 6 months (6 menstrual cycles) after their last dose of MAVENCLAD.

Women taking hormonal contraceptives should add a barrier method for at least 4 weeks after the last dose of MAVENCLAD in addition to hormonal contraceptive.

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 MAVENCLAD.

You should not be vaccinated with 'live' or attenuated live vaccines during or after a MAVENCLAD 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 MAVENCLAD, 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.

Things you must not do

Do not stop taking MAVENCLAD, 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 MAVENCLAD to treat any other complaints.

Things to be careful of

Be careful driving or operating machinery until you know how MAVENCLAD affects you.

Side effects

Tell your doctor as soon as possible if you do not feel well after taking MAVENCLAD.

MAVENCLAD helps most people with MS, but it may have unwanted side effects in some people. 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 side effects. The most important side effect of MAVENCLAD is reduction in number of a type of white blood cell known as lymphocytes. This is very common in patients on MAVENCLAD treatment and may be severe. Reduced lymphocytes may increase your risk of getting an infection, particularly viral infections.

Contact your doctor as soon as possible if you think you are getting an infection.

Shingles is a common side effect observed with MAVENCLAD, with 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 MAVENCLAD may need to be interrupted until the infection is resolved.

Tell your doctor if you notice any of the following and they worry you:

- Cold sore
- Skin rash or hair loss

These are common side effects of MAVENCLAD.

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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Signs of infection, such as fever, chills, muscle weakness, decreased or difficult urination
- Signs of liver problems, such as nausea, vomiting, abdominal pain, tiredness, loss of appetite, yellowing of the skin or whites of the eyes, dark urine

These are signs and symptoms of potentially serious side effects. If you have them, you may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people.

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

MAVENCLAD 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.

Keep MAVENCLAD in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep this medicine where young children cannot reach it.

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

Disposal

If your doctor tells you to stop taking MAVENCLAD or if it has passed its expiry date, return it to your pharmacist for disposal.

Medicines should not be disposed of via wastewater or household waste.

Product description

What it looks like

MAVENCLAD 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.

Ingredients

Each MAVENCLAD tablet contains 10 mg of cladribine.

The tablets also contain:

- hydroxypropylbetadex
- sorbitol
- magnesium stearate

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

Sponsor

MAVENCLAD is made in Italy and supplied in Australia by:

Merck Healthcare Pty Ltd
Suite 1, Level 1, Building B
11 Talavera Road
Macquarie Park NSW 2113

For enquiries call 1800 633 463.

The Australian Register Number is AUST R 166483.

Sponsor in New Zealand:

Healthcare Logistics
58 Richard Pearse Drive, Airport
Oaks, Auckland

For enquiries call 0800 426 252.

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