MAVENCLAD®

10 mg Tablets (cladribine)

Patient Guide

IMPORTANT INFORMATION ON MINIMISING THE RISK OF ADVERSE EVENTS

Reporting Adverse Events

Adverse events should be reported. Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via: the Yellow Card website **www.mhra.gov.uk/yellowcard** the free Yellow Card app available from the **Apple App Store** or **Google Play Store** some clinical IT systems (EMIS/SystmOne/ Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to Merck Serono Limited – Tel: +44(0)20 8818 7373 or email: **medinfo.uk@merckgroup.com**.

Date of last revision of the text: May 2022

Job code: GB-MAV-00151 | May 2022

CONTENTS

This material is not intended to replace any information that has been provided to you by your doctor or any healthcare professional that is involved in the treatment of your MS.

This material should be read alongside the Patient Information Leaflet (PIL) which can be found inside your MAVENCLAD® medication box. The PIL will contain additional information on the potential side effects of MAVENCLAD®.

Job code: GB-MAV-00151 | May 2022

Introduction to MAVENCLAD®

Your doctor has prescribed a medicine for your treatment of multiple sclerosis called MAVENCLAD®. This guide is especially for you and includes important information about MAVENCLAD®.

This educational material contains important information about selected side effects and their potential risks, including guidance on pregnancy. It is important that you read and understand this information before you start treatment as it may help reduce your risk of these occurring.

By carefully reading this guide, you will learn more about MAVENCLAD® and some of its possible side effects.

A step-by-step guide at the end of the Patient Information Leaflet describes how you should handle MAVENCLAD®

How is treatment with MAVENCLAD® given?

The number of MAVENCLAD® tablets that you need to take depends on your body weight. Your doctor will give you clear instructions about the number of tablets and when you should take them. MAVENCLAD® treatment consists of two treatment courses administered at the beginning of two consecutive treatment years. Each treatment course consists of 2 treatment weeks, one at the beginning of the first month and one at the beginning of the second month of the respective year. After you complete the 2 treatment courses in two consecutive years, no further MAVENCLAD® treatment is required in years 3 and 4.

	MONTH 1	MONTH 2	MONTHS 3-12
YEAR 1	4-5 DAYS TREATMENT	4-5 DAYS TREATMENT	NO FURTHER TREATMENT WITH MAVENCLAD® IS REQUIRED IN YEAR 1
YEAR 2	4-5 DAYS TREATMENT	4-5 DAYS TREATMENT	NO FURTHER TREATMENT WITH MAVENCLAD® IS REQUIRED IN YEAR 2
YEAR 3	NO FURTHER TREATMENT WITH MAVENCLAD® IS REQUIRED IN YEAR 3		
YEAR 4	NO FURTHER TREATMENT WITH MAVENCLAD® IS REQUIRED IN YEAR 4		

Job code: GB-MAV-00151 | May 2022

Side effects and potential risks

MAVENCLAD® can be associated with side effects and these are fully described in the Patient Information Leaflet you will receive with your tablets. The following describes important side effects about which you should be aware.

Lymphopenia

MAVENCLAD® causes a temporary decrease of white blood cells called lymphocytes circulating in the blood. Since lymphocytes are a part of the body's immune system (the body's natural defences), a large decrease of the circulating lymphocytes, called lymphopenia, may render the body susceptible to infections. The most important infections are described below.

During MAVENCLAD® clinical studies, the incidence of lymphopenia was very common (observed in at least 1 in 10 patients). It is expected that most patients recover to either normal lymphocyte counts or mild lymphopenia within 9 months. Your doctor will check your blood to ensure that the numbers of lymphocytes do not fall too low.

Liver injury

MAVENCLAD® may be associated with liver injury. This is classified as an uncommon adverse drug reaction (may affect up to 1 in 100 patients). Most cases occur in the 8 weeks after starting the first course of treatment. This risk is increased in those with a liver disorder or a history of liver injury caused by other medicines. Tell your doctor if you have ever had liver problems or if you have any underlying liver disorders. Your doctor will check your blood to ensure that your liver works properly prior to treatment. Symptoms of liver injury can include:

- feeling sick (nausea)
- vomiting, stomach pain
- tiredness (fatigue)
- loss of appetite
- yellow skin or eyes (jaundice)
- dark urine
- widespread itch

If you notice any of the signs or symptoms described above, contact your physician immediately. Your doctor will decide whether your treatment with MAVENCLAD® needs interruption or if you must not receive further MAVENCLAD®.

Herpes zoster (shingles)

Varicella zoster is a virus that causes chickenpox. It can lay dormant in nerves in the body and can reactivate to cause shingles.

Shingles can affect any part of your body, including your face and eyes, although the chest and abdomen (tummy) are the most common areas where shingles develop.

In some cases, shingles may cause some early symptoms that develop a few days before the painful shingles rash first appears. These early symptoms can include:

- headache
- burning, tingling, numbness or itchiness of the skin in the affected area
- feeling of being generally unwell
- fever

Most people with shingles experience a localised "band" of severe pain and blistered rash in the affected area. The affected area of skin will usually be tender.

The shingles rash usually appears on one side of your body and develops on the area of skin related to the affected nerve. Initially, the shingles rash appears as red blotches on your skin before developing into itchy blisters. New blisters may appear for up to a week, but a few days after appearing they become yellowish in colour, flatten and dry out.

Job code: GB-MAV-00151 | May 2022

During MAVENCLAD® clinical studies, the incidence of shingles was a common adverse reaction (observed between 1 in 10 to 1 in 100 patients). If you notice any of the signs or symptoms described above, you should contact your physician immediately. Further symptoms may occur, which your doctor can advise you on. Your doctor can prescribe medicine to treat the infection and early treatment can lead to a less severe or shorter course of the shingles.

Severe infections including tuberculosis

MAVENCLAD® can temporarily reduce lymphocytes. Inactive infections, including tuberculosis, may be activated when the lymphocyte count is significantly decreased. In rare cases, infections may occur that are only seen in persons with a severely weakened immune system, called opportunistic infections. Your doctor will check your blood to ensure that the numbers of cells in the blood, which fight infections, do not fall too low. In addition, you will need to be vigilant of any signs or symptoms that may relate to an infection.

The signs of infections can include:

- fever
- aching, painful muscles
- headache
- generally feeling unwell
- yellowing of the eyes

Job code: GB-MAV-00151 | May 2022

These may be accompanied by other symptoms specific to the site of the infection such as a cough, vomiting, or painful urination.

If you think you have an infection, you should see your doctor who can decide if you need any special treatment.

Your MAVENCLAD® treatment may be stopped or delayed until the infection is clear.

Progressive multifocal leukoencephalopathy (PML)

PML is a rare brain infection caused by a virus (JC virus) that can occur in patients who take medicines which reduce the activity of the immune system. PML is a serious condition which may result in severe disability or death. Though no cases of PML have been observed in multiple sclerosis patients who took MAVENCLAD®, it cannot be excluded that such cases may occur in the future.

An MRI (magnetic resonance imaging) should be performed before you start MAVENCLAD® treatment.

Symptoms of PML may be similar to those of a multiple sclerosis attack. Symptoms might include weakness, changes in mood or behaviour, memory lapses, speech and communication difficulties. If you believe your disease is getting worse or if you notice any new or unusual symptoms, consult your treating physician as soon as possible.

Malignancies

Because of the way MAVENCLAD® works, a potential risk of cancer cannot be excluded. Single events of cancer have been observed in patients who had received MAVENCLAD® in clinical studies. You should undergo standard cancer screening after taking MAVENCLAD®. Your doctor can advise you about cancer screening programmes you might consider using. If you currently have a malignant disease, you must not take MAVENCLAD®. If you have a history of malignancy, inform your doctor before you take MAVENCLAD®.

Prevention of pregnancy during treatment with MAVENCLAD®

MAVENCLAD® can cause damage to genetic material and experience in animal studies showed that MAVENCLAD® caused death and deformations to the developing foetus. MAVENCLAD® may cause miscarriage or birth defects in babies if it is taken by a female patient up to 6 months before a pregnancy or during it. Your doctor may counsel you about the avoidance of pregnancy before prescribing MAVENCLAD®.

Female Patients

MAVENCLAD® must not be taken by women who are pregnant or who are trying to have a baby. All women of child-bearing potential should consider a pregnancy test to exclude pregnancy before start of treatment with MAVENCLAD®. You must not start MAVENCLAD® treatment if you are pregnant. Women who can get pregnant must use effective contraception during MAVENCLAD® treatment and for at least 6 months afterwards. Effective contraception is defined as a method with a failure rate of less than 1% per year when used consistently and correctly. Your doctor will provide guidance on appropriate contraceptive methods.

It is unknown if MAVENCLAD® decreases the effectiveness of oral contraceptives used to avoid pregnancy (the “pill”). If you take such a medication, it is important that you use an additional barrier method such as a cervical cap or a condom during the time of taking MAVENCLAD® and at least four weeks thereafter in each treatment year.

Job code: GB-MAV-00151 | May 2022

If you become pregnant, you should contact your doctor as soon as possible to discuss and get advice about any potential risks with the pregnancy.

Male Patients

MAVENCLAD® can be harmful to your semen and can be transferred to your female partner via your semen. Thus, it could cause harm to the unborn baby. You must take precautions to avoid your partner becoming pregnant, whilst you are taking MAVENCLAD® and for at least 6 months after your last dose in each treatment year, by using an effective contraceptive method (i.e. a method with a failure rate of less than 1% per year when used consistently and correctly). Your doctor will provide guidance on appropriate contraceptive methods.

If your partner becomes pregnant, she should contact her doctor as soon as possible to discuss any potential risks with the pregnancy.

Job code: GB-MAV-00151 | May 2022