



Maby, MAVENCLAD patient since 2019.

# SAFETY & SIDE EFFECTS

Learn about the possible risks of MAVENCLAD.

Safety Overview

Serious Side Effects

Common Side Effects

## The safety profile of MAVENCLAD has been extensively evaluated

When it comes to choosing a relapsing multiple sclerosis (MS) treatment, safety is a key factor. Clinical trial evaluations, follow-ups, and real-world experience support the safety profile of MAVENCLAD.



As part of the **clinical trial** program for MAVENCLAD, about 24% of cladribine-treated patients in the program were followed for up to 8 years. The average time of the study follow-up was about 4.8 years.

It is not known if MAVENCLAD is safe and effective for people to restart MAVENCLAD treatment 2 years after completing their 2 yearly treatment courses.

**56,000+ PEOPLE HAVE BEEN TREATED GLOBALLY WITH MAVENCLAD IN THE REAL-WORLD SETTING.**

## MAVENCLAD side effects

These clinical trials also evaluated the risk of side effects from MAVENCLAD. The types and seriousness of side effects vary from patient to patient. For a list of possible side effects and their symptoms, please see the **Medication Guide**.

This is not intended to replace discussions with your healthcare provider. If you think you are experiencing any of these side effects or symptoms, please talk to your healthcare provider immediately.

**Below are some of the possible, serious side effects with MAVENCLAD.**



### CANCER (MALIGNANCIES)

Treatment with MAVENCLAD may increase your risk of developing cancer. In clinical studies:

#### PATIENTS ON MAVENCLAD

**1.1%** DEVELOPED A MALIGNANCY

**(10 OUT OF 923 PATIENTS)**

VS

#### PATIENTS ON PLACEBO

**0.5%** DEVELOPED A MALIGNANCY

**(3 OUT OF 641 PATIENTS)**

Work with your healthcare team to determine which cancer screenings are necessary.

**BIRTH DEFECTS**

Because of the risk of birth defects, do not take MAVENCLAD if you are pregnant or of childbearing potential and not using effective birth control. Patients should use effective birth control (contraception) while on treatment with MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.

**LOW BLOOD CELL COUNTS**

Low blood cell counts have happened and may increase the risk of infections during treatment with MAVENCLAD. Your healthcare provider will do blood tests before, during, and after your treatment with MAVENCLAD, as needed.

**SERIOUS INFECTIONS**

Patients have experienced TB, hepatitis B or C, and shingles (herpes zoster). Fatal cases of TB (1 case) and hepatitis (1 case) have happened with cladribine during clinical studies. In clinical studies:

**PATIENTS ON MAVENCLAD**

**2%** DEVELOPED  
SHINGLES

**(12 OUT OF 662 PATIENTS)\***

**VS**

**PATIENTS ON PLACEBO**

**0.2%** DEVELOPED  
SHINGLES

**(1 OUT OF 641 PATIENTS)†**

Talk to your healthcare provider to make sure your vaccinations are up to date.

\*6% of MAVENCLAD-treated patients developed a herpes viral infection, of which 2% were herpes zoster and 2.6% were oral herpes.

†2% of placebo patients developed a herpes viral infection, of which 0.2% were herpes zoster and 1.2% were oral herpes.

**PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)**

PML is a rare brain infection that usually leads to death or severe disability. No cases of PML have been seen in MS patients taking MAVENCLAD, but it may happen in people with weakened immune systems.

**LIVER PROBLEMS**

MAVENCLAD may cause liver problems. Your healthcare provider should do blood tests to check your liver before you start taking MAVENCLAD. In clinical studies:

**PATIENTS ON MAVENCLAD**

**0.3%** HAD LIVER PROBLEMS

(2 OUT OF 662 PATIENTS)

VS

**PATIENTS ON PLACEBO**

**0%** HAD LIVER PROBLEMS

(0 OUT OF 641 PATIENTS)

**ALLERGIC REACTIONS (HYPERSENSITIVITIES)**

MAVENCLAD can cause serious allergic reactions such as skin rash, swelling or itching of the face, lips, tongue or throat, or trouble breathing. Stop your treatment with MAVENCLAD and go to the closest emergency room for help right away if you have any signs or symptoms of allergic reactions.

**HEART FAILURE**

MAVENCLAD may cause heart failure, which means your heart may not pump as well as it should. Call your healthcare provider or go to the closest emergency room for medical help right away if you have any signs or symptoms of heart failure. In clinical studies:

**PATIENTS ON MAVENCLAD\***

**0.05%** HAD HEART FAILURE

(1 OUT OF 1,976 PATIENTS)

VS

**PATIENTS ON PLACEBO**

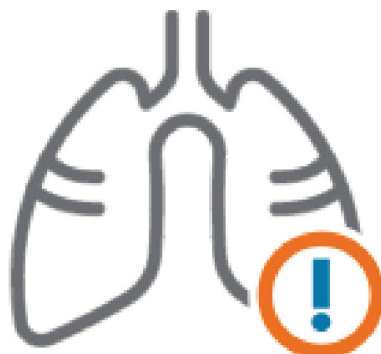
**0%** HAD HEART FAILURE

(0 OUT OF 802 PATIENTS)

\*Includes patients treated with both oral and IV forms of cladribine.

## Common side effects seen in clinical trials

Some of the most common side effects experienced by patients included:



### UPPER RESPIRATORY INFECTION

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<b>PATIENTS ON MAVENCLAD</b>	<b>38%</b>
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<b>PATIENTS ON PLACEBO</b>	<b>32%</b>
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