**Mavenclad**® *(MAY-vin-klad)*

Generic name: cladribine *(KLAD-ri-been)*

**What is Mavenclad®?**

Mavenclad® is a medication that enters the bloodstream when taken orally. It reduces lymphocytes in the blood by disrupting the production of DNA which leads to cell death.

All cells in the human body contain DNA. DNA is the genetic code that provides instructions for cells to function. Lymphocytes are immune cells that reproduce rapidly and are potentially involved with the immune attack on the nervous system contributing to multiple sclerosis. If the process to make DNA is disrupted, the new lymphocyte will be unable to carry out an immune attack on the nervous system and will die off before reproducing.

**Starting on Mavenclad®**

To obtain Mavenclad®, a form must be completed and faxed to the MS Lifelines program. This program, operated by EMD Serono (the manufacturer of Mavenclad®), will start the process of obtaining the medication. The prescriber’s office will assist with completion of these forms and getting insurance approval. It takes about 10-14 days to get insurance approval. The medication is then shipped overnight to either the patient’s home or picked up at their pharmacy (depending on insurance requirements). There are several tests that must be done prior to starting Mavenclad®:

- Routine cancer screenings
- Pregnancy screening
- Blood tests for liver function, kidney function and blood cell counts
- Baseline MRI
- Infection screenings including: HIV, Tb, Hepatitis B and C, Varicella zoster virus

After the medication arrives, the patient may start taking the medication if he or she feels well. If the patient feels ill when the medication arrives, please have him or her call the prescriber’s office before starting Mavenclad®. There is a chance the prescriber will need to delay the start date of the medication.

**Safety Monitoring**

- Blood counts (CBC with differential) 2 and 6 months after each course, at 12 months (just before 2nd course). If lymphocyte counts drop below 200, give herpes prophylaxis medications until lymphocyte counts increase.

**How should Mavenclad® be taken?**

Mavenclad® is taken orally with water and swallowed whole without chewing.

Dose: 10-20 mg (1-2 uncoated tablets)

Frequency: Once daily, see table below for more details

Mavenclad® can be taken with or without food.
Since Mavenclad® can lead to cell death and the tablet is uncoated, it is important to handle this medication carefully. They must be swallowed immediately once removed from their package and not be left on surfaces or handled for any period of time longer than necessary to take this medication. The following precautions may be used by the patient and caregiver to increase safety while taking this medication:

- Patients should wash and dry his or her hands before and after handling this medication. Caregivers or family members giving this medication to a patient should also wear gloves.
- Prepare a glass of water before removing Mavenclad® from its blister pack so that it could be taken immediately.
- Do not take any other drugs or over the counter medications within 3 hours of Mavenclad®.

Mavenclad® is divided into two treatment courses given over 2 years. One treatment course is divided into 2 treatment weeks, which are taken 1 month apart at the beginning of each treatment year.

- For example: if the treatment starts mid-April, the tablets are to be taken as shown:

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st treatment week</td>
<td>1st treatment week</td>
</tr>
<tr>
<td>1 or 2 tablets daily for 4 or 5 days, mid-April</td>
<td>1 or 2 tablets daily for 4 or 5 days, mid-April</td>
</tr>
<tr>
<td>2nd treatment week</td>
<td>2nd treatment week</td>
</tr>
<tr>
<td>1 or 2 tablets daily for 4 or 5 days, mid-May</td>
<td>1 or 2 tablets daily for 4 or 5 days, mid-May</td>
</tr>
</tbody>
</table>

The dose of Mavenclad® is based on weight and the prescriber will guide dosing. Before starting each treatment course, the prescriber will check lymphocyte counts to make sure they are in an acceptable range. If the cell counts are too low, the course may be delayed.

Mavenclad® has not been studied for use beyond the first 2 treatment courses, but the prescriber’s office will continue monitoring lymphocyte counts after each treatment course.

**What if a dose is missed?**

If a dose is missed and the patient remembers to take it that same day, the medication may be taken a few hours late. If a dose is not taken on the scheduled day, then the patient must take the missed dose on the following day and extend the number of days in that treatment cycle. If 2 or more consecutive doses are missed, the treatment cycle is extended by 2 or more days. Do not double up doses of Mavenclad®. Do not take more medication than prescribed as further doses increase risk for malignancy.

**How should Mavenclad® be stored?**

Mavenclad® should be stored at room temperature between 68°F and 77°F in its original package to protect it from moisture. If the medication is damaged or lost, call MS Lifelines. They will replace the tablet as soon as possible, free of charge.

**How supplied:**
Mavenclad® comes in 10 mg white, uncoated tablets. Each tablet is packaged in a child-resistant day pack containing one or two tablets.

**What are the common side effects?**

- **Malignancy:** The most serious side effect of Mavenclad® is malignancy. In clinical studies, malignancies occurred more frequently in Mavenclad-treated patients compared to placebo patients (1.4% versus 0%, respectively). Malignancy cases included pancreatic, skin, and ovarian cancer.

- **Low blood counts:** Mavenclad® causes a marked decrease in white blood counts, which occurred in 0.7% in the treatment group and 0% in placebo. The absolute lowest white blood cell count occurred 2 to 3 months after the start of each treatment course and were lower with each additional treatment course. Red blood cells may also be affected. This may cause:
  - Increased risk of infections (described next)
  - Anemia
  - Difficulty with bleeding or bruising.

- **Infections:** Since Mavenclad® reduces immunity, there is a risk for infection. In clinical trials, infections occurred in 49% of Mavenclad® treated patients compared to 44% of placebo patients. While the general risk of infections may not be increased by Mavenclad®, it is important to make sure patients are screened for certain infections such as HIV, hepatitis, tuberculosis, and herpes to prevent serious infections.
  - In clinical studies, 6% of Mavenclad® patients developed herpes viral infection compared to 2% of placebo patients. Routine vaccinations are recommended prior to starting Mavenclad®.
  - Live and live-attenuated vaccinations should be given at least 4-6 weeks before starting treatment.
  - Progressive multifocal leukoencephalopathy (PML) is a serious and possibly fatal neurologic infection caused by the John Cunningham virus. If a patient is infected with this virus, it may become active when his or her immune system is suppressed. There have been no cases of PML in clinical studies of Mavenclad® but PML has been reported in patients taking this medication for other indications. For more information on the risks of PML, please refer to the PML handout on the MS Center website.

- **Pregnancy Risks:** Animal studies with Mavenclad® have been shown to cause fetal harm and testicular effects. Based on human experience with other agents that interfere with DNA synthesis, Mavenclad® may also cause harm to a fetus. Both males and females taking this medication must use an effective mode of contraception during treatment and for 6 months after the last dose. Woman taking Mavenclad® using a hormonal contraception must also use a barrier method (condoms, diaphragms, etc.)

**Company Support:**
MS Lifeline® 1-866-227-3243

References:
https://pdf.hres.ca/dpd_pm/00042413.PDF