



- Other medicines and MAVENCLAD**
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Dose

1. You will be prescribed the correct number of tablets for each treatment week, based on your body weight as shown in Table 2.
2. You will need one or more packs to provide the correct number of tablets.
3. When you receive your supply of medicine, check that you have the correct number of tablets.
4. In the left column of the table below find the row that fits your body weight (in kg), and then check the number of tablets that should be in the pack(s) for the treatment week you will be starting.

- | If you forget to take MAVENCLAD | |
|--|---|
| If you miss a dose and you remember on the same day you were supposed to take it | If you miss a dose and do not remember it until the following day |
| Take the missed dose on that day. | Do not take the missed dose along with the next scheduled dose.

Take the missed dose on the next day and extend the number of days in that treatment week. |

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 extend the total number of days in the treatment week by 1 day. If you miss 2 consecutive doses (for example both Day 3 and Day 4 doses), take the missed doses for the next 2 days, and then extend the treatment week by 2 days. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be or could become serious Lymphopenia and shingles

The most important side effect is a reduction in the number of white blood cells called lymphocytes (lymphopenia), which is very common (may affect more than 1 in 10 people) and may be severe. Lymphopenia may increase the risk of getting an infection. An infection commonly seen with MAVENCLAD is shingles.

Tell your doctor immediately if you have symptoms of shingles such as a '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 feverish in the early stages of infection.

Shingles will need to be treated, and MAVENCLAD treatment may need to be stopped until the infection is cleared.

Liver problems (uncommon – may affect up to 1 in 100 people)

Tell your doctor immediately if you have symptoms such as feeling sick (nausea), vomiting, stomach pain, tiredness (fatigue), loss of appetite, yellow skin or eyes (jaundice) or dark urine. MAVENCLAD treatment may need to be stopped or interrupted.

Other possible side effects

Common side effects – may affect up to 1 in 10 people

- cold sore (oral herpes)
- rash
- hair loss
- reduction in the number of certain white blood cells (neutrophils)
- allergic reactions, including itching, hives, rash and swelling of the lips, tongue or face

Very rare side effect – may affect up to 1 in 10,000 people

- tuberculosis

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MAVENCLAD

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What MAVENCLAD contains

- The active substance is cladribine. Each tablet contains 10 mg cladribine.
- The other ingredients are hydroxypropylbetadex, sorbitol and magnesium stearate.

What MAVENCLAD looks like and contents of the pack

MAVENCLAD tablets are white, round, biconvex tablets engraved with 'C' on one side and '10' on the other side. Each pack contains 1, 4, 5, 6, 7 or 8 tablets in a blister, sealed in a cardboard wallet and fixed in a child-resistant carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Merck Europe B.V.
Gustav Mahlerplein 102
1082 MA Amsterdam
The Netherlands

Manufacturer

NerPharMa S.R.L.
Viale Pasteur, 10
20014 Nerviano (MI)
Italy

Releasing Site

R-Pharm Germany GmbH
Heinrich-Mack-Strasse
35 89257 Illertissen Germany

This leaflet was last revised in (July 2024).

This is a medicine

- A medicine is a product which affects your health and its consumption, contrary to instructions, is dangerous for you.
- Closely follow your doctor's prescription, the method of use and the instructions of the pharmacist who sold the product
- Your doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the period of treatment prescribed without your doctor's permission.
- Do not repeat the same prescription without consulting your doctor.

Keep medicines out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists