

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only.

Maclivan 500 mg Film Coated Tablets

Each tablet contains:
500 mg amoxicillin (as trihydrate)
125 mg clavulanic acid (as potassium salt)

The list of the additional ingredients is listed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Maclivan is used for adults and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections, including dental infections
- bone and joint infections

Maclivan is an antibiotic that works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called 'penicillins', whose activity can sometimes stop (become inactive). The other active component (clavulanic acid) prevents this from happening.

Therapeutic group:

Amoxicillin – an antibiotic from the penicillin group.
Clavulanic acid – beta-lactamase enzyme inhibitor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients amoxicillin and clavulanic acid, to other medicines from the penicillin group or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients, see section 6).
- you have ever had a severe allergic reaction to any other antibiotic. This can include skin rash or swelling of the face or throat.
- you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→ **Do not take Maclivan if any of the above apply to you.** If you are not sure, consult your doctor or pharmacist before taking Maclivan.

Special warnings regarding use of the medicine

Before treatment with Maclivan, tell the doctor if:

- you have glandular fever (**infectious mononucleosis**).
- you are receiving treatment for liver or kidney problems
- you are not passing urine **properly**

If you are not sure if any of these applies to you, consult your doctor or pharmacist before taking Maclivan.

In certain cases, your doctor will check the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Maclivan or a different medicine.

Conditions you should take note of

Maclivan may worsen certain existing conditions or cause severe side effects. These include: allergic reactions, convulsions (fits), inflammation of the large intestine. To reduce the risk of any problems, pay attention to certain symptoms when taking Maclivan. See '**Conditions you should take note of**' in section 4.

Blood and urine tests

If you are undergoing blood tests (e.g., red blood cell status tests or liver function tests) or a urine test (to check glucose levels), inform the doctor that you are taking Maclivan, since Maclivan may affect the results of such tests.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially:

- if you are taking allopurinol (used for gout), with Maclivan; there is a higher likelihood that you will have an allergic skin reaction.
- if you are taking probenecid (used for gout), the doctor may change the dosage of Maclivan.
- if medicines that help prevent blood clotting (e.g., warfarin or acenocoumarol) are taken with Maclivan, additional blood tests may be necessary.
- Maclivan may affect the way methotrexate works (a medicine used for the treatment of cancer or rheumatic diseases).
- Maclivan may impact the way mycophenolate mofetil works (a medicine used to prevent rejection of transplanted organs).

Use of the medicine and food

Maclivan should be taken with a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, refer to your doctor or pharmacist for consultation before taking this medicine.

Driving and use of machinery

Maclivan can have side effects and the symptoms may cause you to be unfit to drive.

Do not drive or operate machinery unless you feel well.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the medicine dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.

Adults and children weighing 40 kg and over

The recommended dosage is usually: 1 tablet, three times a day.

Children weighing less than 40 kg

In children aged 6 years and under, treatment with the Maclivan oral suspension is recommended. Consult the doctor in the event that tablets are being administered to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Patients with kidney and liver problems

- If you have kidney problems, the dose may be changed. Your doctor may choose a different strength or a different medicine. If you have liver problems, you may be required to undergo blood tests more often to check your liver function.

Do not exceed the recommended dose.

How to take Maclivan:

- Take with a meal.
- Swallow the tablets whole with a glass of water. To ease swallowing, if necessary, the tablet can be halved for immediate use. Swallow the two halves together immediately after splitting. There is no information regarding crushing/chewing.
- Split the dose equally throughout the day, at intervals of at least 4 hours. Do not take 2 doses within one hour.

Duration of treatment: Do not take Maclivan for more than two weeks. If you still feel unwell, you should refer back to your doctor.

If you accidentally took a higher dosage

If you took an overdose or if anyone accidentally swallowed the medicine [signs may include stomach discomfort (nausea, vomiting or diarrhoea) or convulsions (fits)], refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

- If you forgot to take a dose, take it as soon as you remember.
- Do not take the next dose too early, rather, wait approximately 4 hours before taking the next dose. If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult a doctor.

Adhere to the treatment regimen recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in the condition of your health, do not stop treatment with the medicine without consulting the doctor. Every dose is important for you to succeed in fighting the infection. If some of the bacteria survive, they may cause the infection to recur.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Maclivan may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. The following side effects may occur when using this medicine.

Conditions you need to take note of

Discontinue use and refer to a doctor immediately in the following situations:

Allergic reactions:

- skin rash.
- inflammation of blood vessels (vasculitis) which may present as red or purple raised spots on the skin, but can affect other parts of the body.
- fever; joint pain; swollen glands in the neck, armpit or groin.
- swelling, sometimes of the face or throat (angioedema) causing difficulty in breathing.
- collapse.

Inflammation of the large intestine:

Inflammation of the large intestine causes watery diarrhoea, usually accompanied by blood and mucus, stomach pain and/or fever.

→ **Refer to your doctor as soon as possible** for consultation if you experience these symptoms.

Additional side effects:

Very common side effects – may occur in more than one user in ten:

- diarrhoea (in adults).

Common side effects – may occur in up to one user in ten:

- thrush (candida - a yeast infection of the vagina, mouth or skin folds).
- nausea, especially when taking a high dosage.
→ if nausea occurs, take Maclivan with a meal.
- vomiting.
- diarrhoea (in children).

Uncommon side effects – may occur in up to one user in a hundred:

- skin rash, itching.
- raised itchy rash (hives).
- indigestion.
- dizziness.
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in liver enzymes.

Rare side effects - may occur in up to one user in a thousand:

- skin rash, which may include blisters (that look like central dark spots surrounded by a pale area, with a dark ring around the edges – erythema multiforme).

→ if you notice any of these symptoms, refer to a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting.
- low number of white blood cells.

Side effects of unknown frequency (the frequency can not be established from the available data):

- Allergic reactions (see above).
- Inflammation of the large intestine (see above).
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis).
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe effect causing extensive peeling of the skin (more than 30% of the body surface area – toxic epidermal necrolysis).
 - widespread red rash with small pus-containing blisters (bullous exfoliative dermatitis).
 - a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
 - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results [including increased white blood cells (eosinophilia) and liver enzymes] [Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)].

→ **Refer to a doctor immediately if you experience any of these symptoms.**

- inflammation of the liver (hepatitis).
- jaundice, caused by an increase in bilirubin in the blood (a substance produced in the liver) which may cause yellowing of your skin and whites of your eyes.
- inflammation of tubes in the kidney.
- longer coagulation time.
- hyperactivity.
- convulsions/fits (in people taking high doses of Maclivan or who have kidney problems).
- black tongue which looks hairy.

Side effects that may show up in your blood or urine tests:

- severe reduction in the number of white blood cells.
- low number of red blood cells (hemolytic anemia).
- crystals in the urine.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and the blister. The expiry date refers to the last day of that month.
- Store in the original package, below 25°C. 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. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Tablet core:

Croscarmellose Sodium, Cellulose Microcrystalline, Povidone (K25) (Syn. Polyvidone), Talc, Magnesium Stearate.

Tablet coating:

Titanium Dioxide (E171), Talc, Hypromellose 5mPa.s (2% m/m), Ethylcellulose Aqueous Dispersion (Consisting of: Ethyl Cellulose, Sodium Lauryl Sulphate, Cetyl Alcohol), Triethyl Citrate.

The tablet contains 9 mg sodium.

- What the medicine looks like and the contents of the package: an oval, white to light yellow, biconvex tablet, marked with a score line on both sides.

The package contains 10/15/20/21/100 tablets packed in a blister/tray. Not all package sizes may be marketed.

- Registration holder and address: Novartis Israel Ltd., P.O.Box 7126, Tel Aviv.
- Manufacturer and address: Sandoz, Kundl, Austria.
- This leaflet was checked and approved by the Ministry of Health in April 2017 and was revised according to Ministry of Health instructions in April 2018.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 12018.30002