

PACKAGE LEAFLET: INFORMATION FOR THE USER

MACROPEN

175 mg/5 mL granules for oral suspension

MYOCAMYCINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Macropen is and what it is used for
2. Before you take Macropen
3. How to take Macropen
4. Possible side effects
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6. Further information

1. WHAT MACROPEN IS AND WHAT IT IS USED FOR

Macropen medicine belongs to the Group of macrolide antibiotics. ATC code: J01FA11.

It is intended for:

- for the treatment of infections of the respiratory organs, skin and subcutaneous tissue,
- for the treatment of certain infections of the urinary organs and sexual organs,
- for the treatment and prevention of diphtheria and whooping cough,
- for the treatment of some types of diarrhea.

Macropen is often prescribed to patients who are hypersensitive to penicillin.

2. BEFORE YOU TAKE MACROPEN

Do not take Macropen:

- if you are allergic (hypersensitive) to midecamycin or any of the ingredients of Macropen,
- if you have very damaged liver function.

Be especially careful with Macropen:

- if you have damage of liver function,
- if during the treatment and after it you experience strong and persistent diarrhea (antibiotics can alter the intestinal flora and may proliferate bacteria *Clostridium difficile* and cause diarrhoea); in this case, consult a doctor, you may have to stop taking Macropen.

Taking other medicines with Macropen

Please tell your doctor or pharmacist about all medicines you are taking or have recently taken, including those obtained without a prescription or herbal medicines.

Taking some medicines together with Macropen may increase the concentrations of these medicines in the blood and therefore increase a chance for side effects. Consult a doctor if you are taking medicine:

- against blood clotting (e.g. warfarin),
- for braking immunological reactions after transplantation of organs (e.g., Cyclosporine),
- for seizures (e.g., carbamazepine),
- against migraine headaches (ergot alkaloids).

Taking food and drinks with Macropen

Take Macropen before meals.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before taking any medicine.

Since the safety of Macropen in pregnancy has not been confirmed, a doctor will prescribe it for you only when the expected benefits for the pregnant woman are greater than the risk to the fetus. The medicine is excreted into breast milk and therefore you are encouraged not to breast-feed during treatment.

Driving and using machines

Macropen has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Macropen

Granules for oral suspension contain parahydroxybenzoates and azo yellow dye E110 that can cause allergic reactions. Parahydroxybenzoates can cause delayed allergic reactions.

3. HOW TO TAKE MACROPEN

While taking Macropen exactly follow the doctor's instructions. If you are in doubt, consult a doctor or pharmacist.

The dosage of the medicine and duration of treatment are dependent on the type and location of the infection, the patient's age and the response to treatment.

The children under 30 kg- give oral suspension at a dose of 20 mg/kg up to 40 mg/kg of body weight per day, divided into three doses or 50 mg/kg of body weight per day in two doses, and in severe infections in three doses.

Approximate lookup table for dosing children (daily dose of 50 mg/kg body weight).

children	oral suspension 175 mg/5 ml
30 kg (~ 10 years)	2 x 22,5 mL (787,5 mg)
20 kg (~ 6 years)	2 x 15 mL (525 mg)
15 kg (~ 4 years)	2 x 10 mL (350 mg)
10 kg (~ 1 do 2 years)	2 x 7,5 mL (262,5 mg)
5 kg (~ 2 months)	2 x 3,75 mL (131,25 mg)

Treatment usually lasts for 7 to 14 days.

Preparation of oral suspension

Add 100 ml of purified water to granules in a glass bottle, and shake well the prepared oral suspension.

If you think that the effect of Macropen is too strong or too weak, you should consult a doctor or pharmacist.

If you have taken a higher dose of Macropen than you should

By taking large amounts of the medicine at once, you may experience nausea and vomiting.

If you forget to take Macropen

Do not take a double dose if you forget to take the previous tablets.

If you didn't take the dose in a timely manner, take it as soon as possible. If you are approaching a time when you need to take the next dose, skip the missed dose, and then continue with the usual schedule of therapy.

If you stop taking Macropen

Take the medicine as prescribed by the doctor. If you stop too soon with the treatment, the disease can return.

If you have any further questions on the use of Macropen talk to your doctor or to the pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, and Macropen may cause side effects, which do not occur in all patients.

There may be slight disturbances in the digestive tract (decreased appetite, inflammation of the oral mucosa, nausea, vomiting and diarrhea). Very rarely diarrhea is strong and lasts a long time, which can be a sign of inflammation of the colon (pseudomembranous colitis) which can occur when taking antibiotics.

Rare hypersensitivity reactions are manifested as itching, skin rash, urticaria, and eosinophilia.

It can increase the activity of liver enzymes (transaminases) and appearance of jaundice.

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If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE MACROPEN

Keep out of reach and sight of children.

Store at the temperature up to 25 ° c.

The shelf life of the medicinal product is 3 years from the date of manufacture.

Macropen may not be used after the expiry date that is specified on the packaging. Expiration date refers to the last day of that month.

Prepared suspension is stable for 7 days when stored at a temperature below 25°C and 14 days when stored in the fridge.

6. FURTHER INFORMATION

What does Macropen contain?

- active substance in granules for oral suspension is myocamycine (midecamycin acetate). 5 mL of oral suspension (1 measuring spoon) contains 175 mg of myocamycine.
- Auxiliary substances of granules for oral suspension are methyl parahydroxybenzoate, propyl, mannitol, Orange dye FCF (E110), citric acid anhydrous, sodium saccharine, hypromellose, anhydrous sodium phosphate dibasic, the aroma of bananas and silicone emulsion.

How Macropen looks like and contents of the pack

Granules for oral suspension are orange, finely granulated powder with a slight scent of the bananas.

There are boxes with glass bottles with granules for preparation of 115 mL of oral suspension and a measuring teaspoon.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

KRKA, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, Republic of Slovenia

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