

PACKAGE LEAFLET: INFORMATION FOR THE USER

MACROPEN

400 mg film-coated tablets

MIDECAMYCIN

• 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
5. How to store Macropen
6. Further information

1. WHAT MACROPEN IS AND WHAT IT IS USED FOR

Macropen medicine belongs to the group of macrolide antibiotics. ATC code: JO1FA03.

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 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.

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 usual dose for adults and children heavier than 30 kg is one 400 mg tablet three times a day. The maximum daily dose for adults is 1600 mg of midecamycin.

Treatment usually lasts for 7 to 14 days.

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

If you take more than you should Macropen

If you have taken a larger quantity of the medicine, you may experience nausea and vomiting.

If there are signs of overdosing, a doctor will decide on the appropriate treatment.

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 Macropen may cause side effects.

Side effects are classified in the following groups according to frequency:

Very common: Appear in more than 1 in 10 patients

Common: Appear at 1 to 10 patients on 100 patients

Uncommon: Appear at 1 to 10 patients on 1000 patients

Rare: Appear at 1 to 10 patients on 10000 patients

Very rare: Appear at fewer than 1 patient in the 10000 patients

Unknown frequency: Not possible to evaluate from available data

Consult a doctor if you experience:

- hypersensitivity reactions such as rash, pruritus and urticaria;
- strong and persistent diarrhea, which can be a sign of a special form of inflammation of the colon (of pseudo membranous colitis);
- yellow skin (jaundice).

These side effects are very rare (occurring at less than 1 patient on 10000 patients).

Other side effects that may occur during treatment:

Uncommon:

- nausea, decreased appetite, vomiting, diarrhea, inflammation of the mucous membranes of the lips;
- changed values in some laboratory blood tests that indicate damage to liver function (increased activity of liver enzymes).

Very rare:

- increased number of one type of white blood cells (Eosinophilia).

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.

Store in the original packaging to ensure protection from moisture.

Macropen must not be used after the expiry date stated on the package. The shelf life of the medicinal product is 3 years from the date of manufacture. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Macropen contain?

- the active substance is midecamycin. 1 film-coated tablet contains 400 mg of midecamycin.

- the other substances are microcrystalline cellulose, polyacrylic potassium, magnesium stearate and TALC in the Tablet core and a copolymer of methacrylic acid, MACROGOL 4000, titanium dioxide (E171) and talc in the film-coating.

How Macropen looks like and contents of the Pack

Film-coated tablets are white, round, slightly protruding, with break-mark on one side.
There are boxes of 16 tablets in blister (2 blisters containing 8 tablets).

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

Manufacturer of the medicinal product

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