

Package leaflet: Information for the user

Pivmecillinam hydrochloride Karo Pharma 400 mg film-coated tablets pivmecillinam hydrochloride

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pivmecillinam hydrochloride Karo Pharma is and what it is used for
2. What you need to know before you take Pivmecillinam hydrochloride Karo Pharma
3. How to take Pivmecillinam hydrochloride Karo Pharma
4. Possible side effects
5. How to store Pivmecillinam hydrochloride Karo Pharma
6. Contents of the pack and other information

1. What Pivmecillinam hydrochloride Karo Pharma is and what it is used for

Pivmecillinam hydrochloride Karo Pharma belongs to a group of medicines called penicillins. It is a type of antibiotic. Pivmecillinam hydrochloride Karo Pharma works by killing germs (bacteria) that cause infections.

Pivmecillinam hydrochloride Karo Pharma is used to treat Infections of the bladder (cystitis) in adults.

2. What you need to know before you take Pivmecillinam hydrochloride Karo Pharma

Your doctor may have prescribed a different use or dosage than stated in this information. Always follow your doctors instructions.

Do not take Pivmecillinam hydrochloride Karo Pharma:

- If you are allergic (hypersensitive) to pivmecillinam or any of the the other ingredients of this medicine (listed in section 6).
- If you are allergic (hypersensitive) to other antibiotics. Such antibiotics include penicillin or cephalosporins.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Pivmecillinam hydrochloride Karo Pharma or other beta-lactam antibiotics (such as amoxicillin, penicillin V and flucloxacillin).
- If you have narrowing of the food pipe.
- If you suffer from a condition which may reduce the amount of a substance called carnitine in in your body. Such conditions include carnitine transporter defect, methylmalonic aciduria and propionic acidaemia.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Pivmecillinam hydrochloride Karo Pharma. The tablets must be taken with at least half a glass of fluid to prevent that the tablets get stuck in your food pipe.

Before you start the treatment tell your doctor:

- If you have porphyria.

- If you have already used Pivmecillinam hydrochloride Karo Pharma recently, as use for a longer period may reduce the amount of carnitine in your body.

During treatment:

- Serious skin reactions (SCAR) including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Pivmecillinam hydrochloride Karo Pharma treatment. Stop taking Pivmecillinam hydrochloride Karo Pharma and seek medical attention immediately if you experience any of the symptoms related to these serious skin reactions described in section 4.
- If you suddenly have diarrhoea while taking Pivmecillinam hydrochloride Karo Pharma tell your doctor immediately. This may be because your bowel is inflamed (colitis).
- The intake of pivmecillinam shortly before delivery may affect the neonatal screening for inherited metabolic disorders and give a false positive result. A "false positive" means that the test wrongly indicates that your child has the disorder. There is no risk for the newborn, but you should tell your doctor if you took Pivmecillinam hydrochlorid Karo Pharma shortly before delivery.

Children and adolescents

Do not give this medicine to children and adolescents below 18 years because the potential benefits may not be greater than the risks.

Other medicines and Pivmecillinam hydrochloride Karo Pharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor or pharmacist if you use any of the following medicines:

- Probenecid (for treating gout). This may increase the effect of Pivmecillinam hydrochloride Karo Pharma
- Methotrexate (for treating rheumatism, cancer). The excretion of methotrexate from your body may be slower when used together with Pivmecillinam hydrochloride Karo Pharma
- Valproate or valproic acid (for treating epilepsy). This increases the risk of too little carnitine in your body when used together with Pivmecillinam hydrochloride Karo Pharma
- Other anti-inflammatory medicines (e.g. tetracyclines, erythromycin, other beta-lactam antibiotics). This can influence the effect of Pivmecillinam hydrochloride Karo Pharma

Pivmecillinam hydrochloride Karo Pharma with food and drink

You can take your medicine with or immediately after a meal. You must take Pivmecillinam hydrochloride Karo Pharma with at least half a glass of water. It is important to take your medicine with plenty of liquid and in good time before bedtime. This will stop you getting any problems in your food pipe.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Pivmecillinam hydrochloride Karo Pharma can be taken during pregnancy.

Some cases of false-positive newborn screening tests simulating the presence of isovaleric acidemia have been reported. The intake of pivmecillinam shortly before delivery may affect the neonatal screening for metabolic disorders and give a false positive result. A "false positive" means that the test wrongly indicates that your child has the disorder. There is no risk for the newborn, but you should tell your doctor if you took Pivmecillinam hydrochlorid Karo Pharma shortly before delivery.

Breast-feeding

Pivmecillinam hydrochloride Karo Pharma can be taken during breast-feeding.

Fertility

Clinical studies concerning fertility have not been done.

Driving and using machines

Pivmecillinam hydrochloride Karo Pharma has no or negligible influence on your ability to drive or use machines.

3. How to take Pivmecillinam hydrochloride Karo Pharma

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure. You should take the medicine at equally spaced times in the day. When you have to take it three times a day, take it at breakfast, at lunch and then at dinner time. Pivmecillinam hydrochloride Karo Pharma must be taken with at least half a glass of liquid. Your doctor will tell you how long you need to use Pivmecillinam hydrochloride Karo Pharma tablets.

The recommended dose is 400 mg 3 times daily.

Elderly: Dose adjustment is not necessary.

If you have reduced kidney function or reduced liver function dose adjustment is not necessary.

If you take more Pivmecillinam hydrochloride Karo Pharma than you should

Tell your doctor straight away. You may need to stop taking this medicine. You may be sick, feel sick or get an upset stomach.

If you forget to take Pivmecillinam hydrochloride Karo Pharma

If you forget to take your medicine, take it as soon as you remember. Always take it with at least half a glass of water or other liquid. Then take the next dose at the usual time.

If you stop taking Pivmecillinam hydrochloride Karo Pharma

It is very important to take all the medicine that your doctor has told you to take. You must finish this medicine even if you feel better. You must do this because otherwise you may feel ill again.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects:

Stop taking Pivmecillinam hydrochloride Karo Pharma and seek medical help immediately if you notice any of the following symptoms:

- Severe allergic reactions (anaphylactic reactions, angioedema, anaphylactic shock) – signs may include sudden skin rash, swelling of the face, lips, tongue and/or the throat, breathing or swallowing difficulty, fainting due to hypersensitivity. These reactions may be life-threatening.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- Severe and lasting bloody diarrhoea with stomach pain and fever (*Clostridium difficile* colitis).

Anaphylactic reactions and *Clostridium difficile* colitis are uncommon and may affect up to 1 in 100 people. The occurrence of angioedema and anaphylactic shock is not known.

Contact your doctor if you notice the following serious side effect:

- Bleeding from skin and mucous membranes and bruising of the skin due to changes in the blood (low platelet count) (thrombocytopenia). Uncommon: may affect up to 1 in 100 people.

Other side effects:

Common: may affect up to 1 in 10 people.

- Fungal infection of the vagina
- Diarrhoea
- Feeling sick (nausea)

Uncommon: may affect up to 1 in 100 people

- Headache
- Dizziness
- Feeling of spinning
- Being sick (vomiting)
- Stomach pain
- Indigestion (problems with digestion)
- Mouth or food pipe ulcer, inflammation of the food pipe
- Liver function disorders
- Changes in blood or liver values
- Muscle weakness or muscle loss. Tiredness or lack of energy. Too little carnitine in your body may cause these symptoms.
- Nettle rash
- Itching
- Fatigue

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance

Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Pivmecillinam hydrochloride Karo Pharma

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 carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Pivmecillinam hydrochloride Karo Pharma contains

- The active substance is pivmecillinam hydrochloride. One Pivmecillinam hydrochloride Karo Pharma 400 mg film-coated tablet contains 400 mg pivmecillinam hydrochloride.
- The other ingredients are hydroxypropylcellulose, hypromellose 6 cps, magnesium stearate, microcrystalline cellulose, simethicone emulsion 30%, synthetic paraffin.

What Pivmecillinam hydrochloride Karo Pharma looks like and contents of the pack

Pivmecillinam hydrochloride Karo Pharma is a white capsule-shaped, film-coated tablet, size 8 x 17 mm.

Pack sizes: 9, 10, 15 and 20 tablets in a blister pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Karo Pharma AB

Box 16184

103 24 Stockholm

Sweden

medinfo@karopharma.com

Manufacturer:

Recipharm Strängnäs AB

Mariefredsvägen 35

S-645 41 Strängnäs

Sweden

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium: Selexid® 400 mg Tabletten

Denmark: Pivmecillinamhydrochlorid Karo Pharma

The Netherlands: Selexid® 400 mg Filmomhulde tabletten

Ireland: Pivmecillinam hydrochloride Karo Pharma 400 mg film-coated tablets

Italy: XSYSTO®

Luxembourg: Selexid® 400 mg Comprimés pelliculés

Poland: X-SYSTO® 400 mg Tabletki powlekane

Spain: Selexid® 400 mg Comprimidos recubiertos con película

Germany: X-SYSTO® 400 mg Filmtabletten

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