Package leaflet: Information for the user

Pivmecillinam hydrochloride 200 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 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. See section 4.

What is in this leaflet

1. What Pivmecillinam hydrochloride is and what it is used for
2. What you need to know before you take Pivmecillinam hydrochloride
3. How to take Pivmecillinam hydrochloride
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1. What Pivmecillinam hydrochloride is and what it is used for

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

If the infection is not treated, germs can continue to grow in your body. The infection will make you feel very unwell, and could even be life-threatening.

Pivmecillinam hydrochloride is used to treat:
- Infections of the bladder or tubes leading from the kidneys (urinary tract infections).
- Infections caused by a bacteria called Salmonella (salmonellosis).

You must talk to a doctor if you do not feel better or if you feel worse after completing your prescribed course of Pivmecillinam hydrochloride.

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

Do not take Pivmecillinam hydrochloride
- If you are allergic (hypersensitive) to pivmecillinam hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic (hypersensitive) to other antibiotics. Such as penicillin or cephalosporins.
- If you know you have any condition that can make your food pipe become narrow.
- If you know you have any condition that may reduce the amount of a substance called carnitine in your body. Such conditions include primary carnitine deficiency or kidney dialysis.

Warnings and precautions
Talk to your doctor or pharmacist before taking Pivmecillinam hydrochloride.
- If you know that you have a condition called porphyria.
- If you are taking other medicines used to treat epilepsy, called valproic acid or valproate.
- If you are taking another antibiotic called pivampicillin.
- If you have recently taken a course of Pivmecillinam.
- If you have been taking pivmecillinam for a long time already.

Severe skin reactions (SCAR) have been reported in association with Pivmecillinam. Stop taking Pivmecillinam and seek medical help immediately if you experience any of the symptoms described in section 4, as you may need urgent medical treatment.

Tell your doctor or pharmacist if you have diarrhoea, fever or pain in the stomach after the use of pivmecillinam.

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 shortly before delivery.

If you take Pivmecillinam hydrochloride for a long time, your doctor may take regular blood tests. This is to check if your kidneys and liver are working properly.

Other medicines and Pivmecillinam hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes any medicines which you have bought without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following medicines:
- Methotrexate: for arthritis or psoriasis. You may need to take a different dose of methotrexate.
- Probenecid: for gout. This may increase the effect of Pivmecillinam hydrochloride.
- Valproic acid or valproate: for epilepsy.
- Any other antibiotic: for treating an infection such as erythromycin or tetracycline. This may have an effect on how Pivmecillinam hydrochloride works in your body.

Pivmecillinam hydrochloride with food and drink
Pivmecillinam hydrochloride should be taken during or after a meal. Tablets must be swallowed whole with at least half a glass of fluid, while sitting or standing (see section 3').

It is important to take your medicine with plenty of fluid. This will stop you getting mouth ulcers or ulcers in your food pipe. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.

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
This medicine can be taken during pregnancy.

Some cases of false-positive newborn screening tests simulating the presence of isovaleric acidaemia 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 shortly before delivery.
Tell your doctor if you become pregnant while taking this medicine.

Breast-feeding
This medicine can be taken during breast-feeding.

Fertility
Clinical studies concerning fertility have not been done.

Driving and using machines
Usually your medicine may have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

3. How to take Pivmecillinam hydrochloride

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist if you are not sure.

How much Pivmecillinam hydrochloride 200 mg film-coated tablets to take
Your doctor will tell you how many tablets to take or give to your child. Your doctor will tell you how many times each day to take your medicine.

You should take the medicine at equally spaced times in the day.

Remember to always swallow the tablets whole during or immediately after a meal and with at least half a glass of fluid, while sitting or standing.

It is very important to take all the medicine your doctor has told you to take.

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By RA Milpharm at 2:10 pm, Dec 09, 2025

Urinary Tract Infections:

Adults and children weighing more than 40 kg:
- Acute infection: The usual starting dose is 2 tablets taken immediately. Then take 1 tablet every 8 hours. Continue until you have taken all tablets in the pack.
- Repeated infection: The usual dose is 6-8 tablets each day. Take 2 tablets three or four times each day.

For other type of infections, for pregnant women or for children weighing less than 40 kg:
Your doctor will prescribe the right dose for you.

If you take more Pivmecillinam hydrochloride than you should
Tell your doctor straight away. You may need to stop taking this medicine.
You may be sick, or feel sick, or get an upset stomach.

If you forget to take Pivmecillinam hydrochloride
If you forget to take your medicine, take it as soon as you remember. If you can, take it during or immediately after a meal, but always take with half a glass of water while sitting or standing. Then take the next dose at the usual time.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Pivmecillinam hydrochloride
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 or pharmacist.

4. Possible side effects

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

Important side effects to look out for:
You must get urgent medical help if you have any of the following symptoms. You may be having a severe allergic reaction, which may be life-threatening:
- You have difficulty breathing or swallowing.
- Your face, lips, tongue and/or throat swell.
- Your skin develops a sudden rash or areas of sudden swelling.
- You faint due to hypersensitivity.

Stop taking Pivmecillinam and seek medical help immediately as you may need urgent medical treatment, if you experience any of the following symptoms:
- Severe diarrhoea caused by inflammation of the colon (large intestine).
- Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes,mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish); swelling and redness of eye or face; flu-like feeling,fever, chills, body aches, swollen glands, cough, shortness of breath, chest pain or discomfort (Severe Cutaneous Adverse Reactions (SCAR), not known frequency).

Other possible side effects:
Common: may affect upto 1 in 10 people
- Infection or inflammation of the vagina (Vulvovaginal mycotic infection).
- Diarrhoea.
- Feeling sick (nausea).

Uncommon: may affect upto 1 in 100 people
- Headache
- Dizziness
- Being sick (vomiting)
- Stomach Pain
- Inflammation of the colon (large intestine), causing diarrhoea (usually with blood and mucus) and stomach pain.
- Indigestion.
- Trouble chewing or swallowing your food. This may be due to mouth ulcers, ulcers in your food pipe or inflammation of your food pipe, from taking the tablets with insufficient fluids.
- Bruising or bleeding more easily.
- Getting a fever or infections more often. This may be due to a change in certain types of cells found in your body.
- Muscle weakness or muscle loss. This may be due to a decrease in the amount of a substance called carnitine in your body.
- Light-headedness.
- Yellowing of the skin or eyes.
- Unusually dark urine.
- Small changes in blood test results. Your doctor can explain this more.
- Rash.
- Hives (urticaria).
- Itching skin (pruritus).
- Tiredness or lack of energy.

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 the Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pivmecillinam hydrochloride

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

Store below 30°C.
Store in the original package in order to protect from moisture.

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.

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 contains
- The active substance is pivmecillinam hydrochloride. Each film-coated tablet contains 200 mg of pivmecillinam hydrochloride.
- The other ingredients are:
  Tablet core: Cellulose microcrystalline, magnesium stearate.
  Film coating: Hypromellose, triacetin.

What Pivmecillinam hydrochloride looks like and contents of the pack
Film-coated tablet.

White to off-white, round shaped, biconvex, film coated tablets debossed with ‘F’ on one side and ‘48’ on the other side.

Pivmecillinam hydrochloride film-coated tablets are available in triple laminated cold form aluminium blister packs.

Pack sizes: 2, 10, 14 and 100 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

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