

Package leaflet: Information for the patient

Selexid® 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.
- In this leaflet Selexid® 200 mg Film-coated Tablets will be called Selexid.

What is in this leaflet:

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

1. What Selexid® is and what it is used for

Selexid belongs to a group of medicines called penicillins. It is a type of antibiotic. Selexid 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.

Selexid 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 Selexid.

2. What you need to know before you take Selexid®

Do not take Selexid:

- 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 Selexid:

- 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 Selexid.
- If you have been taking Selexid for a long time already.

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

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 Selexid shortly before delivery.

If you take Selexid 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 Selexid

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 Selexid.
- 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 Selexid works in your body.

Selexid with food and drink

Selexid 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 'How to take Selexid®').

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 and 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.

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 Selexid shortly before delivery.

Tell your doctor if you become pregnant while taking this medicine.

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 Selexid®

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

How much Selexid 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.

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 10 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 or for children weighing less than 40 kg:

Your doctor will prescribe the right dose for you.

If you take more Selexid 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 Selexid

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 Selexid

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.

You must get urgent medical help if you have the following symptom:

- Severe diarrhoea caused by inflammation of the colon (large intestine).

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Feeling sick (nausea).
- Diarrhoea.
- Infection or inflammation of the vagina (Vulvovaginal mycotic infection).

Uncommon (may affect up to 1 in 100 people)

- Being sick (vomiting).
- Inflammation of the colon (large intestine), causing diarrhoea (usually with blood and mucus) and stomach pain.
- 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.
- Headache.
- Dizziness.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Selexid®

- 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. The expiry date refers to the last day of that month.
- Store below 25 °C in a dry place.

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 Selexid contains

- The active substance is pivmecillinam hydrochloride. Selexid contains 200 milligrams of pivmecillinam hydrochloride in each tablet.
- The other ingredients are cellulose microcrystalline, hydroxypropylcellulose, magnesium stearate, hypromellose, simethicone and synthetic paraffin.

What Selexid looks like and contents of the pack

Selexid is a white tablet. There is a picture of a lion on one side of the tablet. The other side has 137 written on it.

Selexid comes in blister packs of 10 and 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and ManufacturerMarketing Authorisation Holder:

Karo Pharma AB, Box 16184, 103 24 Stockholm, Sweden

Manufacturer:

Recipharm Strängnäs AB, Mariefredsvägen 35, S-645 41 Strängnäs, Sweden

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