

PACKAGE LEAFLET: INFORMATION FOR THE USER

PALIN

200 mg capsule, hard

PIPEMIDIC ACID

• 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 Palin is and what it is used for
2. Before you take Palin
3. How to take Palin
4. Possible side effects
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1. WHAT PALIN IS AND WHAT IT IS USED FOR

Palin is a urinary antiseptic used to treat infections of the lower urinary tract. It belongs to a group of antibiotics called quinolones.

It works by destroying the bacteria that cause the infection.

Palin is mainly concentrated in the urine, through which it is excreted from the body.

Palin hard capsules are used to:

- treat acute and chronic infection of a part of the urinary tract (bladder, prostate and urinary tract infections, pyelonephritis and pyelitis (bacterial infection of the kidneys and kidney channel))
- Prevent repeated infections of the lower urinary tract (bladder and urinary tract)

2. BEFORE YOU TAKE PALIN

Warn the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitivity to medicine or have had an allergic reaction to some of them.

Do not take Palin

- If you are allergic to Pipemidic acid or any of the other ingredients of the medicine
- If you are allergic to quinolone antibiotics; if you have ever had a rash on the skin, and swelling of the face, neck or body during the treatment or have had difficulties with breathing after the use of quinolone antibiotics.

Palin should not be used in children and adolescents during growth.

Be especially careful when taking Palin:

- If you are older than 70, you can often have unwanted effects
- If you have impaired kidney function, a doctor will adjust the dose
- If you have Porphyria (a type of metabolic diseases)
- If you have a lack of glukozo-6-phosphate dehydrogenase (metabolism disorder of red blood cells in the blood)
- If you have brain damage or a specific disease (including epilepsy), or if you have ever had seizures.

During treatment with Palin you should not be subjected to direct sunlight, or UVA radiation (tanning salon), because it can affect hypersensitivity of the skin.

During treatment you should drink a sufficient amount of fluid.

Contact your doctor if you have any concerns about the above or if any of the above applied to you in the past.

Taking other medicines

Note that this information may apply to medicines that you no longer take, as well as the medicines that you plan to take in the future. Tell your doctor or pharmacist if you are taking or have recently taken any medicine, as well as those obtained without a prescription.

Please note that these data may refer to the medicines that were used in the recent past.

If you are using theophylline (medicine for treatment of asthma or chronic bronchitis) you need to tell your doctor, because it can increase the unwanted effects. Your doctor will determine the concentration of theophylline in the blood and adjust the dose.

Antacids (medicines to treat heartburn) and sucralfate (medicine for stomach) can reduce the effect of Palin and therefore should not be used simultaneously with it. It is recommended to make a time gap of 2 to 3 hours between use of this medicines and Palin.

If you use warfarin (a medicine that reduces blood clotting) its effects may increase and it is therefore necessary to decrease its dosage.

Concomitant use of nonsteroidal anti-inflammatory medicines (NSAIDs-medicines to relieve pain, elevated body temperature and rheumatic discomfort) with Palin increases the possibility of the occurrence of seizures (convulsions).

Taking Palin together with food and drink

It is recommended that Pipemidic acid is taken on a full stomach with sufficient amounts of fluids.

The effects of caffeine, which can be entered into your system with a cup of coffee and some soft drinks, can be increased.

Pregnancy and breastfeeding

Before you start taking any medicine, consult your doctor or pharmacist.

You need to tell your doctor if you are pregnant or if there is a possibility that you are pregnant.

There were no damaging effects on the embryo or fetus in clinical studies and in pregnant women. However, given that there were no well controlled clinical studies on the safety of Pipemidic acid during pregnancy on humans, the use of Palin during pregnancy is not recommended.

You need to tell your doctor if you are breast-feeding. A small amount of this medicine is excreted into breast milk, so the usage of Palin not recommended in nursing mothers.

Ability to drive and use machines

Do not operate motor vehicles and machines, because use the Palin can prevent to safely manage the specified (there is the possibility of dizziness and vision disorders).

Important information about some of the ingredients of Palin.

Palin hard capsules contain black color PN E 151, which can cause allergic reactions, including asthma. Allergic reactions are more common in people who are hypersensitive to acetylsalicylic acid.

3. HOW TO TAKE PALIN

Take Oспен exactly according to doctor's instructions. If you are in doubt, consult a doctor or pharmacist.

Your doctor will tell you how many tablets a day you should take and how long it will take. Do not change the dosage or discontinue treatment without consulting your doctor.

The usual daily dose for adults is twice a day, by taking two hard capsules 200 mg in the morning and two hard capsules 200 mg in the evening, ie. every 12 hours. The duration of treatment is usually 5-10 days, but can last longer, depending on the underlying disease.

Treatment of uncomplicated cystitis in women lasts three days.

It is recommended that you take Pipemidic acid on a full stomach, and drink plenty of fluids during treatment.

If you have impaired kidney function, inform your doctor about it, so that he/she may reduce the dose.

If you have the impression that the effect of Palin is too strong or too weak, talk to your doctor or pharmacist.

If you had taken the required quantity of the medicine, but still have symptoms, please consult with your doctor.

If you have taken more Palin than you should

If you recklessly take more capsules than you should, look for medical assistance immediately. Show your doctor the remaining capsules in a box. Intake of excessive amounts of this medicine can cause distress, vomiting, dizziness, headache, confusion, tremor (shaking) or seizure (convulsions).

You should have just as much medicine as prescribed.

If you forget to take Palin

If you forget to take medicine, please take it as soon as you remember. Try to continue taking the medicine as before (just take the next dose after 12 hours).

Do not take a double dose to make up for the missed dose.

If you stop the treatment with Palin

Essentially, it is important to use this medicine as prescribed by your doctor.

Do not stop using this medicine before your doctor recommended to stop, even if you have no more symptoms of the disease.

If you stop using this medicine earlier than recommended, some of the bacteria can survive and infection can reoccur.

If you have any further questions about this product, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Palin can cause side effects, although not everybody gets them. They are usually mild and transient.

If you experience any of the following, please stop treatment and seek medical help immediately:

- swelling of the face, lips, mouth, throat or any other part of the body, which causes difficulty in swallowing, breathing
- hives (urticaria) or

- loss of consciousness.

These are very rare, but serious side effects. Their appearance indicates that you may be allergic to Palin. In these cases you need immediate medical attention or admission to hospital facility.

You also need to seek emergency medical help if you get:

- severe diarrhoea
- confusion or hallucinations
- seizures (convulsions)
- dark skin changes

These are rare, but serious side effects that require immediate medical treatment.

Very common side effects (occurring in more than 1 in 10 people) are disorders of the digestive tract: nausea, vomiting, diarrhoea or constipation (obstipation), loss of appetite, epigastric pain (pain in the stomach area), heartburn, bloating or abdominal pain.

Other side effects are very rare (affects less than 1 in 10,000 people) or the frequency cannot be estimated:

- change of the blood test results
- tremor (tremors), disorders of the senses
- Visual disorders
- Vertigo
- skin rash and itching, sensitivity of the skin to sunlight or other changes in the skin
- changes in the joints and sinews
- anxiety or depression, sleep disorders

If any of the side effects worsen or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PALIN

Keep out of reach and sight of children.

Store at temperature up to 25 ° c.

Do not use medicine if you notice any sign of damage.

Shelf life is 5 years.

Do not use the medicine after the expiration date stated on the box. The expiration date of the medicine refers to the last day of the month.

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

6. FURTHER INFORMATION

What Palin contains

Each capsule contains 200 mg of Pipemidic acid in the form of trihydrate.

ATC: J01MB04

other substances are:

Contents of capsules:

anhydrous colloidal silicon dioxide, corn starch, magnesium stearate

Coating of capsules:

gelatin, titanium dioxide E171, blue V (E131), black PN (E151), yellow quinolyl (E104), sunset yellow FCF (E110)

Pharmaceutical form and contents of the Pack

Capsules, hard (green cover, light beige layer, content: yellowish and hygroscopic powder).

Hard capsules in blister packages (Alu/PVC foil), box with 20 capsules(2 x 10) which contain 200 mg of Pipemidic acid in the form of trihydrate.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

LEK farmacevtska družba d.d.
Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

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Verovškova 57, Ljubljana, Slovenia