Package leaflet: Information for the user

p-Aminosalicylate sodium 5.52 g
powder for oral solution

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 p-Aminosalicylate sodium is and what it is used for

p-Aminosalicylate sodium 5.52 g powder for oral solution is a second-line medicine for the treatment of tuberculosis. This medicine has bacteriostatic activity against tuberculosis mycobacteria.

In combination with other medicines p-Aminosalicylate sodium is used for the treatment of tuberculosis of various forms and location.

2. What you need to know before you take p-Aminosalicylate sodium

Do not take p-Aminosalicylate sodium:
- if you are allergic to aminosalicylate sodium or any of the other ingredients of this medicine (listed in section 6);
- if you have severe liver failure, inflammation of the liver (hepatitis), liver cirrhosis;
- if you have severe kidney failure;
- if you have severe heart failure;
- if you have gastroduodenal ulcer;
- if you have myxoedema (a chronic disease caused by an underactive thyroid gland);
- if you have amyloidosis (disorder of protein metabolism);
- if you are pregnant or breast-feeding;
- if you have phenylketonuria (disorder of phenylalanine metabolism).

Warnings and precautions
Talk to your doctor before taking p-Aminosalicylate sodium:

– if you have stomach and/or intestinal diseases, liver and/or kidney disorders, or heart failure (in case of severe disorders, this medicine must not be used);
– if you have an underactive thyroid gland. It should be taken into account that prolonged usage of the medicine at high doses may cause a further decrease in thyroid function in tuberculosis patients with impaired thyroid function;
– if you have been advised to restrict your dietary sodium ion intake (as p-Aminosalicylate sodium is not recommended in this case);
– if you are infected with HIV.

When p-Aminosalicylate sodium is used, crystals in the urine, that cause kidney irritation, may develop. Maintaining the urine at neutral or alkaline pH prevents development of crystals in the urine.

In patients with glucose-6-phosphate dehydrogenase deficiency, haemolytic anaemia may develop (anaemia, which is caused by increased break-up of red blood cells).

Blood and urine parameters as well as liver function characteristics should be monitored before starting and periodically during treatment with p-Aminosalicylate sodium.

Children
There is no information that safety of this medicine use is restricted in children of any particular age group. Instructions for use in children, see in section 3.

Other medicines and p-Aminosalicylate sodium
Tell your doctor if you are taking, have recently taken or might take any other medicines.

p-Aminosalicylate sodium therapy delays the development of tuberculosis mycobacteria resistance to isoniazid and streptomycin. Combination with isoniazid causes the risk of haemolytic anaemia.

The efficacy of p-Aminosalicylate sodium decreases when taking in combination with aminobenzoates. When p-Aminosalicylate sodium is taken concomitantly with anticoagulants, the effect of anticoagulants is increased because p-Aminosalicylate sodium also inhibits prothrombin synthesis in the liver.

Probenecid (used to treat gout) inhibits excretion of the drug in the urine. This results in increased p-Aminosalicylate sodium toxicity risk (the dose should be reduced).

p-Aminosalicylate sodium may cause vitamin B12 absorption disorders and avitaminosis. In these cases, parenteral form of vitamin B12 is recommended for administration.

You must not smoke during the treatment.

p-Aminosalicylate sodium with alcohol
You must not consume alcohol during the treatment.

Pregnancy and breast-feeding
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.

This medicine must not be taken during pregnancy and breast-feeding.

Driving and using machines
If there is no inflammation of the brain membranes (meninges), the medicine has no influence on the ability to drive and use machines.

p-Aminosalicylate sodium contains lactose and aspartame (E951)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take p-Aminosalicylate sodium

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

p-Aminosalicylate sodium is used only in combination with other medicines for the treatment of tuberculosis. Concomitant medications and duration of treatment is determined by the phthisiotherapist. All medications should be taken as prescribed by your doctor, regularly and for the indicated period of time.

The medicine should be taken after meals. The content of a sachet should be dissolved by mixing in 100 ml (half a glass) of boiled (cooled to room temperature) water, the prepared solution should be consumed immediately.
The solution containing p-Aminosalicylate sodium is quickly absorbed, and accordingly, drug-induced irritating effect on the stomach mucosa is minimized.

Adults
The dose is 8-12 g (2-3 sachets) daily. The daily dose should be divided into 2-3 single doses.
For cachectic patients (body weight less than 50 kg) and patients with poor drug tolerability, the dose should be reduced to 4-8 g (1-2 sachets) daily. The maximum dose is 12 g daily.

Patients with kidney failure
In patients with kidney failure, the doctor may decrease the dose. Usually, the dose will be 8 g daily divided into 2 single doses.

Patients with liver failure
There are no data indicating the need for dose reduction, however liver function parameters should be monitored during the treatment.

Elderly patients
There is no information regarding p-Aminosalicylate sodium use in elderly patients.

Use in children
In children, the dose is 200-300 mg/kg of body weight daily divided into 2-4 single doses. There is no information that safety of this medicine is restricted in children of any particular age group.

If you take more p-Aminosalicylate sodium than you should
In case of overdose, seek medical attention immediately.
Symptoms: nausea, vomiting, diarrhoea, psychosis may develop.

If you forget to take p-Aminosalicylate sodium
If you forget to take a regular dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking p-Aminosalicylate sodium
Arbitrary discontinuation of treatment may contribute to the development of drug-resistant tuberculosis mycobacteria.
If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Common (affects less than 1 in 10 people):
- gastrointestinal disorders: nausea, vomiting, diarrhoea, abdominal pain. If case adverse effects occur, the doctor will decrease the dose, or will advise you to discontinue the medicine for a short period of time. The adverse effects are less expressed if a regular eating regimen of three meals per day is followed.

Rare (affects less than 1 in 1,000 people):
- decreased leucocyte count;
- haemolytic anaemia (in patients with glucose-6-phosphate dehydrogenase deficiency);
- hypersensitivity reactions (fever, bronchospasm, eosinophilia);
- inflammation of blood vessels;
- jaundice, inflammation of the liver;
- skin rash;
- joint pain;
- crystals in urine that cause kidney irritation;
- thyroid gland problems*.

(*) In subjects also infected with HIV, thyroid gland problems and specifically underactive thyroid or low levels of thyroid hormones are a very common side effect that may affect more than 1 in 10 people.

Not known (the frequency cannot be estimated from the available data):
- decreased appetite, absence or loss of appetite, anorexia;
- upper abdominal pain (epigastric pain, gastric pain), abdominal discomfort, gastric discomfort, heaviness in stomach, abnormal faeces, dyspepsia or exacerbation of its symptoms, heartburn, flatulence and related conditions.

In case such adverse effects occur, the doctor will decrease the dose or will advise you to discontinue the medicine for a short period of time. The adverse effects are less expressed if a regular eating regimen of three meals per day is followed;
- itching;
- weakness including general weakness, asthenia.

Prolonged administration of high doses may cause decrease in thyroid function.

In case fever, aching throat, unusual bleeding or bruising, and rash occur, immediately consult your doctor.

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 State Agency of Medicines, 15 Jersikas Street, Riga, LV 1003. Website: www.zva.gov.lv
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store p-Aminosalicylate sodium

Store in the original package in order to protect from light and moisture. Do not store above 30 °C.

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 package after „EXP". The expiry date refers to the last day of that month.

Do not use if package is damaged.

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 p-Aminosalicylate sodium contains
– The active substance is sodium aminosalicylate dihydrate.
Each sachet contains 5.52 g of sodium aminosalicylate dihydrate, which is equivalent to 4.00 g of aminosalicylic acid.

– The other ingredients are lactose monohydrate, aspartame (E951).

What p-Aminosalicylate sodium looks like and contents of the pack
Powder of almost white to cream colour. Non-uniformity of colour is allowed.

Powder is packed in a sachet of laminated material. Total powder mass is 12.5 g.
25 or 300 sachets of laminated material together with the package leaflet in the cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
JSC "Olainfarm"
Rupnicu Street 5, Olaine, LV-2114, Latvia
Tel.: +371 67013705
Fax: +371 67013777
E-mail: olainfarm@olainfarm.com

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