Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:
1. What p-Aminosalicylate sodium 5.52 g powder is and what it is used for
2. Before you use p-Aminosalicylate sodium 5.52 g powder
3. How to use p-Aminosalicylate sodium 5.52 g powder
4. Possible side effects
5. How to store p-Aminosalicylate sodium 5.52 g powder
6. Further information

1. WHAT P-AMINOSALICYLATE SODIUM 5.52 G POWDER IS AND WHAT IT IS USED FOR

p-Aminosalicylate sodium 5.52 g powder for oral solution is a synthetic second-line agent generally used in combined chemotherapy regiments for the treatment of tuberculosis. p-Aminosalicylate sodium salt has bacteriostatic activity against tuberculosis mycobacteria. In combination with other medicines p-Aminosalicylate sodium salt is used for the treatment of tuberculosis of different forms and localization.

2. BEFORE YOU USE P-AMINOSALICYLATE SODIUM 5.52 G POWDER

Do not use p-Aminosalicylate sodium 5.52 g powder
- if you are allergic (have hypersensitivity) to p-Aminosalicylate sodium salt and/or to any of the excipients
- if you have severe liver insufficiency, hepatitis, cirrhosis of the liver
- if you have severe kidney insufficiency
- if you have severe heart failure
- if you have stomach ulcer and duodenal ulcer
- if you have myxoedema (chronic disease caused by weak activity of thyroid gland)
- if you have amyloidosis (disorders in protein metabolism)
- if you are pregnant or breastfeeding
- if you have phenylketonurea (disorders in phenylalanine metabolism).

Take special care with p-Aminosalicylate sodium in the followed cases
- if you have gastrointestinal diseases, liver and/or kidney activity disorders, cardiac failure, in case of severe disorders, administration is contraindicated;
- it should be taken into account that prolonged usage of the preparation at high doses may cause decrease of thyroid function in tuberculosis patients with hypofunction of thyroid gland;
- when p-Aminosalicylate sodium is used, crystalluria (crystals in the urine) may be developed that cause kidneys irritation. Maintaining the urine at neutral or alkaline pH prevents development of crystals in the urine;
- patients having glucose-6-phosphate dehydrogenase deficiency should use the preparation with caution as haemolytic anaemia may develop;
- patients, who are recommended to decrease the quantity of sodium ion intake, are not recommended to use p-Aminosalicylate sodium;
- monitoring of blood and urine parameters as well as characteristics of liver function is necessary before starting and during p-Aminosalicylate sodium administration.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Taking p-Aminosalicylate sodium in combination with aminobenzoates the efficacy of p-Aminosalicylate sodium is decreased. When p-Aminosalicylate sodium is taken in combination with anticoagulants – the effect of anticoagulants is increased because p-Aminosalicylate sodium causes the depression of prothrombin synthesis in liver.

Probenicid (uricosurics) inhibits the preparation excretion in the urine that can cause increase p-Aminosalicylate sodium toxicity risk. The dose should be decreased.

p-Aminosalicylate sodium salt may cause reduction of vitamin B₁₂ absorption and avitaminosis. In these cases it is recommended to use vitamin B₁₂ medicinal product parenterally.

To use alcohol and to smoke during therapy is prohibited.

Pregnancy and breast-feeding
This medicine is contraindicated during pregnancy and breast-feeding.

Driving and using machines
If you do not have inflammation of the brain membranes (meninges), the medicine does not influence the ability to drive and use the mechanisms.

Important information about some of the excipients of p-Aminosalicylate sodium
Each sachet of powder contains 6.94 g of lactose monohydrate. If the doctor informed you that you have some sugar intolerability, consult the doctor before taking this medicine. Each sachet of powder contains 0.04 g of aspartame. Aspartame is the source of phenylalanine and can be detrimental for patients with phenylketonurea.

3. HOW TO USE P-AMINOSALICYLATE SODIUM
Always use the medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

p-Aminosalicylate sodium is administered in combination with other antituberculous preparations. Simultaneous administration of different antituberculotics and duration of treatment are prescribed by the physician. Take all medicines in the doses as your doctor has instructed you, regularly and during the indicated period of time.
The medicine should be taken after meals. Before administration dissolve the content of a sachet by mixing in 100 ml (half a glass) of boiled (cooled to room temperature) water and use immediately the prepared solution. The solution is quickly absorbed, and accordingly the irritating effect to the stomach mucosa is decreased.

*The adults* are administered in a dose of 8-12 g p-Aminosalicylate sodium (2-3 sachets) a day. The daily dose is divided into 2-3 intakes.
The dose is decreased till 4-8 g per day for cachectic patients (with body weight less than 50 kg) and for those patients who have low tolerability of the preparation.

*Children* are administered in a dose of 200-300 mg/kg of body weight a day divided into 2-4 intakes. There is no information that administration safety of this medicine is restricted to any of children age group.

Maximal dose is 12 g a day.

*Patients with kidney insufficiency* – a doctor may diminish a dose. Usually a dose is 8 g a day, which is divided in 2 intakes.

*Patients with liver insufficiency* - there is no information about necessity to diminish a dose, though, characteristics of liver activity should be monitored during treatment period.

There is no information of p-Aminosalicylate sodium use in *elderly patients* (>65 years old).

**If you have used more p-Aminosalicylate sodium than you should**

*Symptoms:* dizziness, vomiting, diarrhoea, may develop psychosis. In case of overdose, immediately contact a doctor.

**If you forget to take p-Aminosalicylate sodium**

If you forget to take a regular dose, take the next dose immediately when you remember. Do not take a double dose to make up for a forgotten dose.

**If you stop using p-Aminosalicylate sodium**

Arbitrary termination of therapy may contribute to drug-resistant tuberculosis bacteria formation.

If you have any further questions on the use of this medicinal product, ask your doctor.

4. **POSSIBLE SIDE EFFECTS**

Like all others medicines p-Aminosalicylate sodium can cause side effects, although not everybody gets them.

Side effects frequency convention:

- very common – 1 or more often than 1 patient of 10;
- common – less often than 1 of 10, but more often than 1 of 100 patients;
- uncommon - less often than 1 of 100, but more often than 1 of 1000 patients;
- rare - less often than 1 of 1000, but more often than 1 of 10 000 patients;
- very rare - less often than 1 of 10 000 patients, including isolated reports.

Disorders of gastrointestinal tract: nausea, vomiting, diarrhoea, abdominal pain are common. As soon as these adverse effects appear, the dose has to be decreased, or the preparation should be discontinued for a short time. The adverse effects are less expressed if a patient keeps a regular regime of three-time meals.

Rare – reactions of hypersensitivity (fever, urticaria, bronchospasm, eosinophilia), decreased leucocytes quantity, haemolytic anaemia (patients with glucose-6-phosphate dehydrogenase deficiency), jaundice, hepatitis, vasculitis, crystalluria, which cause renal irritation, joint pain. Prolonged administration of high doses may cause decrease of thyroid gland function.
In case of fever, aching throat, unusual bleeding or hemorrhages, and rash immediately consult your doctor.

If side effects, not indicated in the Package Leaflet, were revealed or any of the side effects gets serious, please tell your doctor.

5. HOW TO STORE P-AMINOSALICYLATE SODIUM

Do not store above 25 °C. Protect from light and moisture.
Keep out of the reach and sight of children.
Do not use after the expiry date, which is stated on the package and carton box. The expiry date refers to the last day of that month.
Do not use if package is damaged.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. FURTHER INFORMATION

What p-Aminosalicylate sodium contains
Active substance is aminosalicylic acid sodium salt dihydrate. Each sachet contains 5.52 g of aminosalicylic acid sodium salt dihydrate, which is equivalent to 4.00 g of aminosalicylic acid.
Other components (excipients): lactose monohydrate, aspartame (E951).

What p-Aminosalicylate sodium looks like and contents of the pack
Powder of almost white to cream colour. Colour heterogeneity is acceptable.
Powder is packed into sachet from laminated material. Total powder mass is 12.5 g.
25 sachets and package leaflet in the carton pack or 300 sachets in the carton box.
All package sizes may not be available on the market.

Marketing Authorisation Holder and Manufacturer

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