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.
- 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 PAS-Na 5.52 g POWDER IS AND WHAT IT IS USED FOR

PAS-Na 5.52 g powder for oral solution is a synthetic second-line agent generally used in combined chemotherapy regimens for the treatment of tuberculosis. PAS-sodium salt has bacteriostatic activity against tuberculosis mycobacteria. In combination with other medicines PAS-sodium salt is used for the treatment of tuberculosis

2. BEFORE YOU TAKE PAS-Na 5.52 g POWDER

Do not take PAS-Na 5.52 g powder
- if you are allergic (have hypersensitivity) to PAS-Na 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 or duodenal ulcer
- if you have myxoedema (chronic disease caused by an underactive thyroid gland)
- if you have amyloidosis (disorder of protein metabolism)
- if you are pregnant or breastfeeding
- if you have phenylketonurea (disorder of phenylanine metabolism).

Take special care with PAS-Na in the followed cases
- if you have gastrointestinal diseases, liver and/or kidney disorders, or heart failure (in severe cases of these conditions, administration is contraindicated);
- it should be taken into account that prolonged usage of the preparation at high doses may cause decreased thyroid function in tuberculosis patients with an underactive thyroid gland;
- when PAS-Na is used, crystalluria (crystals in the urine) may develop and cause kidney irritation. Maintaining the urine at neutral or alkaline pH helps prevent 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 have been advised to decrease their sodium intake are not recommended to use PAS-Na ;
- monitoring of blood and urine tests including liver function tests is necessary before starting and during PAS-Na 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.

PAS-Na therapy delays the development of tuberculosis mycobacteria resistance to izoniazid and streptomycin. Combination with izoniazid may increase the risk of haemolytic anaemia.

Taking PAS-Na in combination with aminobenzoates decreases the efficacy of PAS.

When PAS-Na is taken in combination with anticoagulants the effect of anticoagulants is increased because PAS-Na causes decreased prothrombin synthesis in the liver.

Probenicid (uricosurics) inhibits the excretion of the drug in the urine and can increase the risk of PAS toxicity, therefore the dose of PAS-Na should be decreased.

PAS-sodium salt may cause reduction of vitamin B_{12} absorption and vitamin B_{12} deficiency. In these cases it is recommended that vitamin B_{12} be given by injection (parenterally).

You should not use alcohol or smoke during therapy with PAS-Na 5.52 g powder.

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

Driving and using machines
PAS-Na does not influence the ability to drive and use machinery, except in cases of inflammation of the brain membranes (meningitis).

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

3. HOW TO USE PAS-Na

Always use the medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

PAS-Na is administered in combination with other antituberculous preparations. Simultaneous administration of different antituberculotics and duration of treatment are prescribed by the turberculosis specialist. Take all medicines in the doses your doctor has prescribed, regularly and for the indicated period of time.

The medicine should be taken after meals. Before administration dissolve the contents of a sachet by mixing it in 100 ml (half a glass) of boiled (cooled to room temperature) water and

use the prepared solution immediately. The solution is quickly absorbed, and stomach irritation is minimized.

Adults require 8-12 g of PAS-Na (2-3 sachets) a day, which is divided into 2-3 equal doses. This dose is decreased to 4-8 g per day for patients with a body weight of less than 50 kg, and for those patients who have difficulty tolerating higher doses of the preparation.

Children should take a dose of 200-300 mg per kg of body weight, per day, divided into 2-4 doses.

The maximum dose is 12 g per day.

Patients with kidney insufficiency – the doctor may decrease the dose. Usually the dose will be 8 g per day, which is divided into 2 doses.

Patients with liver insufficiency - there are no data to indicate the necessity to decrease the dose, however liver function tests should be monitored during the treatment period.

There is no information regarding PAS-Na use in *elderly patients* (>65 years old).

If you have used more PAS-Na than you should
Symptoms: dizziness, vomiting, diarrhea, possible development of psychosis. In case of overdose, immediately contact a doctor.

If you forget to take PAS-Na
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 PAS-Na
Stopping therapy unnecessarily may contribute to the development of drug-resistant tuberculosis bacteria.

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, PAS-Na can cause side effects, although not everybody gets them.

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

Common: Disorders of the gastrointestinal tract: nausea, vomiting, diarrhea, and abdominal pain. If these adverse effects appear, the dose should be immediately decreased, or, if necessary, the preparation may be discontinued for a short time. The adverse effects may be minimized if the patient follows a regular regimen of three meals per day.

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

If you experience side effects not mentioned in the Package Leaflet, or any of the side effects becomes serious, please contact your doctor.

5. HOW TO STORE PAS-Na

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 PAS-Na contains

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

What PAS-Na looks like and contents of the pack

Powder of almost white to cream colour. Irregularities in the colour of the powder are acceptable.
Powder is packed in a sachet of 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.

Supplier and Manufacturer

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