PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

p-aminosalicylate sodium (PAS sodium) delayed-release granules (60% w/w)*
p-aminosalicylate sodium

Read all of this leaflet carefully before you or your child 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, health care provider or pharmacist.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or as those of your child.
- If you or your child 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 P-AMINOSALICYLATE SODIUM DELAYED-RELEASE GRANULES (60% w/w) IS AND WHAT IT IS USED FOR

P-aminosalicylate sodium delayed-release granules (60% w/w) is indicated for the treatment of drug-resistant tuberculosis in adults and children.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE P-AMINOSALICYLATE SODIUM DELAYED-RELEASE GRANULES (60% w/w) GRANULES

Do not take p-aminosalicylate sodium delayed-release granules (60% w/w):

- if you are hypersensitive (allergic) to p-aminosalicylate sodium (PAS), or any of the other ingredients of p-aminosalicylate sodium delayed-release granules (60% w/w) (See section 6, What p-aminosalicylate sodium delayed-release granules (60% w/w) contains.)
- if you have severe kidney disease

Warnings and precautions

P-aminosalicylate sodium delayed-release granules (60% w/w) may cause skin rash, including severe cases resulting in death**.**

If you are on a sodium restricted diet for any reason, such as kidney problems, heart failure or high blood pressure, it is important that you inform your doctor, since p-aminosalicylate sodium delayed-release granules (60% w/w) may then be unsuitable for you. Treatment of children under age 1 also needs to be carefully considered by your doctor, due to the sodium in the product.

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

It is important that your doctor or health care provider knows about all your symptoms, even when you think they are not related to tuberculosis infection.

Other medicines and p-aminosalicylate sodium delayed-release granules (60% w/w)

It is important that you tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of p-aminosalicylate sodium delayed-release granules (60% w/w), or p-aminosalicylate sodium delayed-release granules (60% w/w) may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

P-aminosalicylate sodium delayed-release granules (60% w/w) may affect isoniazid (INH), another medicine used to treat tuberculosis. Persons taking p-aminosalicylate sodium delayed-release granules (60% w/w) may also absorb vitamin B_{12} poorly. It may be necessary to take additional vitamin B_{12} if you are taking this product for more than one month. Your doctor will advise you about this.

P-aminosalicylate sodium delayed-release granules (60% w/w) with food and drink

P-aminosalicylate sodium delayed-release granules (60% w/w) may be taken without regard to food.

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of the tuberculosis therapy for you and your child.

P-aminosalicylate sodium is present in breast milk. Breast-feeding infants need to be monitored for side effects.

Driving and using machines

It is not known if p-aminosalicylate sodium delayed-release granules (60% w/w) can impair your ability to drive and to use machines.

P-aminosalicylate sodium delayed-release granules (60% w/w) contains hydrogenated castor oil and sodium metabisulphite

This medicinal product contains hydrogenated castor oil, which may cause stomach upset and diarrhoea. This medicinal product also contains sodium metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE P-AMINOSALICYLATE SODIUM DELAYED-RELEASE GRANULES (60% w/w)

P-aminosalicylate sodium delayed-release granules (60% w/w) should always be taken exactly as described by the doctor or health care provider. You should check with your doctor, health care provider or pharmacist if you are not sure.

In **adults** the dose of p-aminosalicylate sodium delayed-release granules (60% w/w) is 9.2 grams twice daily.

In **children** the dose of p-aminosalicylate sodium delayed-release granules (60% w/w) is 345 milligrams per kilogram per day, divided into two equal doses. The total dose in children should not be above the dose for adults. A 2 grams measuring spoon is provided.

P-aminosalicylate sodium delayed-release granules (60% w/w) should be given with caution to children under age 1 year due to the sodium content. Your doctor will advise on this.

Your doctor will decide on the duration of treatment that is suitable for you.

If you take more p-aminosalicylate sodium delayed-release granules (60% w/w) than you should

The effect of taking too much p-aminosalicylate sodium delayed-release granules (60% w/w) is not known. If you take too many doses, immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take p-aminosalicylate sodium delayed-release granules (60% w/w)

If you miss or forget to take a dose, the missed dose should be taken as soon as possible, unless the next regular dose is scheduled within 6 hours.
Skip the missed dose if it is almost time for the next regular dose.
You should not take a double dose to make up for forgotten individual doses.

If you stop taking p-aminosalicylate sodium delayed-release granules (60% w/w)

You should keep taking the medicine for as long as your doctor has ordered, even if you are feeling better. If you stop the medicine too soon, the infection may not be completely cured. You should not stop treatment unless your doctor or health care provider says so.

If you have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, p-aminosalicylate sodium delayed-release granules (60% w/w) can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to be sure about unwanted effects caused by p-aminosalicylate sodium delayed release granules (60% w/w), and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform the doctor or health care provider of any change in your health.

The following side effects have been reported in patients treated with p-aminosalicylate sodium delayed-release granules (60% w/w):

Common (greater than 1 in every 100 patients treated) side effects include nausea, vomiting, and abdominal pain.

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100) include inflammation of the liver (hepatitis), and jaundice (skin and eyes turning yellow). If you notice these you should inform the doctor or health care provider immediately.

Unknown: The following side effects have been reported in patients treated with p-aminosalicylate sodium delayed-release granules (60% w/w). However, frequency estimates for these effects are not available:

-thyroid problems, including swelling of the thyroid gland in the front of the neck
-allergic reactions, including severe skin reactions with fever, blisters and involvement of the mucous membranes which may be life-threatening
- vision problems caused by the optic nerve, brain inflammation
- inflammation of the lungs (pneumonia)
-diarrhea
- low blood sugar
- low blood cell counts, possibly leading to fatigue, weakness and shortness of breath, or increased susceptibility to infections
-low potassium
-blood clotting problems
- inflammation of blood vessels

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. HOW TO STORE P-AMINOSALICYLATE SODIUM DELAYED-RELEASE GRANULES (60% w/w)

Do not Store above 25°C. Store in dry place, protected from light.
Keep this medicine out of the sight and reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What p-aminosalicylate sodium delayed-release granules (60% w/w) contains

The active ingredient is p-aminosalicylate sodium.
The other ingredients are:
Sodium metabisulphite, microcrystalline cellulose, crospovidone, hydrogenated vegetable oil, hydrogenated castor oil, butylated hydroxyl toluene, ethyl cellulose, stearic acid, dibutyl phthalate, methacrylic acid-methyl methacrylate copolymer, purified talc, titanium dioxide, colour iron oxide red and colour quinoline yellow supra (see section 2, “P-aminosalicylate sodium delayed-release granules (60% w/w) contains hydrogenated castor oil and sodium metabisulphite”).

What p-aminosalicylate sodium delayed-release granules (60% w/w) looks like and contents of the pack

Brick red coloured enteric coated granules

100 g granules packed in a triple laminated Alu/PET/Alu/LLDPE sachet. The sachet is further packed in a HDPE bottle along with a blue colour "4.6g measuring spoon (0.5g, 1.0g, 1.5g, 2.0g, 2.5g, 3.0g, 3.5g, 4.0g and 4.6g marking) & tagger sealed" -Overflow Capacity–610 ml–650 ml.

100 g granules packed in LDPE bag and placed in a triple laminated Alu/PET/Alu/LLDPE sachet. The sachet is further packed in a HDPE bottle along with a blue colour "4.6 g measuring spoon (0.5g, 1.0g, 1.5g, 2.0g, 2.5g, 3.0g, 3.5g, 4.0g and 4.6g marking) and tagger sealed" – Overflow Capacity – 610 ml – 650 ml.

9.2g granules packed in a triple laminated (Alu/PET/Alu/LLDPE) sachet, such 30 sachets are contained in a box with the leaflet. The sachets are packed along with a blue colour "4.6g measuring spoon (0.5g, 1.0g, 1.5g, 2.0g, 2.5g, 3.0g, 3.5g, 4.0g and 4.6g marking).

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For any information about this medicinal product, please contact the local representative of the supplier:

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Detailed information on this medicine is available on the World Health Organization (WHO) web site: https://extranet.who.int/prequal/