Scheduling Status:
S4

GRANUPAS
5,52 g powder for oral solution
p-aminosalicylate sodium

Contains sugar (lactose monohydrate) 6,94 g per sachet
Contains sweetener (aspartame) 0,04 g per sachet
Contains sodium 0,6 g per sachet

Read all of this leaflet carefully before you start taking GRANUPAS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- GRANUPAS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GRANUPAS is and what it is used for

GRANUPAS is used to treat resistant tuberculosis (TB) in combination with other medicines. It is used in patients with Multi-drug Resistant TB (MDR-TB) or in situations in which therapy with isoniazid and rifampicin is not possible due to a combination of resistance and/or intolerance.

2. What you need to know before you take GRANUPAS

Do not take GRANUPAS:

- If you are hypersensitive (allergic) to p-aminosalicylate sodium, other salicylates, or any of the other ingredients of GRANUPAS (listed in section 6).
- If you have moderate or severe kidney insufficiency.

- If you have severe liver 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 have phenylketonuria.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with GRANUPAS:

- If you have a kidney activity disorder.
- If you have liver function disorders. Patients with liver disease may not tolerate GRANUPAS as well as normal patients.
- If you have heart failure.
- If you have a glucose-6-phosphate dehydrogenase deficiency.
- If you have phenylketonuria.
- If you are lactose intolerant.
- If you have a stomach ulcer.
- If you are hypersensitive to any other salicylate, including methylsalicylate (wintergreen oil) and medicines called sulphonamides.
- If you have any thyroid problems.
- If you have been advised to restrict your daily salt (sodium) intake.
- If you suffer from certain nutritional problems, such as Vitamin B_{12} deficiency, iron deficiency or malabsorption syndrome. GRANUPAS may aggravate these conditions. You may need to take vitamin B_{12} supplements.

Other medicines and GRANUPAS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines. Co-administration with GRANUPAS may increase the risk of side effects or may cause the medicines to be less effective:

- Isoniazid and ethionamide (antibiotics used to treat tuberculosis)
- Probenecid or sulfinpyrazone (used to treat gout)
- Aminobenzoate (used to treat muscle or skin conditions)
- Anticoagulants (blood thinners)
- Rifampicin (antibiotic). GRANUPAS and rifampin should be taken at least 6 hours apart.
- Digoxin (used to treat heart failure or irregular heartbeat)

Vitamin B_{12}:

GRANUPAS may impair the absorption of vitamin B_{12} from the gastrointestinal tract. You may need to take Vitamin B_{12} supplements while being treated with GRANUPAS.

Laboratory tests:

GRANUPAS has been reported to interfere technically with certain laboratory tests. Inform your doctor or healthcare provider that you are taking GRANUPAS when you are scheduled to have your blood or urine tested.

GRANUPAS with food

Take GRANUPAS after meals to reduce stomach irritation.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking GRANUPAS.

You must not take GRANUPAS if you are pregnant.

The active ingredient in GRANUPAS is excreted in breast milk. You should not breastfeed your baby if you are taking GRANUPAS.

Driving and using machines

Do not drive or use machinery before you know how GRANUPAS affects you.

It is not always possible to predict to what extent GRANUPAS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GRANUPAS affects them.

GRANUPAS contains sodium, aspartame and lactose

GRANUPAS contains sodium. The maximum recommended daily dose of GRANUPAS contains 600 mg sodium (found in table salt). This is equivalent to 30 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need GRANUPAS on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

GRANUPAS contains the sweetener aspartame 0,04 g per sachet. Aspartame is a source of phenylalanine. It will be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

GRANUPAS contains 6,94 g lactose monohydrate per sachet. This should be taken into account in patients with diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GRANUPAS.

3. How to take GRANUPAS

Do not share medicines prescribed for you with any other person.

Always take GRANUPAS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with GRANUPAS will last. Do not stop treatment early because your condition may worsen, and you may become resistant to this medicine. If you have the impression that the effect of GRANUPAS is too strong or too weak, tell your doctor or pharmacist.

GRANUPAS is used in combination with other medicines for the treatment of tuberculosis.

The usual dose for adults is:

- Two sachets (8 g) to 3 sachets (12 g), divided into 2 or 3 single doses.

If you have a body weight of less than 50 kg or you experience difficulty tolerating the medicine, your doctor may decrease the dose to:

- One (4 g) or two (8 g) sachets a day.

The usual dose for children is:

- The dosage should be adapted to the patient's weight: 200 – 300 mg/kg/day, divided into 2 to 4 single doses.

The maximum daily dose is 12 g (3 sachets).

Instructions on taking GRANUPAS

You should take GRANUPAS after meals to lower the irritating effect on your stomach. Dissolve the content of the sachet in 100 ml of cooled, boiled water and drink it immediately.

If you take more GRANUPAS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact your nearest hospital or poison centre.

If you forget to take GRANUPAS

If you miss a dose of GRANUPAS, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with GRANUPAS is stopped

Do not stop treatment early because your condition may worsen, and you may become resistant to this medicine.

4. Possible side effects

GRANUPAS can have side effects.

Not all side effects reported for GRANUPAS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GRANUPAS, please consult your healthcare provider for advice.

If any of the following happens, stop taking GRANUPAS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash, hives, or itching
- fainting
- dark urine, yellowing of the skin and eyes called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to GRANUPAS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Diarrhoea, nausea, stomach pain, vomiting, loss of appetite
- Skin redness or rash

Less frequent side effects

- Blood deficiencies, Vitamin B_{12} deficiency:

  - fatigue, fainting, weakness, drowsiness, dizziness, pins and needles feeling in hands and feet, red sore tongue, mouth ulcers
  - confusion, mental or mood changes
  - headache
  - fast or irregular heartbeat, tremors
  - pale skin

- Infectious disease with symptoms such as fever, malaise, sore throat, swollen glands
- Decrease in thyroid gland function
- Changes in cholesterol levels
- Serious mental illness with loss of contact with reality
- Inflammation of the blood vessels
- Bloating, abnormally foul-smelling or loose stools, severe right-sided stomach pain (steatorrhoea)
- Joint pain
- Crystals in urine that cause kidney irritation

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GRANUPAS.

5. How to store GRANUPAS

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light and moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GRANUPAS contains

The active ingredient is p-aminosalicylate sodium dihydrate. Each sachet contains 5,52 g of p-aminosalicylate sodium dihydrate which is equivalent to 4 g of p-aminosalicylic acid.

The other ingredients are aspartame and lactose monohydrate.

What GRANUPAS looks like and contents of pack

Almost white to cream colour powder. Colour heterogeneity is acceptable. The powder is packed into white, opaque sachets of laminated material. Each sachet contains 12,5 g powder. The sachets are packed into an outer cardboard carton containing 30 sachets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Full Professional Information Leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.

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