

Package leaflet: Information for the patient

GRANUPAS 4 g gastro-resistant granules para-aminosalicylic acid

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 GRANUPAS is and what it is used for
2. What you need to know before you take GRANUPAS
3. How to take GRANUPAS
4. Possible side effects
5. How to store GRANUPAS
6. Contents of the pack and other information

1. What GRANUPAS is and what it is used for

GRANUPAS contains para-aminosalicylic acid which is used in adults and children aged 28 days and older to treat resistant tuberculosis in combination with other medicines, in cases of resistance or intolerability with other treatments.

2. What you need to know before you take GRANUPAS

Do not take GRANUPAS

- if you are allergic to para-aminosalicylic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney disease.

If you are not sure, talk to your doctor or pharmacist before taking GRANUPAS.

Warnings and precautions

Talk to your doctor or pharmacist before taking GRANUPAS

- if you have liver problems or mild or moderate kidney disease
- if you have a stomach ulcer
- if you are infected with HIV

Children

Use of GRANUPAS is not recommended in newborn babies (under 28 days of age).

Other medicines and GRANUPAS

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking any of the following:

- Antituberculosis medicines or ethionamide (other treatments against tuberculosis)
- Vitamin B12
- Digoxin (for heart disease)

- Diphenylhydramine (for allergic reactions)

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.

GRANUPAS is not recommended during pregnancy and should only be used if advised by your physician.

Do not breastfeed whilst taking GRANUPAS. This is because small amounts of the medicine can pass into mother's milk.

Driving and using machines

GRANUPAS is unlikely to affect your ability to drive any vehicle and use machines.

In case it does, please report it to your doctor or pharmacist.

3. How to take GRANUPAS

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

Adults

The recommended dose for adults is 1 sachet three times a day, with a schedule of 1 sachet every 8 hours. Your physician may need to start with a lower dose to prevent possible side effects.

Do not take more than 3 sachets per day. Treatment is usually given for two years (24 months).

- Add the contents of the sachet to a drink of tomato or orange juice.
- Drink straight away
- If some granules are left in the glass, add some more juice and drink straight away.

Use in infants, children and adolescents

The dose in infants, children and adolescents will be calculated by your doctor based on the patient's body weight. The recommended total dose per day is 150 mg for each kg of body weight. This daily amount is divided into two doses spread out through the day.

- Use the spoon that comes with the medicine to measure the dose.
- To measure the dose:
 - Lines on the spoon indicate the amount (in milligrams of para-aminosalicylic acid). Take the correct amount as prescribed by your doctor.
 - Put granules directly into the spoon.
 - Tap the spoon once on a table to give a horizontal level of granules and continue filling if necessary.
- Sprinkle the granules onto apple sauce or yogurt.
- Make your child eat it straight away.

Taking this medicine

- Do not crush or chew the granules. Swallow the granules whole. It is important that you do not dissolve, crush or chew the granules as they may not absorb properly and may cause stomach ache or bleeding.
- Do not use the sachet if it is swollen or the granules have lost their light brown colour.
- You may notice granules appearing in your stools; this is normal.

If you take more GRANUPAS than you should

Speak to a doctor or pharmacist.

If you forget to take a dose of GRANUPAS

Do not take a double dose to make up for a forgotten dose. Wait until the next dose is due, then take your normal dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

During the first 3 months of your treatment with GRANUPAS, you must be attentive to any sign of allergic reaction (for example skin eruption, itchy red spots on the skin, itching, rash, watery or itchy eyes or stuffy nose) or hepatitis (for example fever, fatigue, dark urine, pale stool, abdominal pain, yellow skin and eyes). If you experience any of these symptoms, you must contact to your doctor immediately.

Common side effects (may affect more than 1 in 100 people):

- giddiness,
- stomach ache (abdominal pain),
- vomiting,
- nausea,
- bloating,
- diarrhoea,
- soft stools,
- skin redness or rash,
- disturbance of gait and equilibrium.

Uncommon side effects (may affect more than 1 in 1,000 people):

- loss of appetite (anorexia).

Rare side effects (may affect more than 1 in 10,000 people):

- thyroid gland problems*,
- reduced ability to absorb nutrients from food ulcer,
- bleeding in the gut,
- yellowing of skin or eyes (jaundice),
- metallic taste,
- itchy rash.

(*) 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. Regular monitoring of the thyroid function is indicated for all people living with HIV.

Very rare side effects (may affect less than 1 in 10,000 people):

- reduction in blood platelets,
- red spots on the skin,
- reduction in numbers of white blood cells,
- reduction in numbers of red blood cells,
- reduction of the ability of red blood cells to release oxygen
- low levels of blood sugar,
- tendon pain,
- headache,

- visual abnormalities,
- nerve damage in the hands and feet,
- dizziness,
- crystals in urine.
- prolonged bleeding time,
- destruction of liver cells
- elevated liver enzymes,
- weight loss.

Not known side effects (frequency cannot be estimated from the available data):

- Hepatitis.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GRANUPAS

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 carton and sachet after EXP. The expiry date refers to the last day of the month.

Do not store above 25°C. The sachets can be stored below 25°C up to 24 hours after opening.

Do not use this medicine if you notice the sachets are swollen or if the granules are dark brown or purple.

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 GRANUPAS contains

The active substance is para-aminosalicylic acid.

Each sachet of gastro-resistant granules contains 4 g of para-aminosalicylic acid.

The other ingredients are silica, colloidal hydrated, dibutyl sebacate, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent, hypromellose, cellulose, microcrystalline, talc.

What GRANUPAS looks like and contents of the pack

This medicine is presented as light brown gastro-resistant granules in sachets.

Each box contains 30 sachets. A calibrated measuring spoon is provided.

Marketing Authorisation Holder

Eurocept International BV

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The Netherlands

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

There are also links to other websites about rare diseases and treatments.