PACKAGE LEAFLET: INFORMATION FOR THE USER
Pyrazinamide Atb 500 mg tablets
pyrazinamide

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. Do not pass it on to others. It may do 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What pyrazinamide Atb is and what it is used for

Pyrazinamide Atb is an antibiotic used in combination with other drugs for tuberculosis treatment:
- Treatment of new pulmonary tuberculosis cases, concurrently with other standard antibiotics (rifampicin, isoniazid and ethambutol), during the first two months of therapy.
- Treatment of pulmonary and extra-pulmonary tuberculosis caused by bacilli resistant to isoniazid and/or rifampicin, in association with other recommended antibiotics.

2. What you need to know before you take Pyrazinamide Atb

Do not take Pyrazinamide Atb if:
- You are allergic (hypersensitive) to pyrazinamide or any of the other ingredients of the medicine (see section 6);
- You have hepatic failure;
- You have hyperuricemia diagnosticated as a result of laboratory analysis;
- You have renal failure. Nevertheless, your doctor may prescribed Pyrazinamide Atb when the treatment is absolutely necessary
- You have porphyria;
- Pregnancy.

Warnings and precautions
Talk to your doctor and pharmacist before taking Pyrazinamide Atb.
Take special care with Pyrazinamide Atb:
- If you have a liver disease. Before starting the treatment with pyrazinamide your doctor will recommend a testing of hepatic function (transaminase, alkaline phosphatase, and total bilirubin), renal function and uraemia (in order to avoid hepatic or renal failure and hyperuricemia). In case of hepatic function disorder, and/or in the presence of hepatic risk factors (such as alcoholism or a history of hepatitis), pyrazinamide should be used only if absolutely necessary (e.g. in case of multiresistant tuberculosis), with caution and under strict medical supervision. Hepatic function monitoring should include: transaminase determination every 8 days during of those 2 months of pyrazinamide treatment,

and strict monitoring of the hepatic intolerance clinical symptoms (see Possible side-effects). The treatment should be discontinued in case of very high transaminase values.
An adequate treatment should be initiated in case of high values of uric acid.

Moderate arthralgia is usually sensitive to symptomatic treatment. If arthralgia persists and changes of its characteristics, your doctor may decide an immediate discontinuation of treatment.
If you have renal failure, you will take pyrazinamide only it is absolutely necessary. However, your doctor will recommend a complete set of analysis monthly in order to investigate renal function.
Caution should be manifested in patients with a history of diabetes, because the glycemia may be difficult to control during pyrazinamide therapy.
Prolonged exposure to sunlight should be avoided because pyrazinamide may cause an increase of tegument sensitivity following exposure to UV radiations.

Other medicines and Pyrazinamide Atb
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you buy without a prescription.
The concurrent use of pyrazinamide, rifampicin and isoniazid should be done under clinical and biological supervision, because of their additive hepatotoxic effects and the potential occurrence of severe adverse reactions.
Pyrazinamide may cause false test results with urine ketone determinations, such as the test method using sodium nitroprusside, inducing a coffee-tinted urine colour.
Pyrazinamide may decrease the efficacy of anti-gout medicines (e.g. Allopurinol, Colchicine, Probenecid, Sulfinpyrazone) and Cyclosporine administered concurrently.

Pyrazinamide Atb with food and drink
Ethanol consumption increases the risk of hepatic disorders during the treatment with Pyrazinamide Atb.
Pregnancy, breast-feeding and fertility
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.
Do not take Pyrazinamide Atb if you are pregnant or think you are pregnant.
Pyrazinamide is excreted in the human breast milk in small amounts and that is way your doctor should evaluate the possibility of initiating pyrazinamide therapy.

Driving and using machines
Pyrazinamide Atb has no influence on the capacity to drive or use machines.

3. How to take Pyrazinamide Atb
Always take Pyrazinamide Atb exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Tuberculosis treatment is under a national programe called *Plan for prevention and management of TB.*Pyrazinamide Atb should be used only in combination with other drugs for the treatment of tuberculosis to avoid the quick installation of the resistance.
The recommended dose is:
Adults: 3 – 4 tablets of 500 mg daily, in a single dose.
Children: 20 mg per kg of bodyweight per day, in a single dose, if no other adequate alternatives are available.

If you take more Pyrazinamide Atb than you should
Hepatic, neurological and respiratory disorders may occur if you take more **Pyrazinamide Atb** than you should.
If such symptoms occur, tell your doctor or go to a hospital emergency department straight away.

If you forget to take Pyrazinamide Atb
If you forgot a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten tablets.

If you stop taking Pyrazinamide Atb
Do not discontinue the treatment with Pyrazinamide Atb unless your doctor will recommend this.
If you have any further questions, ask your doctor or your pharmacist.

4. Possible side effects

Like all medicines, Pyrazinamide Atb can cause side effects, although not everybody gets them.

Hepatobiliary disorders
Hepatic function disorder may occur frequently and apparently depends on the dosage and the duration of treatment. It may take place anytime during pyrazinamide therapy. If losses of appetite, nausea, vomiting, abdominal pains, weakness, fever, mild jaundice occur, the hepatic functions determination should be performed. Rarely, severe cases of toxic hepatitis have been reported, when pyrazinamide was use concomitantly with other hepatotoxic medicines, particularly isoniazid.
Blood and lymphatic system disorders
Very rare: anaemia, low number of thrombocytes or porphyria.
Nervous system disorders
Occasionally: headaches, dizziness, nervousness, insomnia.
High level of uric acid
Very common: joint pains (affect 1% of the patients treated), myalgia and gout episodes.
Renal and urinary disorders
Hyperchromic urine, dysuria and interstitial nephritis have been reported.
Other side effects
Diabetic patients may experience difficulties in normalising their glycaemia because pyrazinamide decreases their glycaemia.
Allergic reactions (rash) and photosensitivity phenomena.

The frequency of adverse reactions are ranked using the following convention:

Very common	≥ 1/10
Common	≥1/100, < 1/10
Uncommon	>1/1,000, <1/100
Rare	>1/10,000, <1/1,000
Very rare <1/10,000	<1/10,000
Not known	Cannot be estimated from the available data

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 any side effects directly to the national reporting system via the internet at Romanian Agency for Medicines and Medical Devices website, http://www.anm.ro. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pyrazinamide Atb

Keep out of the sight and reach of children.
Store below 25 °C, in the original package.

Do not use this medicine after the expiry date that is stated on the package (EXP). The expiry date refers to the last day of that month.
Do not use this medicine if you notice visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pyrazinamide Atb contains
- Active substance is pyrazinamide. Each tablet contains 500 mg of pyrazinamide.
- Other ingredients: microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate.

What Pyrazinamide Atb looks like and contents of the pack
The tablets are yellowish-white, round, flat, marked on one side with “PZ”.

Outer carton containing 2 or 150 PVC/Al blisters of 10 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Antibiotice S.A.
1 Valea Lupului, 707410 Iasi, Romania, EU

If you have any questions about this medicine please contact the local representatives of the Marketing Authorisation Holder:

Antibiotice S.A.
1 Valea Lupului, 707410 Iasi, Romania, EU

This leaflet was last revised in August 2013.