



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FORTE 250 & 500 TABLETS

Azithromycin 250mg & 500mg

your doctor.

Forste 250 & 500 are partially passed through the mother's milk, therefore they should not be used if you are breastfeeding.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

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1. WHAT FORSTE 250 & 500 ARE AND WHAT THEY ARE USED FOR Forste 250 & 500 respectively belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by micro-organisms like bacteria. Forste 250 & 500 are used for the treatment of certain infections caused by bacteria that are sensitive to Azithromycin, such as:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat [pharyngitis] and sinusitis).
- ear infections.
- skin and soft tissue infections.
- infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by Chlamydia trachomatis (bacteria).

2. BEFORE YOU TAKE FORSTE 250 & 500

Do not take Forste 250 & 500

- if you are **allergic** (hypersensitive) to Azithromycin or any of the other ingredients of Forste 250 & 500 dihydrate, erythromycin or any macrolide or ketolide antibiotic.

Take special care with Forste 250 & 500

Talk with your doctor or pharmacist before taking Forste 250 & 500 if:

- you have severe liver or kidney problems.
- you have severe heart problems or problems with your heartbeat such as long QT syndrome (shown on an electro-cardiogram or ECG machine).
- your blood levels of potassium or magnesium are too low.
- you develop signs of another infection.
- you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with Forste 250 & 500 (see section "Taking other medicines").
- you have a certain type of muscle weakness called myasthenia gravis.
- you have nervous (neurological) or mental (psychiatric) problems.

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- antacids - used for heartburn and indigestion. Forste 250 & 500 should be taken at least 1 hour before or 2 hours after the antacid.
- ergotamine - (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain).
- cholesterol lowering medicines (statins).
- warfarin or similar medicines - used to thin the blood. Forste 250 & 500 can thin the blood even more.
- cisapride - (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine).
- terfenadine - (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine).
- zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with Forste 250 & 500 may mean that you get more of the side effects listed in this leaflet.
- rifabutin - used to treat tuberculosis (TB).
- quinidine - used to treat heart rhythm problems
- cyclosporin - used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose.

Tell your doctor or pharmacist if you are taking any of the following medicines. Forste 250 & 500 can make the effects of these other medicines stronger. Your doctor may change your dose:

- theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD)

Taking Forste 250 & 500 with food and drink

This medicine can be taken with or without food.

Pregnancy and breast-feeding

Ask your health care provider for advice before taking any medicine. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. There is insufficient information available about the use of Forste 250 & 500 during pregnancy. Therefore, you should not use Forste 250 & 500 during pregnancy, unless explicitly advised by

Driving and using machines

There are no data available about the influence of Forste 250 & 500 on the ability to drive or operate machines. However, Forste 250 & 500 may cause dizziness and seizures, so make sure you are not affected before driving or operating machinery.

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

3. HOW TO TAKE FORSTE 250 & 500

Always take Forste 250 & 500 exactly as your health care provider has told you. The usual dose is:

For adults and young people with a body weight of 45 kg or over 500 mg once daily for three days with a total dose of 1500 mg. Alternatively your doctor may decide to prescribe the total dose of 1500 mg over a period of 5 days, with 500 mg the first day and 250 mg on days 2 to 5.

For infections of the neck of the womb and urethra caused by Chlamydia trachomatis One dose of 1000 mg, to be taken one time.

Children and adolescents under 45 kg body weight

The tablets are not recommended. Young people with a body weight of less than 45 kg should use other forms of this medicine.

Patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

For the elderly

For elderly, the same dosage as for adults applies. The tablet can be divided into equal doses.

Method of administration

The tablets should be taken with ½ glass of water. The tablets can be taken with or without food.

If you take more Forste 250 & 500 than you should

If you have taken too much Forste 250 or Forste 500, contact your doctor, pharmacist or go to your nearest hospital at once.

Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdosage admission into hospital may be necessary.

If you forget to take Forste 250 & 500

If you forget to take Forste 250 or Forste 500, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later. Do not take a double dose to make up for a forgotten dose.

If you stop taking Forste 250 & 500

Never stop the treatment with Forste 250 or Forste 500 on your own, but first discuss this with your doctor. If the prescribed treatment is not completely finished, the infection may come back again.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Forste 250 & 500 can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

- Sudden difficulty in breathing, speaking, and swallowing.
- Swelling of the lips, tongue, face, and neck.
- Extreme dizziness or collapse.
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth, or genital organs.
- If you experience any of the following side effects, contact your doctor as soon as possible.
- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can rarely happen after taking antibiotics.
- Yellowing of the skin or whites of the eyes caused by liver problems.
- Inflammation of the pancreas, which causes severe pain in the abdomen and back.
- Increased or reduced urine output, or traces of blood in your urine.
- Skin rash caused by sensitivity to sunlight.
- Unusual bruising or bleeding
- Irregular heartbeat.

These are all serious side effects. You may need urgent medical attention. Serious side effects are uncommon (may affect up to 1 in 100 people) or the frequency cannot be estimated from the available data. Other side effects include:

FOR THE USER FORSTE 250 & 500 TABLETS

Very common (may affect more than 1 in 10 people). • diarrhoea

Azithromycin 250mg & 500mg

Common (may affect up to 1 in 10 people) • headache



- feeling angry, aggressive.
- anxiety.
- confusion.
- hallucination.
- fainting (syncope).

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- being sick (vomiting), stomach pain or cramps, loss of appetite
- change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.

Uncommon (may affect up to 1 in 100 people)

- thrush (candidiasis) - a fungal infection
- fungal infection
- bacterial infection
- inflammation of the throat (pharyngitis)
- breathlessness, chest pain, wheeze and cough (respiratory disorder)
- inflammation of the mucous membrane inside the nose (rhinitis)
- stomach flu (gastroenteritis)
- inflammation inside your vagina (vaginitis)
- pneumonia
- changes in the number of white blood cells
- angioedema
- hypersensitivity
- lack of appetite (anorexia)
- nervousness
- feeling drowsy (somnolence)
- changes in your sense of taste
- sensation of pins and needles or numbness (paraesthesia)
- visual impairment
- having difficulty sleeping (insomnia)
- ear disorder
- dizziness
- spinning sensation (vertigo)
- palpitations
- hot flushes
- shortness of breath
- nosebleed
- inflammation of the lining of the stomach (gastritis)
- constipation
- loose wind (flatulence)
- difficulty swallowing
- swollen abdomen
- dry mouth
- belching
- mouth ulcer
- increased salivary flow
- skin rash
- itching
- inflammation of the skin (dermatitis)
- dry skin
- increased sweating
- pain, swelling and reduced motion in your joints (osteoarthritis)
- muscle pain
- chest pain
- face swelling
- urticaria
- testicular disorder
- spotting
- pain in the upper back (renal pain)
- painful or difficult urination
- increase in blood urea levels
- back pain
- neck pain
- fever
- pain
- swelling of extremities (peripheral edema)
- swelling (edema)
- general feeling of being unwell (malaise)
- fatigue
- weakness (asthenia)
- change in liver enzyme levels and blood levels.
- post procedural complication.

Rare (may affect up to 1 in 1,000 people)

- feeling agitated
- abnormal hepatic function, yellowing of the skin and whites of the eyes, dark urine, pale stool. • allergic skin reactions such as being sensitive to sunlight.
- skin eruption that is characterised
- By the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid).

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

- gut (colon) infection (pseudomembranous colitis)
- reduced number of red blood cells due to destruction (haemolytic anaemia); reduction in number of platelets (thrombocytopenia)

- anaphylactic reaction.
- fits (convulsions).
- reduced sense of touch (hypoesthesia).
- feeling hyperactive.
- change in your sense of smell (anosmia, parosmia).
- change in your sense of taste (ageusia).
- exacerbation or aggravation of muscle weakness (myasthenia gravis).
- impaired hearing including loss of hearing, ringing in your ears.
- rapid (ventricular tachycardia) or irregular heartbeat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes)
- low blood pressure.
- inflammation of the pancreas (pancreatitis).
- change in colour of the tongue
- liver failure
- severe allergic skin reactions
- joint pain (arthralgia)
- kidney failure, inflammation within the kidneys.

The following side effects have been reported in prophylactic treatment against mycobacterium avium complex (mac):

Very common (may affect more than 1 in 10 people)

- diarrhoea
- abdominal pain
- feeling sick (nausea)
- loose wind (flatulence)
- abdominal discomfort
- loose stools

Common (may affect up to 1 in 10 people):

- lack of appetite (anorexia).
- feeling dizzy.
- headache.
- sensation of pins and needles or numbness (paraesthesia).
- changes in your sense of taste.
- visual impairment.
- deafness.
- being sick (vomiting), stomach pain Or cramps, loss of appetite, problems digesting your food. • skin rashes and itching.
- joint pain (arthralgia).
- fatigue.

Uncommon (may affect up to 1 in 100 people):

- reduced sense of touch (hypoesthesia)
- hearing loss or ringing in your ears
- palpitations
- liver problems such as hepatitis
- severe form of skin flushing
- allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin
- general feeling of being unwell (malaise)
- weakness (asthenia)

5. HOW TO STORE FORSTE 250 & 500

Keep all medicines out of the reach and sight of children.

Store below 30°C in a dry place.

Do not use Forste 250 or Forste 500 after the expiry date "Exp. Date" which is stated on the carton. The expiry date refers to the last day of that month.

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

6. FURTHER INFORMATION

What Forste 250 or Forste 500 contains:

- The active pharmaceutical ingredient is Azithromycin.

What Forste 250 or Forste 500 looks like and contents of the pack:

Forste 250: 6 tablets in a sachet placed in an outer carton with insert

Forste 500: 1x3 tablets and 1x10 tablets in a sachet placed in an outer carton with insert

Applicant/Manufacturer

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