PACKAGE LEAFLET: INFORMATION FOR THE USER

ARATRO 200 mg / 5 ml Powder for oral suspension

Azithromycin

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 harm them, even if their signs of illness 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.

What is in this leaflet:

1. WHAT ARATRO 200 MG / 5 ML POWDER FOR ORAL SUSPENSION IN BOTTLE IS AND WHAT IT IS USED FOR

ARATRO 200 mg / 5 ml is a powder for oral suspension in bottle. Each pack contains one bottle of 15 ml or 30 ml.
Azithromycin belongs to a group of antibiotics called macrolides. It is used to treat the following infections:
- Lower and upper respiratory tract infections, such as otitis media, sinusitis, pharyngotonsillitis, bronchitis and pneumonia.
- Skin and soft tissue infections.
- Sexually transmitted diseases.

2. BEFORE YOU TAKE ARATRO 200 mg / 5 ml POWDER FOR ORAL SUSPENSION IN BOTTLE

Do not take ARATRO 200 mg / 5 ml
If you are allergic (hypersensitive) to azithromycin or any of the other ingredients of ARATRO 200 mg / 5 ml.

Take special care with ARATRO 200 mg / 5 ml
- If you suffer severe liver disease. If this were the case, warn your doctor.
- If you develop severe and persistent diarrhoea during or after the treatment, inform your doctor.
- It is possible that, as with other antibiotics, during the treatment with this medicine there is a fungal infection. If this were the case, inform your doctor.
- If during the treatment with ARATRO 200 mg / 5 ml any allergic reactions characterized by symptoms such as itching, redness, rash, swelling or breathing difficulties occurs, you should inform your doctor immediately.

Other medicines and ARATRO 200 mg / 5 ml
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
ARATRO 200 mg / 5 ml may interact with other medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ergot derivates (such as ergotamine, used to treat migraine)
- Ciclosporin (medicine used in transplanted patients)
- Digoxin (used to treat heart arrhythmias)
- Antacids, cimetidine (medicines used in digestive problems). If you are taking ARATRO 200 mg / 5 ml and antacids, avoid simultaneous administration of both medicines at the same hour of the day.
- Nelfinavir, zidovudine (medicines used in the treatment of human immunodeficiency virus infection)
- Dicumarinic anticoagulants (medicines used to prevent blood clot formation)
- Terfenadine (medicine used to treat allergic reactions and hay fever)
- Rifabutin (medicine used for the treatment of pulmonary tuberculosis and non-pulmonary infections caused by mycobacteria)

Pregnancy and breast-feeding
Ask your doctor or pharmacist 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, ask your doctor or pharmacist for advice before taking this medicine.
ARATRO 200 mg / 5 ml is not recommended during pregnancy and breast-feeding, unless, under medical judgement, the benefit outweighs the risk for the child.

Use in children
ARATRO 200 mg / 5 ml should not be given to children under 6 months old.

Driving and using machines
There are no evidences that ARATRO 200 mg / 5 ml have an effect on the ability to drive or operate machinery.

Important information about some of the ingredients of ARATRO 200mg / 5ml
Each 5 ml of prepared suspension of this medicine contains 3.62 g of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ARATRO 200 mg / 5 ml POWDER FOR ORAL SUSPENSION IN BOTTLE

Always take this medicine exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure.
Remember to take your medicine. Your doctor will inform you of the duration of the treatment with ARATRO 200 mg / 5 ml. The dose will be determined by the doctor according to your individual needs and the type of infection. For optimal efficiency, faithfully follow your doctor's instructions regarding the dose and duration of treatment.
ARATRO 200 mg / 5 ml is administrated orally. For ease of administration, each bottle comes with a dosing syringe. The powder for suspension may exceed the signal level marked on the bottle. This fact is normal and due to the density of the preparation.

Preparation of the suspension
- Turn the bottle and shake gently until all the powder moves freely.
- Open the bottle and add the following amount of water depending on the size of the bottle, using the syringe that accompanies: 15 ml bottle: add 10 ml of water. 30 ml bottle: add 15 ml of water.
- Place the perforated plastic cap and press it until it is introduced into the mouth of the bottle.
- Close the bottle with the metal cap.
- Shake vigorously until a homogeneous suspension.
- Do not forget to shake the suspension before each intake.

Administration of the preparation
- Open up the metal cap. Insert the syringe in the perforated plastic cap.
- Turn the bottle upside down so it remains in a vertical position while holding the syringe in place.
- Fill the syringe to the extent corresponding to the dose prescribed by your doctor.
- Invert the bottle again, remove the syringe and proceed to the administration.
- Wash the syringe after each administration.

As a general rule, the dose of medicine and the frequency of administration are as follows:

Adults (including elderly patients):
To adjust more easily the dose, it is convenient to use other presentations. The recommended dose is 500 mg/day, in one take, for 3 consecutive days; therefore, the total dose is 1500 mg. As an alternative, the same total dose can be distributed over 5 days as one single dose of 500 mg the first day, and then 250 mg once daily from day 2 to day 5. For the treatment of sexually transmitted diseases, the dose is 1000 mg taken as a single oral dose.

Children and adolescents:
In general, with the only exception of the treatment of streptococcal pharyngotonsillitis, the recommended dose is 10 mg/kg/day, administered in a single dose for 3 consecutive days. As an alternative, the same total dose can be distributed over 5 days, administering 10 mg/kg on day one, to continue with 5 mg/kg/day for the 4 remaining days. The dosage regimen is based on the weight as follows:

Less than 15 kg:	10 mg/kg/day (given in one dose) during 3 consecutive days; as an alternative, 10 mg/kg on day one, to continue with 5 mg/kg/day for the remaining 4 days, administered in a daily single dose.
15-25 kg:	200 mg/day (given in one dose) during 3 consecutive days; as an alternative, 200 mg on day one, to continue with 100 mg/day for the remaining 4 days, administered in a single daily dose.
26-35 kg:	300 mg/day (given in one dose) during 3 consecutive days; as an alternative, 300 mg on day one, to continue with 150 mg/day for the remaining 4 days, administered in a single daily dose.
36-45 kg:	400 mg/day (given in one dose) during 3 consecutive days; as an alternative, 400 mg on day one, to continue with 200 mg/day for the remaining 4 days, administered in a single daily dose.
More than 45 kg: ...	The same adult dose (500 mg/day, in one take, for 3 days).

For the treatment of streptococcal pharyngotonsillitis should be given a dose of 20 mg/kg/day for 3 consecutive days, without exceeding the maximum daily dose of 500 mg. If you consider that the action of ARATRO 200 mg / 5 ml is too strong or too weak, talk to your doctor or pharmacist.

If you take more ARATRO 200 mg / 5 ml than you should
Contact your doctor or pharmacist immediately.

If you forget to take ARATRO 200 mg / 5 ml
Do not take a double dose to make up for a forgotten dose.

If you stop taking ARATRO 200 mg / 5 ml
There is a risk of relapse of the disease.

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

4. POSSIBLE SIDE EFFECTS
Like all medicines, ARATRO 200 mg / 5 ml can cause side effects although not everybody gets suffer them.
Most adverse effects observed in clinical trials were of mild to moderate nature, reversible after discontinuation of the medicine and they mainly affected the digestive system and consisted mainly of nausea, vomiting, diarrhoea or abdominal pain.
Potentially serious adverse reactions such as laryngeal edema (due to allergic reaction) or impaired liver function are accompanied by yellowing of the skin rarely occurred. Also, during treatment with ARATRO 200 mg / 5 ml any of the following side effects, described for Azithromycin when administered orally, could appear.
- Thrombocytopenia (low platelet count) and transient episodes of mild neutropenia (low white blood cell count).
- Aggressive reactions, nervousness, agitation, anxiety, dizziness/vertigo, convulsions, headache, drowsiness and hyperactivity.
- Hearing impairment and exceptionally, altered taste.
- Cardiac disorders.
- Digestive disorders such as anorexia, nausea, vomiting/diarrhoea (reaching an exceptional cause dehydration), loose stools, abdominal discomfort (stomach pain/cramps), constipation, gas, and rarely severe diarrhoea, discolouration of the tongue.
- Impaired function of liver (rarely severe) and kidney.
- Skin reactions such as itching, rash, sensitization to light, fluid accumulation or urticaria (rash). Exceptionally severe skin reactions have taken place.
- Joint pain.
- Vaginal fungal infection (vaginitis).
- Fungal infections, fatigue, tingling sensation and allergic reactions.

If you consider that any of the side effects you suffer are serious or if you suffer any adverse effect that has not been mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ARATRO 200 mg / 5 ml
Store below 30 ºC.
The validity period of the reconstituted suspension is 10 days.
Keep this medicine out of the reach and sight of children.
Do not take ARATRO 200 mg / 5 ml after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Do not take ARATRO 200 mg / 5 ml if you notice visible signs of deterioration.
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 ARATRO 200 mg / 5 ml contains
The active substance is azithromycin (dihydrate). Each 5 ml of reconstituted suspension contains 200 mg of azithromycin.
The other ingredients are sucrose, hydroxypropylcellulose, trisodium phosphate anhydrous, xanthan gum, cherry, banana and vanilla flavours.

What ARATRO 200 mg / 5 ml looks like and contents of the pack
ARATRO 200 mg / 5 ml is a powder for oral suspension in bottle. Each pack contains one bottle of 15 ml or 30 ml.

Marketing Authorisation Holder and Manufacturer
ARAFARMA GROUP, S.A.
C/ Fray Gabriel de San Antonio, 6-10
Pol. Ind. del Henares
19180 Marchamalo (Guadalajara), Spain.

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