PACKAGE 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.
- 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 symptoms are the same as yours.

In this leaflet:

ZITHROFORTE® 500 mg film-coated tablets

The active substance is azithromycin. Each tablet contains 500 mg of azithromycin.
The other ingredients (excipients) are calcium hydrogen phosphate anhydrous, crospovidone, glycerol triacetate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, pregelatinised starch, sodium lauryl sulfate, titanium dioxide (E171).

Marketing Authorisation Holder
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1. WHAT ZITHROFORTE® IS AND WHAT IT IS USED FOR

Zithroforte® 500 mg are film-coated tablets and are available in pack sizes of 3 tablets.

Azithromycin is one of a group of antibiotics called macrolides. It is used to treat the following infections:

- Upper and lower respiratory tract infections such as, sinusitis and otitis media, tonsillopharyngitis, bronchitis and pneumonia.
- Skin and soft tissue infections.
- Sexually transmitted diseases.

Approved as presented

Regulatory Pharmacist

2. BEFORE YOU TAKE ZITHROFORTE®

Do not take Zithroforte®
If you are allergic (hypersensitive) to azithromycin or to any other macrolide antibiotic or any of the other ingredients of Zithroforte®.

Take special care with Zithroforte®
- If you have severe kidney problems, please tell you doctor.
- If you develop diarrhoea during or after treatment, tell your doctor immediately.
- It is possible that, as with other antibiotics during treatment with this medication you could suffer fungal superinfection, tell your doctor.
- If you have allergic reactions including itching, redness, rash, swelling or difficulty breathing, during treatment with Zithroforte®, please tell you doctor.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Azithromycin may interact with other medicinal products. Check with your doctor if you are taking any of the following:

- Ergot derivatives, such as ergotamine (used to treat migraine).
- Ciclosporin (used in treating patients with transplanted organs).
- Digoxin (used to treat heart arrhythmias).
- Antacids, Cimetidine (used to treat stomach problems) If you are taking antacids and Zithroforte®, you should not take both medicines at the same time of day.
- Coumarin anticoagulants (used to stop the blood clotting).
- Nelfinavir, Zidovudine (used in the treatment of HIV).
- Terfenadine (an antihistamine that is used to treat allergies and hay fever).
- Rifabutin (used in 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.

Tell your doctor before using Azithromycin if you are pregnant, planning on becoming pregnant, or breast-feeding.

Zithroforte® is not recommended if you are pregnant or planning to become pregnant or during the breast-feeding unless this has been discussed with your doctor and the benefit outweighs the risk to the child.

Use in Children
Zithroforte® should not be used for children younger than 6 months of age.

Driving and using machines
There is no evidence that Zithroforte® affects the ability to drive or operate machinery.

3. HOW TO TAKE ZITHROFORTE®

Always take use Zithroforte® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you the duration of treatment with Zithroforte®. Do not stop taking his medication early due to the risk of relapse of the disease. Zithroforte® is administered orally.

The tablets should be swallowed whole and preferably with a drink of water (a glass of water).

The dose will be determined by the doctor according to your individual needs and the type of infection.

For optimal efficiency, you should follow the exact instructions that your doctor has given you regarding the dose and duration of treatment.

The usual dose is:

Adults (including the elderly)
500 mg (1 tablet) once daily for 3 days. The total dosage is 1500 mg (3 tablets).

For sexually transmitted diseases the dosage is 1000 mg (2 tablets) as a single oral dose.

Children and adolescents
The dose of 500 mg of this pharmaceutical form is appropriate only for those children and adolescents over 45 kg of body weight, whom is recommended the same dose that adults. For those weighing less is recommended other pharmaceutical forms.

If you feel that the effect of Zithroforte® is too strong or too weak, please tell your doctor or pharmacist.

If you take more Zithroforte® than you should
If you (or someone else) have taken too much Zithroforte®, contact immediately your nearest hospital casualty department, with your doctor or pharmacist.

If you forget to take Zithroforte®
Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zithroforte® can cause side effects, although not everybody gets them.

Most side effects reported in clinical trials were mild to moderate, reversible after discontinuation of the medicine and affected the digestive system and consisted mainly of nausea, vomiting, diarrhea or abdominal pain.

Potentially serious side effects such as laryngeal edema (due to allergic reaction) or impaired liver function that are accompanied by yellowing of the skin, these effects occurred of rare form.

Also, during treatment with Zithroforte® you may be experiencing the following side effects, described for azithromycin when is administered for oral route:

- Thrombocytopenia (low platelet count) and transient episodes of mild neutropenia (low white blood cell count).
- Reactions of aggression, nervousness, agitation, anxiety, dizziness/vertigo, convulsions, headache, drowsiness and hyperactivity.
- Hearing disturbances and excepcionally taste disorders.
- Cardiac alterations.
- Digestive problems such as anorexia, nausea, vomiting/diarrhea (reaching an exceptional cause dehydration), loose stools, abdominal discomfort (pain/cramps), constipation, gas, and rarely severe diarrhea, discolouration of the tongue.
- Alterations of liver function (rarely severe) and the kidney.
- Skin disorders such as itching, rash, sensitivity to light, fluid accumulation or urticaria (rash). Exceptionally have been ocurred severe skin reactions.
- Joint pains.
- Vaginal yeast infection (vaginitis).
- Fungal infections, fatigue, tingling and allergic reactions.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ZITHROFORTE®

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use Zithroforte® after the expiry date which is stated on the outer packaging.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.

This leaflet was last approved in September 2003