ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension
Azithromycin

Framed

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

•Keep this leaflet. You might need to read it again.

•If you have any further questions, ask your doctor, pharmacist or nurse.

•This medicine has been prescribed. Do not give this to anyone else. 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, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

What does this booklet contain ?

1. WHAT IS ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: Antibacterials for systemic use - ATC code: J01FA10
This medication is an antibacterial antibiotic from the macrolide family.
It is indicated for the treatment of certain bacterial infections caused by sensitive germs in children from 3 years of age.

2. WHAT YOU NEED TO KNOW BEFORE TAKING ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension?

If your doctor has informed you of an intolerance to certain sugars, contact your doctor before taking this medicine.

Do not take ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension:

• If you are allergic to azithromycin, erythromycin, any macrolide antibiotic in the ketolide or any of the other ingredients of this medicine listed in section 6,

– in combination with dihydroergotamine and ergotamine (anti-migraine drugs),

– in combination with cisapride (anti-reflux medicine),

– in combination with colchicine (treatment of gout),

• In patients with severe hepatic impairment.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension .

If you experience swelling of the face or neck (edema) or a severe rash with blisters on the skin, sores in the mouth, or inflammation of the eyes, YOU MUST STOP TREATMENT AND CONTACT YOUR DOCTOR IMMEDIATELY because these effects can be life threatening or lead to death.

If you notice a symptom on your skin corresponding to a rash even without other associated effects, a yellowing of the skin, dark urine, a tendency to bleeding, a change in your level of consciousness or in your behavior, the occurrence of severe diarrhea, myasthenia gravis (an autoimmune muscle disease which mainly results in muscle weakness) or heart problems, tell your doctor immediately so that he can tell you if you need to stop your treatment and replace it with another antibiotic .

The use of this medication is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase / isomaltase deficiency (rare hereditary diseases).

This medicinal product contains 3.87 g of sucrose per 5 ml of reconstituted suspension, which must be taken into account in the daily ration in the event of a low-sugar diet or in the event of diabetes.

This medicine contains sodium. The sodium level is less than 1 mmol per ml of suspension, that is to say "sodium-free"

Before taking this treatment, tell your doctor if during previous antibiotic treatment you have had hives or other rashes, itching, angioedema (sudden swelling of the face and neck of allergic origin)

Before taking this treatment, tell your doctor if you:

• Kidney disease,

• Severe liver disease,

• QT interval (abnormality observed on the electrocardiogram),

• Hypokalemia, hypomagnesemia (low potassium or magnesium in the blood),

• Bradycardia, cardiac arrhythmia, severe heart failure,

• Concomitant treatment with treatments that prolong the QT interval: including certain antiarrhythmic drugs (eg quinidine, amiodarone, sotalol), antipsychotics (eg phenothiazines, pimozide), tricyclic antidepressants (eg, citalopram) or other antibiobiques (eg: moxifloxacin, levofloxacin),

• Hyper-reactivity to food or vomiting your newborn.

Children

Not applicable.

Other medicines and ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension

This medication is contraindicated in combination with dihydroergotamine, ergotamine, cisapride and colchicine (see “Never take ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension”).
To avoid possible interactions between several drugs, and in particular bromocriptine (drug against the flow of milk, against Parkinson's disease), cabergoline (drug against excess prolactin-hormone causing lactation), pergolide (medicine used to treat Parkinson's disease), lisuride (medicine used in Parkinson's disease or against excess prolactin-hormone causing lactation), atorvastatin and simvastatin (medicines to lower the level of cholesterol), ciclosporin (an immunosuppressant medicine), digoxin and ivabradine (medicines used in certain heart problems), medicines which can cause torsades de pointes (heart rhythm disorder) and vitamin K (medicine that prevents blood clotting). blood),systematically report any other current treatment to your doctor or pharmacist.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension with food and drink

Not applicable.

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.
It is best not to use this medicine during the first three months of pregnancy. From the beginning of the 4 thmonth of pregnancy, the drug will be used only on the advice of your doctor.
If you discover that you are pregnant during treatment, consult your doctor as only he can judge the need for continued treatment.
Breast-feeding is not recommended while taking this medication.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may experience side effects, such as dizziness, drowsiness, certain visual or hearing disturbances during treatment with azithromycin. You should take precautions while performing certain activities such as driving vehicles, and using any tools or machines. If you experience fatigue, you should avoid performing potentially hazardous tasks, including driving vehicles or using tools or machines.

ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension contains sucrose, sodium, glucose (contained in the vanilla cream flavoring).

3. HOW TO TAKE ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.
This medicine has been prescribed for you in a specific situation:

- It can be adapted to another case
- Do not reuse without medical advice,
- Do not advise it to another person.

Dosage

The dosage is determined by your doctor according to the weight of the child.
The dose to be administered must be withdrawn using the syringe for oral administration graduated in kilograms (graduation every half kilogram).

•**Below 25 kg** : the daily dosage varies according to the weight of the child (20 mg / kg / day). The weight indicated corresponds to the dose for one intake. For example, the graduation 15 on the syringe corresponds to the dose to be administered for a child weighing 15 kg.

•**CAUTION: From 25 kg and above** : in all cases, the daily dosage is fixed and must not exceed the graduation " **25 kg = max dose / per day** " of the syringe.

The treatment takes place over 3 days with only 1 dose per day.
One vial corresponds to 3 days of treatment.
Strictly follow your doctor's prescription.
If you have the impression that the effect of ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension is too strong or too weak, talk to your doctor or pharmacist.

Method and route of administration

Oral route.
The graduated syringe provided is specific to ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension.
The oral suspension can be administered with or without food.
Administer the oral suspension only after its reconstitution.
Instructions for reconstitution and administration of the drug:

Reconstitution of the oral suspension

1. **SHAKE** the vial vigorously to loosen the powder from the bottom. 
2. **OPEN** the vial by exerting strong pressure on the cap and turning it at the same time (safety cap).
3. **FILL** the enclosed pouring cup with water to the mark shown. 
4. **POUR** the contents of the pouring cup into the vial containing the powder (once only). 
5. **SEPARATE** the adapter cap from the graduated syringe and **INSERT it** firmly into the vial.
6. **CLOSE** the bottle with the safety cap.
7. **SHAKE** the vial vigorously several times until a homogeneous suspension is obtained.

Drug administration

1. **SHAKE** the oral suspension before each dose.
2. **OPEN** the safety cap on the vial.
3. **INSERT** the syringe for oral administration into the adapter cap and **TURN** the vial + syringe for oral administration assembly while keeping the assembly in an upright position. 

4. **ASPIRE** the dose prescribed by the doctor using the oral syringe. It is graduated in kg. Thus, the weight indicated by the graduations corresponds to the dose for one intake.

•**If a child weighs less than 25 kg** : the daily dosage varies according to the weight of the child (20 mg / kg / day).

• For example, the scale 15 on the syringe corresponds to the dose to be administered to a child of 15 kg and the graduation 20 on the syringe corresponds to the dose administered to a 20 kg child.

•**If the child weighs 25 kg or more** : in all cases, the daily dosage is fixed (500 mg / day) which corresponds to the graduation " **25 kg = max dose / day** " on the syringe.

5. **REMOVE** the oral syringe from the vial and give the medicine to the child.
6. **CLOSE** the bottle by screwing on the safety cap.
7.  **RINSE** the oral syringe with water after use, then **STORE it** in the carton.

If you take more ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension than you should

Immediately consult your doctor or pharmacist.

If you forget to take ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension

Do not take a double dose to make up for the dose you forgot to take.

If you stop taking ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension

Not applicable.

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

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

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

Diarrhea.

Common side effects (may affect up to 1 to 10 in every 100 people)

Headache, vomiting, abdominal pain, nausea, decrease in lymphocytes (white blood cells) in the blood, increased blood levels of eosinophils, basophils, monocytes, neutrophils (white blood cells), decrease in bicarbonate in the blood.

Uncommon side effects (may affect up to 1 in 10 in 1,000 people)

Infection due to microscopic fungi especially in the mouth, pneumonia, infection due to bacteria, pharyngitis, gastroenteritis, trouble breathing, rhinitis, low number of white blood cells in the blood (leukocytes, neutrophils, eosinophils), allergy, nervousness , insomnia, dizziness, drowsiness, taste disturbance, tingling sensation, blurred vision, hearing disturbance, vertigo, loss of appetite, palpitations, hot flush, difficulty breathing, nosebleeds, constipation, gas, discomfort abdominal, difficult digestion, difficulty swallowing, abdominal distension, dry mouth, burping, mouth ulceration, salivary hypersecretion, rash, itching, hives, inflammation of the skin, dry skin, excessive sweating, osteoarthritis, muscle pain,back pain, neck pain, difficulty urinating, kidney pain, vaginal

bleeding (between periods), testicular problem, fatigue, malaise, swelling (especially facial edema, angioedema), chest pain , fever, pain, swelling of limbs and extremities, increased blood levels of liver enzymes (aspartate aminotransferases, alanine aminotransferases), bilirubin, urea, creatinine, alkaline phosphatase, chlorides, glucose , platelets, bicarbonates, decrease in blood level of red blood cells, abnormal blood level of potassium, sodium, post-procedure complication.swelling (edema especially of the face, angioedema), chest pain, fever, pain, swelling of the limbs and extremities, increase in the blood level of liver enzymes (aspartate aminotransferases, alanine aminotransferases), bilirubin, urea, creatinine, alkaline phosphatase, chlorides, glucose, platelets, bicarbonates, decrease in blood level of red blood cells, abnormal blood level of potassium, sodium, post-procedure complication.swelling (edema especially of the face, angioedema), chest pain, fever, pain, swelling of the limbs and extremities, increase in the blood level of liver enzymes (aspartate aminotransferases, alanine aminotransferases), bilirubin, urea, creatinine, alkaline phosphatase, chlorides, glucose, platelets, bicarbonates, decrease in blood level of red blood cells, abnormal blood level of potassium, sodium, post-procedure complication.bicarbonates, decrease in blood level of red blood cells, abnormal blood level of potassium, sodium, post-procedure complication.bicarbonates, decrease in blood level of red blood cells, abnormal blood level of potassium, sodium, post-procedure complication.

Rare side effects (may affect up to 1 in 10 in 10,000 people)

Restlessness, liver disorder, cholestatic hepatitis (liver disease characterized by fever and pain), photosensitivity (skin reaction to sun or UV exposure), rash on the skin which may be accompanied by fever, occurring suddenly and beginning in the face or in the folds and can become generalized (acute generalized exanthemous pustulosis).

Allergic reaction with increased number of eosinophils (a type of white blood cell) and systemic symptoms (DRESS Syndrome).

Side effects whose frequency is not known

Severe diarrhea (pseudomembranous colitis), decreased level of platelets in the blood (important parts of clotting), hemolytic anemia (destruction of red blood cells in the blood), generalized allergic reaction, aggressive behavior, anxiety, delirium, hallucination, syncope, seizure, decreased skin sensitivity, hyperactivity, loss of smell or taste, gum disease, myasthenia gravis (muscle autoimmune disease), hearing disorder including deafness and / or ringing, heart rhythm disturbances (torsades de pointes, arrhythmia, prolongation of the QT interval visible on the electrocardiogram), drop in blood pressure, inflammation of the pancreas, discoloration of the tongue, liver damage which may rarely be life-threatening, fulminant hepatitis (acute hepatitis severe), hepatic necrosis,peeling of the skin which can quickly spread to the whole body, especially the mucous membranes (Stevens-Johnson syndrome and toxic epidermal necrosis), erythema multiforme, joint pain, acute renal failure, interstitial nephritis (inflammation of the kidney).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr .

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension?

Keep this medication out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the bottle. The expiration date refers to the last day of that month.
No special storage conditions.
After reconstitution, the suspension can be stored for a maximum of 5 days at a temperature not exceeding + 25 ° C.
Discard the pouring cup after reconstitution.
Throw away the syringe and vial at the end of treatment.
Do not throw away any medicine 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 PACKAGE AND OTHER INFORMATION

What ZITHROMAX 40 mg / ml CHILDREN contains, powder for oral suspension

- The active substance is:

Azithromycin .... 40.00 mg

As azithromycin dihydrate .... 41.92 mg

For 1 ml of reconstituted suspension

One vial contains 600 mg of azithromycin in 15 ml of reconstituted suspension, equivalent to 30 doses-kg.

One vial contains 900 mg of azithromycin in 22.5 ml of reconstituted suspension, equivalent to 45 doses-kg.

One vial contains 1200 mg of azithromycin in 30 ml of reconstituted suspension, equivalent to 60 doses-kg.

One vial contains 1500 mg of azithromycin in 37.5 ml of reconstituted suspension, equivalent to 75 doses-kg.

- The other ingredients are:

Sucrose, anhydrous trisodium phosphate, hydroxypropylcellulose, xanthan gum, cherry flavor, cream of vanilla flavor (notably contains glucose), banana flavor.

What is ZITHROMAX 40 mg / ml CHILDREN, powder for oral suspension and contents of the pack?

This medication is in the form of a powder for oral suspension in a vial.

Marketing authorization holder

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23-25, AVENUE DU DOCTEUR LANNELONGUE

75014 PARIS

Marketing authorization operator

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