

PACKAGE LEAFLET: INFORMATION FOR THE USER

SUMAMED

SUMAMED 100mg/5ml, SUMAMED forte 200mg/5ml, SUMAMED 1200 200mg/5ml, Powder for oral suspension

AZITHROMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • Do not pass it on to others • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What SUMAMED is and what it is used for
2. Before you take SUMAMED
3. How to take SUMAMED
4. Possible side effects
5. How to store SUMAMED
6. Further information

1. WHAT SUMAMED IS AND WHAT IS IT USED FOR

SUMAMED contains azithromycin which belongs to the group of antibacterial medicinal products for systemic use, macrolide.

SUMAMED is indicated for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms:

- Upper respiratory tract infections including pharyngitis/tonsillitis, sinusitis and otitis media.
- Lower respiratory tract infections including bronchitis and community-acquired pneumonia
- Skin and soft tissue infections including moderate acne vulgaris, erythema chronicum migrans (first stage of Lyme disease), erysipelas, impetigo and secondary pyoderma.
- Sexually transmitted diseases including uncomplicated genital infections due to Chlamydia trachomatis
- Gastric and duodenal infections caused by Helicobacter pylori.

2. BEFORE YOU TAKE SUMAMED

Do not take SUMAMED

- if you are allergic (hypersensitive) to azithromycin, to any macrolide, or to any of the other ingredients of SUMAMED
- if you have liver problems
- concomitantly with ergot derivatives, because of the theoretical possibility of ergotism.

Take special care with SUMAMED

If the answer to any of the following questions is "YES" consult your doctor or pharmacist before using SUMAMED:

- Are you pregnant or trying to get pregnant?
- Are breast-feeding?
- Do you have any heart problems?
- Do you have any problems with your liver or kidneys or have ever been subjected to dialysis?
- Are you using warfarin or any similar medicine to prevent blood clotting?
- Are you using cyclosporin (used to suppress the immune system in order to avoid the rejection of a transplanted organ or bone marrow), digoxin (used to treat heart failure) or theophylline (used to treat asthma)?
- Do you use antacids (for indigestion or heartburn)?
- Are you using terfenadine (for high temperature or skin allergy)?
- If you are taking any other medication, make sure your doctor knows.

Taking other medicines

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

Important information about some of the ingredients

SUMAMED syrup contains saccharose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

3. HOW TO TAKE SUMAMED

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

Dosage

SUMAMED is taken once a day, at least one hour before or two hours after meal. The dose should be measured using a syringe or spoon with the markings (up to 15 kg - syringe, over 15 kg - spoon).

Preparation of the suspension**SUMAMED syrup:**

12 ml of purified water should be added into vial containing 400 mg of azithromycin to prepare 25 ml of oral suspension.

SUMAMED forte syrup:

9.5 mL of purified water should be added into vial containing the powder to prepare 20 ml of oral suspension containing 600 mg of azithromycin.

SUMAMED syrup in 1200:

16.5 ml of purified water should be added into vial containing the powder to prepare 35 ml of oral suspension containing 600 mg of azithromycin.

The usual dose is:

- Upper and lower respiratory tract infections and skin and soft tissues infections: a total dose of 30 mg/kg (with exception of erythema migrans): 10 mg/kg once daily throughout 3 days.

The doses for children are weight dependent, i.e.:

Body weight (kg)	SUMAMED syrup 100 mg/5 ml	SUMAMED forte syrup 200mg/5 ml SUMAMED syrup 1200 200mg/5 ml
5	2,5 ml (50 mg)	/
6	3 ml (60 mg)	/
7	3,5 ml (70 mg)	/
8	4 ml (80 mg)	/
9	4,5 mg (90 mg)	/
10 - 14	5 ml (100 mg)	2,5 ml (100 mg)
15 - 24	/	5 ml (200 mg)
25 - 34	/	7,5 ml (300 mg)
35 - 44	/	10 ml (400 mg)
≥ 45	/	Doza za odrasle

Azithromycin has shown efficacy in the treatment of streptococcal pharyngitis in children in single doses of 10 mg / kg or 20 mg / kg. However, penicillin is the usual drug of choice in the prophylaxis of pharyngitis caused by *Streptococcus pyogenes* and rheumatic fever as a secondary disease.

For erythema migrans the total dose is 60 mg/kg: 20 mg/kg on the first day, followed by 10 mg/kg on days 2 through 5, all as single daily doses.

In the treatment of gastric and duodenal infections caused by *Helicobacter pylori* dose of 20 mg / kg daily in combination with antisecretory and other drugs is used, depending on the doctor's decision.

If you take more SUMAMED than you should

Overdosage with macrolide antibiotic is manifested as a loss of hearing, severe nausea, vomiting and diarrhea. In this case, vomiting should be provoked and medical help sought immediately.

If you forget to take SUMAMED

Do not take a double dose to make up for a forgotten dose. Missed dose should be taken as soon as possible and the following ones in 24 hour intervals.

If you stop taking SUMAMED

Do not stop taking your medicine, even if you feel that you are healthy, unless your doctor advises you to do so.

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

4. POSSIBLE SIDE EFFECTS

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

According to frequency, reported adverse events in the treatment of drug SUMAMED are classified as:

Very common > 1/10 (> 10%),

Common > 1/100 <1/10 (> 1% and <10%),

Uncommon > 1/1000 <1/100 (> 0.1% and <1%),

Rare > 1/10 000 and <1/1000 (> 0.01% and <0.1%),

Very rare <10 000 (<0.01%).

SUMAMED seldom causes transient and mild adverse effects. Gastrointestinal disturbances (nausea, diarrhea, stomach pain, vomiting and flatulence) and rash may occur. Reversible elevations in hepatic enzymes may occur. If changed, those values return back to normal two to three weeks after the finishing drug therapy. Hypersensitivity reaction such as rash, urticaria or photosensitivity have been reported. In rare cases, azithromycin has been reported to have caused serious allergic (rarely fatal) reactions. Some of these reactions

have resulted in recurrent symptoms and required a longer period of observation and treatment. Reversible unspecific effects such as tiredness, headache, dizziness, smell and taste disturbances, paresthesia, nervousness and insomnia were reported very rarely. Arthralgia occurs occasionally. Palpitations, arrhythmias with associated ventricular tachycardia have rarely been reported. Rare side effects were: discomfort, sensitivity to sunlight, hepatitis and jaundice, including disruption of LFTs.

Side effects of unknown frequency are: reducing the number of platelets (which can cause bruises and tendency to prolonged bleeding after an injury), hemolytic anemia, aggressiveness, anxiety, hallucinations, convulsions, fainting, hyperactivity, myasthenia gravis, a rapid or irregular heartbeat, liver failure, inflammation of the kidneys or renal failure, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis).

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.

5. HOW TO STORE SUMAMED

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (2 years). The expiry date refers to the last day of that month.

Do not store above 25 °C.

Once made up, suspension of SUMAMED syrup and SUMAMED forte syrup should be used within five days, and SUMAMED syrup within 1200 ten days.

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. FURTHER INFORMATION

What SUMAMED contains

The active ingredient in SUMAMED azithromycin.

SUMAMED syrup: 5 ml of suspension contains 100 mg of azithromycin in the form of dihydrate.

SUMAMED forte syrup: 5 ml of suspension contains 200 mg of azithromycin in the form of dihydrate.

SUMAMED syrup 1200: 5 ml of suspension contains 200 mg of azithromycin in the form of dihydrate.

Other ingredients: sucrose, trisodium phosphate anhydrous, hydroxypropyl cellulose, xanthan gum, cherry flavour, banana flavour, vanilla flavour, colloidal anhydrous silica.

What SUMAMED looks like and contents of the pack

Powder for oral suspension.

SUMAMED syrup *: powder for preparation of 20 ml of the suspension in 50 ml HDPE bottle with a suitable "child-resistant" cap

SUMAMED forte syrup *: powder for preparation of 15 ml of the suspension in 50 ml HDPE bottle with a suitable "child-resistant" cap.

SUMAMED syrup * 1200: powder for preparation of 30 ml of the suspension in 100 ml HDPE bottle with a suitable "child-resistant" cap.

Each bottle is packed in carton box together with calibrated two side dosing spoon and oral dosing syringe.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

PLIVA Croatia d.o.o, Prilaz Baruna Filipovića 25, 10000 Zagreb, Croatia

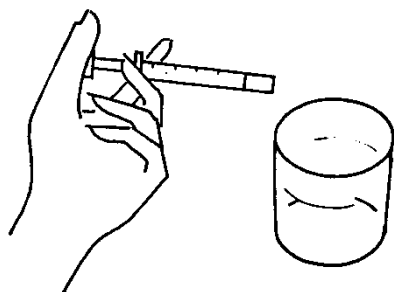
Manufacturer of the medicinal product

PLIVA Croatia d.o.o, Prilaz Baruna Filipovića 25, 10000 Zagreb, Croatia

Preparation of oral suspension

If oral suspension has not been prepared in the pharmacy, dosing syringe can be used for measuring of water necessary for preparing the suspension.

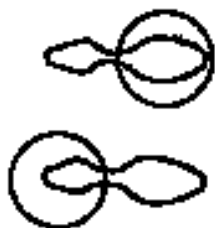
1. Bottle contains powder from which oral suspension is produced by addition of water.
2. Push the stopper of the bottle downwards and thus turn it counterclockwise.
3. It is necessary to add 9,5 ml of water for SUMAMED forte syrup. Measure 2 times 4 ml water from clean glass and add to bottle with the drug. It is necessary to add 12 ml of water for SUMAMED syrup. Measure 2 times 5 ml water from clean glass and add to bottle with the drug. It is necessary to add 16,5 ml of water for SUMAMED 1200 syrup. Measure 3 times 5 ml and once 1,5 ml of water from clean glass and add to bottle with the drug.



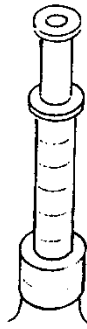
4. Shake well until uniform suspension is produced.
5. Validity of prepared suspension is 5 days for syrups of 15ml and 20ml, and 10 days for syrup of 30 ml.

Instructions on handling of spoon and dosing syringe

Please read the following instructions for use carefully before you give the drug to a child. Received packing contains dosing syringe and double-sided spoon. A physician/pharmacist will give you an advice whether you will use a spoon or syringe. Double sided spoon: spoonfull large spoon contains 5 ml and smaller spoon 2.5 ml

**Filling of syringe with the drug**

6. Shake suspension before use
7. Push the stopper downwards and thus turn it counterclockwise
8. Immerse the syringe into suspension and by drawing the piston upwards pull corresponding quantity of suspension.



9. If you notice a bubble in the syringe, return the drug into the bottle and repeat procedure

Giving the drug to the child

10. Put a child into position for feeding.

11. Put the tip of the syringe into child's mouth and slowly squeeze the content.

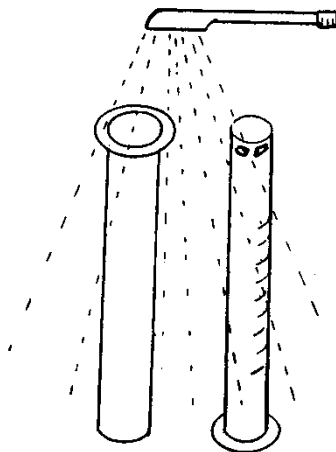
12. Enable a child to swallow it gradually.



13. After a child has swallowed the drug give him/her some tea or juice to wash out and swallow remaining content in the mouth.

Cleansing and storage

14. Take apart used syringe, wash it under running water, dry it and put it on dry and clean place along with the drug.



15. After you have given a last dose to a child dispose of it together with a bottle.