

Patient Leaflet According to the Pharmacists' Regulations
(Preparations) - 1986
This medicine requires a physician's prescription
Please read the entire leaflet carefully before using your medication

Pen-Rafa VK 500 Caplets

Pen-Rafa VK Forte Powder for preparing 60 ml syrup

Composition:

Pen-Rafa VK 500 Caplets

Active ingredient:

Each caplet contains: Penicillin V (as potassium) 500mg

Inactive ingredients:

Magnesium stearate, macrogol 6000, povidone, talc, hypromellose, titanium dioxide

Pen-Rafa VK Forte Powder for preparing syrup

Active ingredient:

Each prepared teaspoon of syrup (5 ml) contains: Penicillin V (as potassium) 250mg

Inactive ingredients:

Simethicone, saccharin sodium, sodium benzoate, citric acid anhydrous, aspartame, carmellose sodium, strawberry flavouring powdered, raspberry flavouring powdered, trisodium citrate anhydrous, sucrose

Each teaspoon contains 15 mg sodium, 1.5 g sugar.

Therapeutic activity:

This medicine is indicated for the treatment of infections caused by organisms susceptible to penicillin.

Therapeutic Group:

An antibiotic of the penicillin group.

When should this medicine not be used?

Do not use this medicine if you are sensitive to penicillin, cephalosporins or penicillamine.

Do not use this medicine if you are sensitive to any of its ingredients.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or breastfeeding; if you suffer or have suffered in the past from impaired function of the: respiratory tract (e.g. asthma), liver, kidney/urinary tract, digestive system (e.g. colitis), or if you suffer or have suffered in the past from any kind of allergy.

Warnings:

The syrup contains the sweetener aspartame, which may harm patients who have phenylketonuria.

Do not use this medicine frequently, or for a long period, without consulting a physician. If you are sensitive to any foods or medications notify your physician before starting treatment.

Drug Interactions:

If you are taking any other medications or if you have recently finished treatment with another drug, please notify your physician in order to prevent any potential risks or a potential reduction in efficacy that may result from drug interactions. This is especially important for medicines belonging to the following groups: antidiarrheals, other antibiotics, oral contraceptives, probenecid (prolongs the duration of action of penicillin), cyclosporine, methotrexate.

Side Effects:

In addition to the desired effect of the drug, unwanted side effects may also appear while taking this medicine. These may include: heartburn, diarrhea, nausea, sore mouth and tongue, or a change in the color of the tongue. If these side effects persist, please consult your physician.

Side effects that require special attention:

Rash or itching of the skin, difficulty breathing – Stop the treatment and consult your physician immediately!

If at any time you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your physician immediately!

Side effects and drug interactions in children and infants:

Parents should report to the physician any side effects as well as any additional medication taken by the child.

Dosage:

Administer according to the physician's instructions only. Do not exceed the recommended dose.

This medication is to be taken at specified time intervals as determined by your physician's instructions. If you have forgotten to take a dose at the specified time, take it as soon as you remember. However do not take two doses together!

Unless otherwise directed by the physician the recommended dosage is as follows:

Caplets**Streptococcal pharyngitis ("strep throat")**

In Streptococcal pharyngitis the recommended dosage for adults is: 2 caplets of Pen-Rafa VK 500 in the morning (in total 1000 mg) and 2 caplets of Pen-Rafa VK 500 in the evening (in total 1000 mg), for 10 days.

For children the recommended dosage is: 1 caplet of Pen-Rafa VK 500 in the morning and 1 caplet of Pen-Rafa VK 500 in the evening, for 10 days.

Prophylaxis against bacterial endocarditis

In patients at high risk of acquiring bacterial endocarditis, when undergoing dental procedures or surgical procedures of the upper respiratory tract, the recommended dosage in adults and children over 25 kg bodyweight is: 4 caplets of Pen-Rafa VK 500 (in total 2000 mg) one hour before the procedure and 2 caplets of Pen-Rafa VK 500 (in total 1000 mg) 6 hours after the procedure.

For other infections, the recommended dosage of Pen-Rafa VK 500 for adults and children above 12 years of age is: 1 caplet of Pen-Rafa VK 500, 4 times a day.

Syrup

Streptococcal pharyngitis ("strep throat")

The recommended dosage for children over 25kg is:

2 teaspoons of syrup in the morning (in total 500 mg) and 2 teaspoons of syrup in the evening (in total 500 mg), for 10 days.

Dosage for babies and children weighing less than 25kg: 25-50mg/kg/day in divided doses every 6-8 hours.

The recommended dosage for adults is:

4 teaspoons of syrup in the morning (in total 1000 mg) and 4 teaspoons of syrup in the evening (in total 1000 mg), for 10 days.

Prophylaxis against bacterial endocarditis

In patients at high risk of acquiring bacterial endocarditis, when undergoing dental procedures or surgical procedures of the upper respiratory tract, the recommended dosage in adults and children over 25 kg bodyweight is: 8 teaspoons of syrup (in total 2000 mg) one hour before the procedure and 4 teaspoons of syrup (in total 1000 mg) 6 hours after the procedure.

In children weighing less than 25 kg, the recommended dosage is: 4 teaspoons of syrup (in total 1000 mg) one hour before the procedure and 2 teaspoons of syrup (in total 500 mg) 6 hours after the procedure.

Directions for use:

The medicine may be taken with meals.

Caplets

Swallow with some water.

The caplet can be divided in 2, according to the line down the middle.

Powder for preparing syrup

Shake the bottle before adding water to aid the dissolution.

The pharmacist must fill the bottle with purified water until below the marked sign and shake the bottle. The pharmacist must then add more purified water up to the marked sign and shake the bottle again for a few minutes. Alternatively, it is possible to add 45 ml of purified water and to shake the bottle.

Measure carefully the correct dosage with the measuring spoon (enclosed).

How can you contribute to the success of your treatment?

Complete the entire course of treatment as directed by your physician.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your physician.

Help prevent poisoning!

This medicine, like all medicines, should be kept in a closed cupboard, out of the reach of children/infants in order to prevent accidental poisoning.

If you or a child accidentally took an overdose of the medicine, go immediately to the emergency room of the hospital and bring with you any remaining drug and the original packaging.

Do not induce vomiting without explicit instructions from the physician!

This medicine was prescribed to treat your ailment; in another patient, it may be harmful.

Do not give this medicine to your relatives, neighbors, or acquaintances.

Do not take any medicine in the dark! Carefully check the label and dose each time you take the medicine. Wear your glasses if you need them.

Storage: Store this medicine below 25°C. Protect from moisture.

The prepared syrup must be kept in the refrigerator (2-8°C) up to 14 days from the day of its preparation. Do not freeze the syrup.

Even if kept in the original container and stored properly according to the manufacturer's recommendations, all medicines have a limited shelf life. Please pay attention to the expiry date of your medicine! If you have any doubts, please consult the dispensing pharmacist. Do not store different medicines in the same container.

Drug Registration License No.:

Pen-Rafa VK 500 caplets: 1375228678

Pen-Rafa VK Forte powder for preparing 60 ml syrup: 1373831570

Manufacturer: Sandoz, Kundl, Austria

Marketed by: Rafa Laboratories Ltd. POB 405, Jerusalem

The format of this leaflet has been set by the Ministry of Health, and its contents has been checked and approved in March 2009.

901004-S