

## **Vancomycin Hydrochloride for Injection USP 250mg Taj Pharma**

Vancomycin Hydrochloride for Injection USP  
500mg Taj Pharma

Vancomycin Hydrochloride for Injection USP  
1000mg Taj Pharma

### **Package Leaflet: Information for the user** Vancomycin

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet**

1. What is Vancomycin and what it is used for
2. What you need to know before you use Vancomycin
3. Using Vancomycin

4. Possible side effects
5. How to store Vancomycin
6. Contents of the pack and other information

#### **1. What Vancomycin is and what it is used for**

Vancomycin is an antibiotic which helps your body fight infections by eliminating certain bacteria that cause infections. Vancomycin is used for the treatment of the following serious infections:

Infections of the bones, lung infections, skin and muscle (soft tissue) infection and infection of the valves or lining of the heart.

Vancomycin can also be used before some types of surgery to prevent possible infections of the lining of the heart.

Vancomycin may also be administered orally in the treatment of:

- inflammation of the lining of the small and large intestine with damage to the mucosa (pseudomembranous colitis) caused by a certain type of bacteria (*Clostridium difficile*), as a result of treatment with antibiotics;
- inflammation of the lining of the small and large intestine (enterocolitis) as a result of a certain type of bacteria (*Staphylococci*).

#### **2. What you need to know before you use Vancomycin**



### **Do not use Vancomycin**

- If you are allergic (hypersensitive) to vancomycin or any other ingredients of this medicine (listed in Section 6).

Tell your doctor if you have had some problems with this product or with others in the past.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Vancomycin.

Before treatment with vancomycin, make sure your doctor knows your medical history, especially:

- If you have kidney problems
- If you have difficulty hearing
- If you are over 65 years old

The rapid injection of Vancomycin can cause low blood pressure, shock, and rarely, cardiac arrest. Stopping the infusion usually results in immediate cessation of these reactions.

Injection site pain, inflammation of the vein wall and blood coagulation may occasionally occur in severe form; slow administration can also reduce these side effects.

If you are allergic to another antibiotic called teicoplanin, you may also be allergic to vancomycin. Please tell your doctor.

If you suffer from renal (kidney) impairment or receive treatment simultaneously with other substances that are

toxic to the kidney, the possibility of developing toxic effects is very high. Your doctor can perform several tests to see if your kidneys and liver are working properly. If you are elderly or have kidney problems, your doctor may also perform regular tests to your hearing and measure the amount of vancomycin in the blood.

Transient or permanent hearing loss, which may be preceded by noises in the ears, can occur in patients with prior deafness treated with excessive doses, or in concomitant treatment with other toxic substances to the ear. To reduce this risk, blood levels should be determined periodically and periodic tests for hearing function are recommended. Prolonged use of Vancomycin may result in over-abundance of resistant organisms, so your doctor will monitor you.

### **Other medicines and Vancomycin**

Tell your doctor, pharmacist or nurse if you are taking or have recently taken, or might take any other medicines. Moreover, do not take any new medicine without consulting your doctor.

The following medicines may react with vancomycin if you take them at the same time, such as medicines for the treatment of:

- infections caused by bacteria (streptomycin, neomycin, gentamicin, kanamycin, amikacin, bacitracin, tobramycin, polymixin B, colistin),

- tuberculosis (viomycin),
- fungal infections (amphotericin B),
- cancer (Cisplatin) and
- medicines for muscle relaxation during anaesthesia,
- anaesthetic agents (if you are going to have general anaesthesia).

Your doctor may need to test your blood and adjust the dosage if vancomycin is given simultaneously with other medicines.

### **Pregnancy**

If you are pregnant, think you may be pregnant or plan to become pregnant, tell your doctor before taking this medicine. Vancomycin should be given during pregnancy and breast-feeding only if clearly needed. Your doctor will decide if you should take Vancomycin.

### **Breast-feeding**

Tell your doctor if you are breastfeeding, since Vancomycin passes into breast milk. Your doctor will decide whether vancomycin is really necessary or whether you should stop breastfeeding.

### **Driving and using machines**

Vancomycin has no or negligible effect on the ability to drive and use machines.

## **3. How to use Vancomycin**

This medicine will always be administered by a healthcare professional. Your doctor will decide at which rate and how long you will be given the medicine. The dose your doctor gives you will depend on your age, weight, kidney function and the severity of the infection.

The amount of medicine in your blood will usually be measured at regular intervals. Your doctor may also do blood tests to check your kidneys and tests to check your ears, especially if you are elderly.

The medicine is given into a vein, usually in your arm, slowly over at least one hour.

### **Dosage**

The dose given to you will take into account your age, the type of infection you have, the functioning of your kidneys, your hearing, and other medicines you may be taking.

### **Adults and children over 12 years:**

The usual dose is 2000 mg per day in 2 or 4 doses.

**Children 1 month to 12 years:** The dosage will be calculated depending on their body weight. The usual intravenous dosage is 10mg/kg per dose given every six hours (total daily dosage 40mg/kg of body weight).

### **Newborn infants (full-term):**

0-7 days of age: A starting dose of 15 mg/kg, followed by 10 mg/kg every 12 hours. 7-30 days of age: A starting dose of 15 mg/kg, followed by



10 mg/kg every 8 hours.

**Patients with impaired renal function, elderly and preterm infants:** The doctor will reduce the dose or increase the interval between two doses.

#### **Oral administration**

##### **Adults and elderly**

The usual daily dose is 500 mg divided into three or four administrations for 7 to 10 days. The total daily dose should not exceed 2000 mg.

##### **Children**

The usual daily dose is 40 mg/kg divided into three or four administrations for 7 to 10 days. The total daily dose should not exceed 2000 mg.

During treatment you may need to have blood and urine tests and possibly hearing tests for signs of any side effects.

##### **Duration of treatment**

The duration of treatment depends on the infection, and can last several weeks.

##### **If you receive more Vancomycin than you should**

As this product will be given to you while you are in the hospital, it is unlikely that you will be given too much. However, tell your doctor or nurse immediately if you have

any concerns.

If you have further questions about using this medicine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

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

**The most common side effects** are pain, swelling and inflammation of veins at the infusion site and pseudo-allergic reactions when intravenous infusion of Vancomycin is carried out too fast.

**Stop taking the medicine immediately** and seek medical attention if any of the following signs of allergic reaction occur:

- hives (nettle rash), swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, dizziness.

If you think you have any of the following side effects or symptoms, tell your doctor as soon as possible:

**Common side effects** (may occur in fewer than 1 in 10 patients):

- decrease in blood pressure

- thrombophlebitis
- dyspnoea
- stridor
- exanthema and mucosal inflammation
- pruritus
- urticaria
- redness of the upper body and face, pain and spasm of the chest and back muscles
- renal insufficiency manifested primarily by increased blood concentrations of creatinine or urea

**Uncommon side effects** (may occur in fewer than 1 in 100 patients):

- temporary or permanent hearing loss

**Rare side effects** (may occur in fewer than 1 in 1,000 patients):

- thrombocytopenia, neutropenia, agranulocytosis, eosinophilia, anaphylactic reactions, hypersensitivity reactions
- tinnitus, dizziness
- vasculitis
- fever, shivering
- nausea, diarrhoea
- interstitial nephritis, acute renal failure

**Very rare side effects** (may occur in fewer than 1 in 10,000 patients):

- exfoliative dermatitis
- Stevens-Johnson syndrome
- Lyell's syndrome
- IgA induced bullous dermatitis
- cardiac arrest
- pseudomembranous enterocolitis

**Side effects of unknown frequency and single reported cases:**

- syndrome that may cause a rash, fever, inflammation of internal organs, and characteristic abnormalities of your blood (so called "DRESS"),
- sudden formation of pustules within large swollen areas (so called "AGEP"),
- acute tubular necrosis.

Severe anaphylactoid reactions are possible during or a short time after fast intravenous infusion. The reactions disappear after the infusion is stopped.

Ototoxicity has primarily been reported in patients given high doses, or concomitant treatment with other ototoxic medicinal products, or with pre-existing reduction in kidney function or hearing.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### **5. How to store Vancomycin**

Before reconstitution: Store below 25°C.



Keep the vial in the outer carton in order to protect from light. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the solution is cloudy or there are particles in suspension.

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 to protect the environment.

### **Contents of the pack and other information What is the composition of Vancomycin**

- The active substance is vancomycin (as hydrochloride).  
Vancomycin 500 mg: Each vial contains 500 mg of vancomycin equivalent to 525,000 IU. Vancomycin 1000 mg: Each vial contains 1000 mg of vancomycin equivalent to 1,050,000 IU.

### **What Vancomycin looks like and contents of the pack**

Vancomycin 500 mg comes in the form of a white or slightly brownish powder in clear glass vials with a rubber stopper and orange aluminium cap.

Vancomycin 1000 mg comes in the form of a white or slightly brownish powder, in clear glass vials with a rubber stopper and white aluminium cap.

Each package contains 1, 5, 10 or 20 vials.

Before use, the powder is dissolved and diluted with an intravenous liquid, obtaining a solution which will be administered to you slowly into a vein (“drip”), by a doctor or nurse.

Each 500 mg vial contains 512.57 mg of vancomycin hydrochloride, equivalent to 500 mg of vancomycin. After reconstitution with 10 ml of water for injections is obtained a solution with a concentration of 50 mg/ml, and after further dilutions a solution with a concentration of 5 mg/ml is obtained.

Each 1000 mg vial contains 1025.16 mg of vancomycin hydrochloride, equivalent to 1000 mg of vancomycin. After reconstitution with 20 ml of water for injections is obtained a solution with a concentration of 50 mg/ml, and after further dilutions a solution with a concentration of 5 mg/ml is obtained.

### **7.Manufactured in India by:**



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