Vancomycin is an antibiotic that belongs to a group of medicines called glycopeptides. It is used to treat infections that are not responding to other antibiotics. Vancomycin is used mainly in severe infections of the lungs, skin, blood, and heart.

### Indications
- **Infections of bone and joints.**
- **Infected surgical wounds and burns.**
- **Septicemia.**

### Administration
- **Peri-operative prophylaxis of bacterial endocarditis.**
- **Infections caused by bacteria resistant to other antibiotics.**

### Dosage
- **Adults and adolescents (from 12 years and over):**
  - The recommended dose is 10 to 15 mg/kg body weight in a single daily infusion.
  - The duration of treatment depends on the infection. For example, for infections such as pneumonia, the duration may be 7 to 14 days.
- **Children:**
  - The recommended dose is an initial dose of 15 to 20 mg/kg body weight, and then 10 to 15 mg/kg body weight every 6 to 12 hours.

### Contraindications
- **Hypersensitivity to vancomycin or similar glycopeptides.**
- **Pregnancy:** The use of vancomycin during pregnancy is not recommended.

### Adverse Effects
- **Skin reactions:** Rash, itching, and redness.
- **Hepatic effects:** Jaundice, liver enzyme elevations.
- **Renal effects:** Nephrotoxicity.

### Warnings and Precautions
- **Hypersensitivity reactions:** Immediate allergic reactions can occur.
- **Drug interactions:** May potentiate the effects of other medicines.

### Special Populations
- **Pregnant women:** Use only if the expected benefit justifies the potential risk to the fetus.
- **Breastfeeding mothers:** Discontinue breastfeeding during therapy with vancomycin.

### Renal Impairment
- **Dose adjustments:** Modifying the dose based on renal function is necessary.

### Laboratory Tests
- **Urinalysis:** To monitor renal function.
- **Liver function tests:** To monitor liver function.

### Additional Information
- **Precautions:** Vancomycin should be used with caution in patients with renal or hepatic impairment.
- **Adverse effects:** May include nausea, vomiting, diarrhea, and headache.

### Administration
- **Dilution:** Concentrate vancomycin in a suitable solvent.
- **Infusion:** Administer over a period of 1 to 2 hours.

### Monitoring
- **Blood counts:** To monitor hematological effects.
- **Liver function tests:** To monitor liver function.

### Pregnancy
- **Risk:** Use only if the potential benefit justifies the potential risk to the fetus.

### Breastfeeding
- **Experience:** Limited.

### Initial Dose
- **Adults and adolescents:** 15 to 20 mg/kg body weight in a single daily infusion.
- **Children:** Initial dose of 15 to 20 mg/kg body weight, followed by 10 to 15 mg/kg body weight every 6 to 12 hours.

### Monitoring
- **Concentration:** Monitor serum vancomycin levels.
- **Renal function:** Monitor renal function.

### Renal Replacement Therapy
- **Continuous renal replacement therapy (CRRT):**
  - Initial dose of 15 to 20 mg/kg body weight in a single daily infusion.
  - Followed by 10 to 15 mg/kg body weight every 6 to 12 hours.

### Renal Function
- **Creatinine clearance:**
  - Men: [Weight \( \times 140 - \text{age (years)} \)/72] x serum creatinine (mg/dl)
  - Women: [Men x 0.85]

### Other Factors
- **Body weight:**
  - Women: [Men x 0.85]
  - Pediatrics: [Age (months) x 140 - weight (kg)] / 72 x serum creatinine (mg/dl)

### Dosage in Special Populations
- **Children:**
  - Initial dose of 15 to 20 mg/kg body weight, followed by 10 to 15 mg/kg body weight every 6 to 12 hours.

### Concomitant Administration
- **Antibacterials:** May potentiate the effects of other antibiotics.
- **Anaesthetic agents:** May potentiate the effects of anaesthetic agents.

### Pregnancy
- **Risk:** Use only if the potential benefit justifies the potential risk to the fetus.

### Breastfeeding
- **Experience:** Limited.

### Additional Information
- **Use in Pregnancy:** Use only if the potential benefit justifies the potential risk to the fetus.
- **Use in Breastfeeding:** Discontinue breastfeeding during therapy with vancomycin.
4. POSSIBLE SIDE EFFECTS

Side effects of vancomycin may occur, although not occurring often. Slightly more common side effects may include:

- Rash
- Itching
- Nausea
- Vomiting
- Diarrhea
- Pain in muscles and joints
- Fever
- Headache

Rare side effects include:

- Blood vessel inflammation
- Increase in some of the white cells in the blood
- Nephritis and/or nephrosis
- Impairment of the bone marrow leading to the suppression of the production of red blood cells, white blood cells and platelets

These side effects are only rare. However, if they occur, consult a health care professional immediately.

Other side effects that may be caused by vancomycin are:

- Shock (may affect up to 1 in 10,000 people)
- Infusion reactions (may affect up to 1 in 1000 people)
- Rare cases of anaphylactic reaction (anaphylactic shock) are rare. Tell your doctor immediately if you experience any symptoms of anaphylactic shock.

5. HOW TO STORE VANCOMYCIN

Keep the medicine in the original packaging to protect from light and moisture.

- Store below 25 ºC.
- Do not freeze the product.

6. ADDITIONAL INFORMATION

For detailed information about the preparation of the solution, see section 6.3 of the SmPC.

Further dosage information

Dosage is based on the individual requirements of each patient. Contact your doctor for information on the right dosage for you.

How to use reconstituted solution

- Reconstituted solution: 500 mg/50 ml or 1000 mg/100 ml
- After reconstitution, the solution is clear and free from particles.
- Appearance of reconstituted concentrate
- Follow the instructions provided by the manufacturer for any other additional information.

Before administering

- Follow the instructions provided by the manufacturer for any other additional information.
- Consult with healthcare professionals before use.

7. COMBAT RESISTANCE

When reconstituted with 20 ml of water for injections, the resulting concentrate for solution for infusion contains 50 mg/ml vancomycin.

- The active substance is vancomycin (as hydrochloride).