Vantin (also known as Cefpodoxime) tablets are indicated for the treatment of infections caused by the following susceptible organisms:

- Upper respiratory tract infections caused by organisms sensitive to Vantin, including sinusitis. In tonsillitis and pharyngitis, Vantin should be reserved for recurrent and chronic infections or infections with known or suspected resistance of the cause of infection to antibiotics commonly used.
- Lower respiratory tract infections caused by organisms sensitive to Vantin, bronchitis including acute, relapse or exacerbation of chronic bronchitis, and bacterial pneumonia.
- Infections of the upper and lower urinary tract caused by organisms susceptible to Vantin including cystitis and acute pyelonephritis.
- Infections of skin and soft tissue infections caused by organisms sensitive on Vantin such as abscesses, cellulitis, infectious wounds, furunculi, folliculitis and ulcers.
- Gonorrhea - uncomplicated gonococcal urethritis.

### Dosage and administration

Adults with normal renal function:

- Sinusitis: 200 mg twice daily.
- Pharyngitis, tonsillitis: 100 mg twice daily.
- Acute bronchitis, exacerbation of chronic bronchitis and bacterial pneumonia: 100-200 mg two times a day, depending on the severity of the infection.
- Uncomplicated lower urinary tract infections: 100 mg twice daily.
• Uncomplicated upper urinary tract infections: 200 mg twice a day.
• Skin and soft tissue infections: 200 mg twice daily.
• Uncomplicated gonococcal urethritis: 200 mg should be taken as a single dose

Elderly: Dose adjustment is not necessary in elderly patients with normal renal function.

Children: The recommended dosage for children is 8 mg/kg body weight/day administered in two divided dose in the 12-hour interval. Vantin oral suspension is available for the treatment of infants (older than 15 days) and children.

Liver damage: Dose adjustment is not necessary in the case of damage to the liver.

Kidney damage: It is not necessary dose adjustment Vantin if creatinine clearance exceeds 40 ml/min. Below this value, the elimination half-life is prolonged and the increase of maximum plasma concentration, which necessitates corresponding adaptation of the dose.

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>39-10</td>
<td>A single dose administered as a single dose every 24 hours (e.g., half of the usual dosage for adults)</td>
</tr>
<tr>
<td>10</td>
<td>A single dose administered as a single dose every 48 hours (for example, a quarter of the usual dose for adults)</td>
</tr>
<tr>
<td>Patients on hemodialysis</td>
<td>A single dose was applied after each dialysis treatment</td>
</tr>
</tbody>
</table>

A single dose is 100 mg, or 200 mg, depending on the type of infection. The duration of treatment depends on the patient, the indication and the causative pathogen.

Method of application: Apply through the mouth. Tablets should be taken with food because optimal absorption.

**Warning and precautions**

Do not use this medicine if:

• You have a hypersensitivity to Vantin or a cephalosporin antibiotics such as:
  ○ cefaclor (*Raniclor*),
  ○ cefadroxil (*Duricef*),
  ○ cefazolin (*Ancef*),
  ○ cefdinir (*Omnicef*),
  ○ cefditoren (*Spectracef*),
  ○ cefprozil (*Cefzil*),
  ○ cefuroxime (*Ceftin*),
  ○ cephalaxin (*Keflex*),
  ○ cephradine (*Velosef*),
  ○ ceftazidime.

• Serious hypersensitivity reactions (e.g. anaphylactic reactions) on any beta-lactam antibiotics (*penicillins, monobactams or carbapenems*) in history.

Before prescribing cephalosporins it is necessary to examine whether is present hypersensitivity
to penicillins, since the crossover occurs in the sensitization of 5-10% of the cases. Particular caution is required in patients hypersensitive to penicillin: strict medical supervision is required from the first dose. When there is a doubt, medical assistance must be available at the beginning of the application in the case of treatment of anaphylactic episodes.

In patients who are allergic to other cephalosporins, it is necessary to think of the possibility of cruciate hypersensitivity to Vantin.

Vantin should not be given to patients who previously had early type hypersensitivity to cephalosporins. Hypersensitivity reactions (anaphylaxis) observed with beta-lactam antibiotics can be serious and sometimes fatal. Report of any event that indicates that there is sensitivity, it is necessary to interrupt the treatment.

Vantin should be the antibiotic of choice for treatment of staphylococcal pneumonia and should not be used in the treatment of atypical pneumonia caused by organisms such as Legionella, Mycoplasma and Chlamydia. In cases of severe renal insufficiency, it may be necessary to reduce the dose according to the creatinine clearance.

Possible side effects include gastrointestinal disturbances such as:

1. nausea,
2. vomiting,
3. abdominal pain.

Antibiotics should always be prescribed with caution in patients with a history of gastrointestinal disease, particularly colitis. Vantin may cause diarrhea, colitis associated with the use of antibiotics and pseudomembranous colitis. These side effects can occur more often in patients receiving higher doses over a longer period, and they should be considered as potentially serious.

It is necessary to investigate the presence of C. difficile. In all potential cases of colitis, treatment must be immediately discontinued. It is necessary to confirm the diagnosis with sigmoidoscopy and if deemed clinically necessary should consider introducing the substitution antibiotic therapy (vancomycin).

Application of products who lead to fecal routes, should be avoided. Although any of the antibiotic can cause pseudomembranous colitis, a risk is higher in a wide range of medicines, such as cephalosporins. Agranulocytosis, especially during prolonged treatment, can be caused. In cases of treatment lasting longer 10 days, it is necessary to check blood counts and discontinue treatment if neutropenia occurred.

Cephalosporins may be absorbed onto the surface of the membrane of red blood cells and react with an antibody directed against the medicine. This may cause the positive Coombs' test, and, rare, a hemolytic anemia. Cross-reactions of this reaction can occur with penicillin. Changes in kidney function were observed with the antibiotics of the same group, especially when are administered simultaneously with potentially nephrotoxic medicines such as aminoglycosides, and/or potent diuretics. In such cases, it is necessary to monitor the function of the kidneys.

As with other antibiotics, prolonged use of Vantin may lead to growth of nonsusceptible organisms. With oral antibiotics a normal flora may be a column changed, allowing the growth of Clostridia with consequent pseudomembranous colitis. It is necessary to repeatedly review the patient and if superinfection occurs during treatment is necessary to take adequate measures.
Use with other medicines (*Interactions*)

During clinical trials have not observed any significant interactions with other medicines. Histamine H$_2$ receptor antagonists (*ranitidine, famotidine, nizatidine, cimetidine*) and antacids reduce the bioavailability of Vantin.

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Tests show that the reduced bioavailability by approximately 30% when the Vantin applying the medicine to neutralize the pH of the stomach and inhibiting the secretion of acid. Therefore the medicines such as antacids and H$_2$ type mineral -blockers such as:

- ranitidine,
- famotidine,
- nizatidine,

which may lead to an increase in the pH of the stomach to be taken 2-3 hours after administration of Vantin. The bioavailability is increased when the medicine is administered during the meal. False- positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution or with copper sulphate test tablets, but not with tests based on enzymatic the reaction of glucose oxidase.

- Antiviral medicines
  - adefovir,
  - cidofovir,
  - foscarnet.
- Diuretics
  - furosemide,
  - torasemide,
  - bumetanide,
  - indapamide,
  - hydrochlorothiazide,
  - spironolactone.
- Medicines used to treat ulcerative colitis
  - mesalazine,
  - sulfasalazine.
- Cancer medicines
  - carmustine,
  - cisplatin,
  - oxaliplatin,
  - plicamycin,
  - streptozocin,
  - aldesleukin.
- pain medicine
  - aspirin,
  - acetaminophen,
  - naproxen,
  - diclofenac,
  - ibuprofen,
  - etodolac,
- indomethacin.
- and medicines used to prevent organ transplant rejection
  - sirolimus,
  - tacrolimus.

please inform your doctor!

### Pregnancy and lactation

The tests conducted in several species of animals showed no teratogenic or fetotoxic effects. However, the safety of Vantin in pregnancy has not been established and, as other medicines, it should be taken with caution during the first months of pregnancy. Vantin is excreted in breast milk. It should stop using Vantin or breastfeeding in mothers who are breastfeeding.

### Effects on ability to drive and use machines

Caution is advised because of the risk of occurrence of vertigo.

### Side effects

Reported adverse events were classified according to the categories described below:

- system organ class and frequency. The frequency is defined as follows:
  - very often (1/10),
  - common (>= 1/100 1/10),
  - uncommon (>= 1/1000 of and 1/100),
  - rare (>= 1/10, 000 and to 1/1000)
  - and very rare (1/10, 000),
  - not known (can not be estimated from available data). Within each organ system side effects are listed by severity.

#### Blood and lymphatic system:

- Rare: Hematological disorders, as well as a reduction in hemoglobin, thrombocytosis, thrombocytopenia, leucopenia and eosinophilia.
- Very rare: Hemolytic anemia. As with other Beta-lactam (antibiotics) neutropenia and more rarely agranulocytosis may be develop during treatment with cefpodoksime, especially if it is used for prolonged periods.

#### Ear and labyrinth disorders:

- Uncommon: Tinnitus.

#### Gastrointestinal disorders:

- Common:
  1. Pressure in the stomach,
  2. nausea,
  3. vomiting,
  4. abdominal pain,
  5. bloating,
6. diarrhea. Bloody diarrhea can occur as a symptom of enterocolitis. It is necessary to consider the possibility of pseudomembranous colitis if during or after treatment occur a severe and persistent diarrhea.

General disorders on administration place:

- Uncommon: Asthenia or fatigue.

Hepatobiliary disorders:

- Rare: Transient mild elevation of serum values of AST, ALT and alkaline phosphatase and/or serum bilirubin. These laboratory findings, which may be explained by infection, may rarely be twice higher than the upper value of the reference interval of each analyte and confirm the cause of hepatic damage, usually cholestatic and usually asymptomatic.
- Very rarely: Liver damage.

Immune system disorders: Hypersensitivity reactions were observed, and all degrees of severity.

- Uncommon:
  - Allergic reactions,
  - mucocutaneous reactions,
  - skin rashes,
  - urticaria,
  - and pruritus.
- Very rare: Skin reactions with blistering (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis). The treatment should be stopped in case of occurrence these symptoms. As with other cephalosporins, very rarely there were reports of anaphylactic reactions, bronchospasm, purpura, angioedema, reactions similar serum sickness, fever and arthralgia.

Infections and infestations: There may be a breeding insensitive organisms. Metabolism and nutrition disorders:

- Common: Loss of appetite.

Nervous system disorders:

- Uncommon: headache, paresthesia, vertigo.

Renal and urinary system disorders:

- Very rare: A slight increase in urea and creatinine levels. Changes in kidney function were observed with the antibiotics of the same class, and which is Vantin, especially when it is applied simultaneously with the aminoglycosides, and/or strong diuretics.

### Overdose

In case of overdose with Vantin it should be taken supportive and symptomatic measures. In the event of an overdose particularly in patients with acute renal failure may occur encephalopathy. Encephalopathy is usually reversible, when the level of cepodoxime in plasma fall.