

## **Package leaflet: Information for the user**

### **Doktacillin 1 g powder for solution for injection/infusion**

### **Doktacillin 2 g powder for solution for injection/infusion**

#### **Ampicillin**

**Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

1. What Doktacillin is and what it is used for
2. What you need to know before you are given Doktacillin
3. How Doktacillin is given
4. Possible side effects
5. How to store Doktacillin
6. Contents of the pack and other information

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

Doktacillin is a medicine used for treatment of bacterial infections (antibiotic) and works by killing bacteria that cause infections. The active substance is ampicillin which belongs to the group of medicines called penicillins. Doktacillin is used to treat infections caused by bacteria susceptible to ampicillin.

Doktacillin is used to treat the following conditions:

- acute exacerbation of bronchitis
- upper urinary tract infection
- heart valve infection
- blood poisoning
- meningitis caused by a bacterium called listeria
- severe infections in newborns.
- pneumonia when penicillin has failed or is unsuitable for other reasons

#### **2. What you need to know before you are given Doktacillin**

##### **You should not be given Doktacillin:**

- if you are allergic to ampicillin or other penicillins.

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given Doktacillin:

- if you are allergic to cephalosporins (another group of antibacterial medicines).

##### **Inflammation of the large intestine**

Be particularly alert to symptoms suggestive of inflammation of the large intestine such as watery diarrhoea, often containing blood and mucus, abdominal pain and/or fever. See section 4.

##### **Urine tests**

Doktacillin may alter the results of some laboratory tests. Tell your doctor or nurse that you are being given Doktacillin if you have to provide a urine sample for glucose measurement.

### **Other medicines and Doktacillin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Doktacillin can affect or be affected by other medicines, such as:

- allopurinol (a medicine used to treat gout). It may be more likely that you will develop an allergic skin reaction
- methotrexate (a medicine used to treat cancer or rheumatism). There is an increased risk of side effects from methotrexate.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### **Driving and using machines**

There is no information to indicate that Doktacillin affects a patient's ability to drive or operate machines.

You are responsible for judging whether you are in a fit condition to drive a motor vehicle or perform other tasks that demand focused concentration. One of the factors that can affect your abilities in these respects is the use of medicines due to their effects and/or side effects. Descriptions of these effects and side effects can be found in other sections. Therefore read all the information in this leaflet for guidance. Check with your doctor or pharmacist if you are not sure.

### **Doktacillin contains sodium**

Doktacillin 1 g

This medicine contains 65.8 mg sodium (main component of cooking/table salt) in each injection vial. This is equivalent to 3.3% of the recommended maximum daily dietary intake of sodium for an adult.

Doktacillin 2 g

This medicine contains 131.6 mg sodium (main component of cooking/table salt) in each injection vial. This is equivalent to 6.6% of the recommended maximum daily dietary intake of sodium for an adult.

## **3. How Doktacillin is given**

This medicine will be administered by a healthcare professional. It will be injected into a muscle or blood vessel or given as a drip (infusion) in a blood vessel.

Your doctor will determine the appropriate dose for you/your child. The dose depends on the type, location and severity of the infection.

### **If you are given more Doktacillin than you should**

If you are given more Doktacillin than you should or if, for example, a child has taken the medicine accidentally, talk to your doctor, hospital or Poisons Information Centre (tel. 112) for risk assessment and advice.

Signs of Doktacillin overdose may include nausea, vomiting, diarrhoea, reduced level of consciousness, involuntary muscle twitching, seizures, coma, kidney failure. In exceptional cases, a severe acute allergic reaction (anaphylactic reaction) may occur within 20–40 minutes.

If you have any further questions on the use of 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.

**Contact your doctor immediately if you experience any of the following serious side effects:**

- Severe acute allergic reaction (anaphylactic reaction). Such reactions are potentially life-threatening. One or more of the following symptoms may occur: skin redness, itchy hive-like rash (urticaria), breathlessness and dizziness (*rare, may affect up to 1 in 1,000 patients*).
- Doktacillin can affect white blood cells so that your immune system is weakened. If you get an infection with symptoms such as fever and severe debilitation, or fever with local infection symptoms such as a sore throat/pharynx/mouth or urinary problems, you should contact your doctor at once for blood tests to exclude a deficiency of white blood cells (agranulocytosis). It is important that you then provide information about your medication (*uncommon, may affect up to 1 in 100 patients*).
- Inflammation of the large intestine with symptoms such as watery diarrhoea, often containing blood and mucus, abdominal pain and/or fever (*uncommon, may affect up to 1 in 100 patients*)

**Other possible side effects:**

**Common** (*may affect up to 1 in 10 patients*):

- Loose stools
- Skin rashes

**Uncommon** (*may affect up to 1 in 100 patients*):

- Reduction in red blood cell count causing pale skin, weakness and breathlessness (anaemia)
- Reduction in blood platelet count (thrombocytopaenia)
- Reduction or increase of white blood cell count (leukopaenia, eosinophilia)
- Inflammation of the tongue and oral mucosa
- Nausea and vomiting
- Inflammation of the large intestine
- Diarrhoea
- Hives

**Rare** (*may affect up to 1 in 1,000 patients*):

- Severe inflammation of the skin with scaling (exfoliative dermatitis)
- Skin lesions, sometimes severe (erythema multiforme)

Fungal overgrowth in the oral cavity and vagina may occur. Local pain may occur after intramuscular injection.

Elevation of liver enzymes may occur.

**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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The Swedish Medical Products Agency  
Box 26  
751 03 Uppsala  
[www.lakemedelsverket.se](http://www.lakemedelsverket.se)

**5. How to store Doktacillin**

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

The reconstituted solution should be used immediately after preparation.

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

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. Contents of the pack and other information

### What Doktacillin contains

- The active substance is ampicillin. Each vial contains ampicillin sodium equivalent to 1 g or 2 g ampicillin.
- There are no other ingredients.

### What Doktacillin looks like and contents of the pack

Powder for solution for injection/infusion.

White to off-white powder.

Pack sizes:

Vial 10 x 1 g and 10 x 2 g.

### Marketing Authorisation Holder

Meda AB

Box 906

170 09 Solna

Tel.: 08-630 19 00

**This leaflet was last revised: 2020-11-13**

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**The following information is intended for healthcare professionals only:**

#### Osmolality

1 g Doktacillin contains 3 mmol Na<sup>+</sup> which is equivalent to approx. 20 ml isotonic sodium chloride solution. The osmolality of the final solution is dependent on the amount of Doktacillin used and which solvent is used for dilution.

#### Reconstitution instructions for solution for injection/infusion

Depending on the amount of Doktacillin to be administered, water for injections or sodium chloride solution is recommended for dilution (see table below).

| <i>Type of solution</i>              | <i>Instructions for reconstitution</i>                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Solution for intramuscular injection | 1 g should be dissolved in 4 ml water for injections.                                                                                                                                                                                                                                                                                                                                                                               |
| Solution for intravenous injection   | 1 g should be dissolved in 10 ml water for injections,<br>2 g should be dissolved in 20 ml water for injections.                                                                                                                                                                                                                                                                                                                    |
| Solution for intermittent infusion   | 1 g should be dissolved in 100 ml isotonic sodium chloride solution,<br>2 g should be dissolved in 100 ml water for injections or isotonic sodium chloride solution.<br>Preferably, the solution obtained should be administered through a multi-way stopcock. The solution should be infused over 20–30 minutes.<br>Mini-Set: The solution should be prepared in a Mini-bag plastic container with the help of a transfer adapter. |

|                                  |                                                                                                                                                                                                                                                                        |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Solution for continuous infusion | 2 g should be dissolved in 15 ml water for injections<br>The obtained solution should be mixed with an appropriate infusion solution: Isotonic sodium chloride solution, Ringer's acetate, glucose solution 50 mg/ml with sodium and potassium, Rehydrex with glucose. |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Shelf life

Injectable solutions should be used immediately after reconstitution. Freshly prepared solutions may have a yellowish colour.

Solutions intended for infusion must be added to the infusion immediately.

#### Incompatibilities

In the absence of compatibility studies, penicillin solutions should not be mixed with other medicinal products.