

Summary Public Assessment Report

Piperacillin/Tazobactam Reig Jofre (piperacillin sodium, tazobactam sodium)

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piperacillin sodium, tazobactam sodium

Powder for solution for infusion, 2 g/0,25 g, 4 g/0,5 g

This is a summary of the public assessment report (PAR) for Piperacillin/Tazobactam Reig Jofre. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Piperacillin/Tazobactam Reig Jofre and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Tazocin.

Piperacillin/Tazobactam Reig Jofre is used in adults and adolescents aged above 12 years to treat bacterial infections, such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, skin or blood. Piperacillin/Tazobactam Reig Jofre may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobactam Reig Jofre is used in children aged 2-12 years to treat infections of the abdomen such as appendicitis, peritonitis (infection of the fluid and lining of the abdominal organs), and gallbladder (biliary) infections. Piperacillin/Tazobactam Reig Jofre may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

In certain serious infections, Piperacillin/Tazobactam Reig Jofre may be used in combination with other antibiotics.

How does Piperacillin/Tazobactam Reig Jofre work?

Piperacillin belongs to the group of medicines known as "broad-spectrum penicillin antibiotics". It can kill many kinds of bacteria. Piperacillin/Tazobactam Reig Jofre can prevent some resistant bacteria from surviving the effects of piperacillin. This means that when piperacillin and tazobactam are given together, more types of bacteria are killed.

How is Piperacillin/Tazobactam Reig Jofre used?

The pharmaceutical form is powder for solution for infusion for intravenous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Piperacillin/Tazobactam Reig Jofre have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Tazocin.

What are the possible side effects from Piperacillin/Tazobactam Reig Jofre?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Piperacillin/Tazobactam Reig Jofre approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Tazocin, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Piperacillin/Tazobactam Reig Jofre?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Piperacillin/Tazobactam Reig Jofre

The full PAR for Piperacillin/Tazobactam Reig Jofre can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Piperacillin/Tazobactam Reig Jofre, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-05.