

# **Summary Public Assessment Report**

## **Piperacillin/Tazobactam STADA**

**(piperacillin, tazobactam, tazobactam sodium,  
piperacillin sodium)**

**SE/H/2107/01-02/DC**

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Piperacillin/Tazobactam STADA

piperacillin, tazobactam, tazobactam sodium, piperacillin sodium

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

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

For practical information about using Piperacillin/Tazobactam STADA, patients should read the package leaflet or contact their doctor or pharmacist.

## **What is Piperacillin/Tazobactam STADA and what is it used for?**

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

The company has provided additional own data to demonstrate the safety and efficacy of Piperacillin/Tazobactam STADA regarding this difference from the reference medicine.

Piperacillin/Tazobactam STADA is used in adults and adolescents to treat bacterial infections, such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, skin or blood.

Piperacillin/Tazobactam STADA may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

## **How does Piperacillin/Tazobactam STADA work?**

Piperacillin belongs to the group of medicines known as "broad-spectrum penicillin antibiotics". It can kill many kinds of bacteria.

Tazobactam 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 STADA used?**

The pharmaceutical form of Piperacillin/Tazobactam STADA is, powder for solution for infusion.

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 STADA have been shown in studies?**

No additional studies were needed as Piperacillin/Tazobactam STADA 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 STADA?**

Because Piperacillin/Tazobactam STADA 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 STADA approved?**

It was concluded that, in accordance with EU requirements, Piperacillin/Tazobactam STADA has been shown to have comparable quality and is considered to be similar to the reference medicine Tazocin. 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 STADA?**

A risk management plan has been developed to ensure that Piperacillin/Tazobactam STADA 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 for Piperacillin/Tazobactam STADA, 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 STADA**

The full PAR for Piperacillin/Tazobactam STADA can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Piperacillin/Tazobactam STADA

This summary was last updated in 2021-11.