# EU Risk Management Plan for

Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion
Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion

| **RMP version to be assessed as part of this application:** | |
|---|---|
| RMP Version number | 0.1 |
| Data lock point for this RMP | 29 June 2025 |
| Date of final sign-off | 03-07-2026 |
| Rationale for submitting an updated RMP | Not applicable for initial marketing authorisation application submission |
| Summary of significant changes in this RMP | None |
| Other RMP versions under evaluation | None |
| Procedure Number | Italy National (AIN/2024/1401) |
| Previously Evaluated version | None |
| QPPV name | Sisir Gupta |
| QPPV Signature |  |
| Date | 03-07-2026 |

# Part VI: Summary of the risk management plan

## Product 1: 200 mg

Summary of risk management plan for Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion (Teicoplanin)

This is a summary of the risk management plan (RMP) for Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion . The RMP details important risks of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion how these risks can be minimized, and how more information will be obtained about Teicoplanin SGS Pharma´s 200 mg Powder for solution for injection/infusion risks and uncertainties (missing information).

Teicoplanin SGS Pharma´s 200 mg Powder for solution for injection/infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Teicoplanin SGS Pharma´s 200 mg Powder for solution for injection/infusion risk management plan.

## I. The medicine and what it is used for

Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion is authorised in adults and in children from birth for the parenteral treatment of the following infections:

- complicated skin and soft tissue infections,
- bone and joint infections,
- hospital acquired pneumonia,
- community acquired pneumonia,
- complicated urinary tract infections,
- infective endocarditis,
- peritonitis associated with Continuous Ambulatory Peritoneal Dialysis (CAPD),
- bacteraemia that occurs in association with any of the indications listed above.

Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion is also indicated as an alternative oral treatment for Clostridium difficile infection-associated diarrhoea and colitis.

Where appropriate Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion should be administered in combination with other antibacterial agents (see SmPC for the full indication).

It contains teicoplanin as the active substance and it is given by oral route or injection/infusion.

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion , together with measures to minimise such risks and the proposed studies for learning more about Teicoplanin SGS Pharma´s 200 mg Powder for solution for injection/infusion risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;

- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (with prescription only) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.
In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion is not yet available, it is listed under 'missing information' below.

### *II.A List of important risks and missing information*

Important risks of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion . Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

| List of important risks and missing information | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

### *II.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal product.

### *II.C Post-authorisation development plan*

### *II.C.1 Studies which are conditions of the marketing authorisation*

There are no studies which are conditions of the marketing authorisation or specific obligation

of Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion .

### *II.C.2 Other studies in post-authorisation development plan*

There are no studies required for Teicoplanin SGS Pharma 200 mg Powder for solution for injection/infusion .

## Product 2: 400 mg

Summary of risk management plan for Teicoplanin SGS Pharma 400 mg powder for solution for injection/infusion (Teicoplanin)

This is a summary of the risk management plan (RMP) for Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion . The RMP details important risks of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion how these risks can be minimized, and how more information will be obtained about Teicoplanin SGS Pharma´s 400 mg Powder for solution for injection/infusion risks and uncertainties (missing information).

Teicoplanin SGS Pharma´s 400 mg Powder for solution for injection/infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion should be used. Important new concerns or changes to the current ones will be included in updates of Teicoplanin SGS Pharma´s 400 mg Powder for solution for injection/infusion risk management plan.

### I. The medicine and what it is used for

**Teicoplanin SGS Pharma 400 mg** Powder for solution for injection/infusion is authorised in adults and in children from birth for the parenteral treatment of the following infections:

- complicated skin and soft tissue infections,
- bone and joint infections,
- hospital acquired pneumonia,
- community acquired pneumonia,
- complicated urinary tract infections,
- infective endocarditis,
- peritonitis associated with Continuous Ambulatory Peritoneal Dialysis (CAPD),
- bacteraemia that occurs in association with any of the indications listed above.

Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion is also indicated as an alternative oral treatment for Clostridium difficile infection-associated diarrhoea and colitis.

Where appropriate Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion should be administered in combination with other antibacterial agents (see SmPC for the full indication).

It contains teicoplanin as the active substance and it is given by oral route or injection/infusion.

### II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion , together with measures to minimise such risks and the proposed studies for learning more about Teicoplanin SGS Pharma´s 400 mg Powder for solution for injection/infusion risks, are outlined below.
Measures to minimise the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;

- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (with prescription only) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion is not yet available, it is listed under 'missing information' below.

### *II.A List of important risks and missing information*

Important risks of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion , are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion . Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

### *II.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal product.

### *II.C Post-authorisation development plan*

#### II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion .

#### II.C.2 Other studies in post-authorisation development plan

There are no studies required for Teicoplanin SGS Pharma 400 mg Powder for solution for injection/infusion .