



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Questions and answers on Targocid and associated names (teicoplanin, powder or powder and solvent for solution for injection, infusion or oral solution, 100, 200 and 400 mg)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 30 May 2013, the European Medicines Agency completed a review of Targocid. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Targocid in the European Union (EU).

### What is Targocid?

Targocid is an antibiotic that contains the active substance teicoplanin. It is used by injection or infusion (drip) to treat serious bacterial infections. It can also be given by mouth to treat diarrhoea and colitis (inflammation of the bowel) caused by infection with a bacterium called *Clostridium difficile*.

The active substance, teicoplanin, is one of a group of antibiotics known as glycopeptides. It works by attaching to the surface of bacteria. This prevents the bacteria from building their cell walls, and eventually kills them.

Targocid is also available in the EU under other trade names: Targosid, Teicomid.

The company that markets these medicines is Sanofi-Aventis.

### Why was Targocid reviewed?

Targocid is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Targocid was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 17 November 2011, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Targocid in the EU.



## What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

### 4.1 Therapeutic indications

The CHMP agreed that Targocid should be used by injection or infusion to treat the following infections in adults and children:

- complicated infections of the skin and soft-tissues;
- bone and joint infections;
- hospital- or community-acquired pneumonia (infection of the lung caught in or outside hospital);
- complicated urinary tract infections (infections of the structures that carry urine);
- endocarditis (infection of the inner lining of the heart – most commonly the valves of the heart);
- peritonitis (inflammation of the peritoneum, the membrane lining the abdominal cavity) in patients undergoing 'continuous ambulatory peritoneal dialysis';
- bacteraemia (bacterial infection in the blood) resulting from any of the above.

The Committee also agreed that Targocid could be taken by mouth to treat diarrhoea and colitis (inflammation of the bowel) associated with infection by bacteria called *Clostridium difficile*.

The Committee did not recommend the use of Targocid to prevent infections.

Since Targocid is only effective against certain kinds of bacteria, it should be used in combination with other antibiotics if necessary, and in line with official recommendations on antibiotic use.

### 4.2 Posology and method of administration

The Committee also agreed on specific dose ranges for adults and children (from birth) for the various infections. This includes initial doses as well as doses for maintenance treatment and doses to be used in patients with reduced kidney function. For certain types of infections, a higher initial dose of 12 mg per kg body-weight twice daily (used in a few member states of the EU), was agreed by the CHMP. The amount of the medicine in the blood should be measured to ensure that effective levels have been reached.

### 4.4 Special warnings and precautions for use

The CHMP agreed to harmonise the warnings and precautions for the medicine. These include the fact that Targocid may cause serious life-threatening hypersensitivity (allergic) reactions which require immediate cessation of the medicine and emergency treatment; care is needed in patients who are allergic to another antibiotic, vancomycin, as they may be at greater risk. Other possible effects for which treatment may need to be stopped or altered include infusion-related reactions called 'red man syndrome', severe skin rashes, thrombocytopenia (low blood-levels of cells called platelets that are important for clotting), kidney damage, and effects on hearing. Regular blood and kidney function tests and monitoring of any effects on hearing are recommended during treatment. Patients should be particularly carefully monitored if given higher initial doses (12 mg per kg body-weight twice daily).

Targocid should be used to treat severe infections where standard antibiotic treatment is not suitable. It is only effective against certain types of bacteria (called Gram-positive bacteria) and should be used

in combination with other antibiotics if necessary. Prolonged use may encourage the growth of bacteria against which it is not active.

#### Other changes

The Committee also harmonised other sections of the SmPC, including sections 4.3 (contra-indications), 4.5 (interactions with other medicines), 4.6 (use in pregnancy and breast feeding), 4.8 (undesirable effects), 5.1 (pharmacodynamic properties), 5.2 (pharmacokinetic properties) and 5.3 (preclinical safety data).

The Committee asked the company that markets the medicine to submit a risk management plan for the safe use of Targocid, including a study to monitor the safety of the increased initial dose recommendations (12 mg per kg body-weight twice daily).

The amended information to doctors and patients is available [here](#).

The European Commission issued a decision on 12 September 2013.