29th September 2014

Product Information Update for Healthcare Professionals

Re: Targocid (teicoplanin) 400mg Powder and Solvent for Solution for Injection/infusion or oral solution PA 540/21/2
Targocid (teicoplanin) 200mg Powder and Solvent for Solution for Injection/infusion or oral solution PA 540/21/1

Important Update to Indications, Dosage and Duration of Use

Dear Healthcare Professional,

The product information for Targocid (teicoplanin) has been updated following a harmonisation procedure (European Commission Decision on Article 30 referral procedure EMEA/H/A-30/1301, issued September 12th 2013). Sanofi confirms that the Summary of Product Characteristics, (SmPC) Labelling and Package Information Leaflets on the Irish market have been updated (Please note that there may be a period of time when packs with both old and new information are available on the Irish market).

All sections of the Targocid SmPC have changed, including sections 4.1 Therapeutic Indications and 4.2 Posology and method of administration.

The most significant updates to both sections 4.1 & 4.2 are summarised below. This communication does not highlight all changes to the product information. Healthcare Professionals should refer to the updated Summary of Product Characteristics (SmPC) and Package Information Leaflets for full prescribing information, which are available at www.hpra.ie. and www.medicines.ie.

Section 4.1 Therapeutic Indications: General indications have been replaced with more specific indications outlined below. Please note a new indication for **oral treatment** for Clostridium difficile infection associated diarrhoea and colitis has been added.

New indications for Targocid:

Targocid is indicated 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.*

Targocid is also indicated as an alternative oral treatment for Clostridium difficile infection associated diarrhoea and colitis

Where appropriate, teicoplanin should be administered in combination with other antibacterial agents

Please note: Targocid is no longer recommended as antimicrobial prophylaxis in orthopaedic and vascular surgery at risk of gram-positive infection.

The above changes to section 4.1 have been made as a result of an EU harmonisation procedure.

Section 4.2: Posology and Method of Administration: The posology for adults and children has been revised to reflect the specified indications. In addition, specific targeted trough concentrations are provided for each of the approved indications in adults.

Adults and elderly patients with normal renal function:

Indications	***Loading dose***		***Maintenance dose***	
	Loading dose regimen	***Targeted trough concentrations at day 3 to 5***	***Maintenance dose***	***Targeted trough concentrations during maintenance***
Complicated skin and soft tissue infections Pneumonia *Complicated urinary tract infections*	*400mg intravenous or intramuscular (this equates to approximately 6mg/kg body weight) every 12 hours for 3 administrations*	*>15mg/L1*	*6mg/kg body weight intravenous or intramuscular once a day*	*>15 mg/L[1] once a week*
Bone and joint infections	*800mg intravenous (this equates to approximately 12mg/kg body weight) every 12 hours for 3 to 5 administrations*	*>20 mg/L[1]*	*12mg/kg body weight intravenous or intramuscular once a day*	*>20mg/L[1]*
Infective endocarditis	*800mg intravenous (this equates to approximately 12mg/kg body weight) every 12 hours for 3 to 5 administrations*	*30-40mg/L[1]*	*12mg/kg body weight intravenous or intramuscular once a day*	*>30mg/L[1]*

[1] *Measured by FPIA*

Duration of treatment

The duration of treatment should be decided based on the clinical response. For infective endocarditis a minimum of 21 days is usually considered appropriate. Treatment should not exceed 4 months.

Clostridium difficile infection-associated diarrhea and colitis
The recommended dose is 100-200 mg administered orally twice a day for 7 to 14 days.

Children & patients with renal impairment – For updates to the posology and administration for these patients please refer to the Summary of Product Characteristics (SmPC) which can be found on www.hpra.ie. and www.medicines.ie. **Please ensure that all relevant staff are made aware of the content of this letter.**

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
Adverse events should also be reported to Sanofi Ireland Ltd. directly.

Company contact point

If you have any questions or require additional information, please contact Medical Information at sanofi -aventis Ireland Limited T/A SANOFI, Citywest Business Campus, Dublin 24, Ireland.
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Yours Sincerely,

Dr. Mark Toms
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