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# Questions and answers on Tavanic (levofloxacin; 250 and 500 mg film-coated tablets and 5mg/ml solution for infusion)

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

On 24 May 2012 the European Medicines Agency completed a review of Tavanic. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the product information for Tavanic in the European Union (EU).

## What is Tavanic?

Tavanic is an antibiotic that belongs to the group 'fluoroquinolones'. It works by blocking an enzyme that bacteria use to make copies of their DNA. By doing this, it stops the bacteria that are causing an infection from growing and multiplying. Tavanic is currently used to treat various infections and is available as tablets or solution for infusion.

Tavanic is marketed in the following EU Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

The company that markets these medicines is Sanofi.

## Why was Tavanic reviewed?

Tavanic 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.

Tavanic was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 11 October 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Tavanic in the EU.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

## 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

After reviewing the available data supporting the use of the medicine, the CHMP agreed that:

- Tavanic 250 mg and 500 mg film-coated tablets are indicated in acute bacterial sinusitis, acute exacerbation of chronic bronchitis, community-acquired pneumonia and complicated skin and soft tissue infections only when other commonly used antibacterial agents are not recommended. They are also indicated in pyelonephritis and complicated urinary tract infections (UTI), chronic bacterial prostatitis, uncomplicated cystitis and for the post-exposure prophylaxis and curative treatment of inhalation anthrax.
- Tavanic 5mg/ml solution for infusion is indicated in community-acquired pneumonia and complicated skin and soft tissue infections only when other commonly used antibacterials are not recommended. It is also indicated in pyelonephritis and complicated urinary tract infections (UTI), chronic bacterial prostatitis, and for the post-exposure prophylaxis and curative treatment of inhalation anthrax.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on the posology and frequency of administration of Tavanic, including the posology for acute exacerbations of chronic bronchitis and pyelonephritis.

4.3 Contra-indications

Based on the data reviewed, the CHMP decided a harmonisation of the contraindications of Tavanic in patients hypersensitive (allergic) to levofloxacin, any other quinolone or any of the excipients, in patients with epilepsy, in patients with history of tendon disorders related to fluoroquinolone administration, in children or growing adolescents, during pregnancy and in breast-feeding women.

Other changes

The CHMP also harmonised other sections of the SmPC including the addition of a new warning in section 4.4 recommending that an eye specialist should be consulted if vision becomes impaired or any effects on the eyes are experienced. In addition, the Committee added new side effects in section 4.8 including ligament rupture, hypoglycaemic coma, benign intracranial hypertension, as well as palpitations and ventricular tachycardia, which may result in cardiac arrest.

The amended information to doctors and patients is available here for solution for infusion and tablets.

The European Commission issued a decision on 31 July 2012.