IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Tylan Soluble Powder for Oral Solution

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Tylan Soluble Powder for Oral Solution
Active substance(s)	Tylosin
Marketing Authorisation Holder	Elanco GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany
Legal basis of application	Variation to full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of Authorisation	01/10/1988
Target species	Calves, pigs and poultry
Indication for use	For the treatment and metaphylaxis of *Mycoplasma synoviae* airsacculitis in chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys. For the treatment and metaphylaxis of necrotic enteritis in chickens caused by *Clostridium perfringens*. For the treatment and metaphylaxis of enzootic pneumonia, and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin, in pigs. For information regarding swine dysentery see section 3.5. For the treatment and metaphylaxis of pneumonia in cattle associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin. The presence of the disease in the group or flock must be established before the product is used.
ATCvet code	QJ01FA90

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Safety/Efficacy Changes

Summary of change **Case Reference Number 700452**	**Approval date**
<u>Addition of an indication</u> Section 4.2 – add As an aid in the control of outbreaks of necrotic enteritis in chickens caused by *Clostridium perfringens*. Section 4.9 – add As an aid in the control of outbreaks of necrotic enteritis caused by *Clostridium perfringens* in chickens use Tylan in the drinking water for 5 days at a concentration of 0.15 g per litre water (150ppm), to provide 20-50 mg/kg bw, depending on the age and the water consumption of the birds.	21/04/2008