**IPAR**

# Publicly Available Assessment Report for a Veterinary Medicinal Product

## Sedivet 10 mg/ml Solution for Injection for horses

## PRODUCT SUMMARY

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|---|---|
| Name, strength and pharmaceutical form | Sedivet 10 mg/ml Solution for Injection |
| Active substance(s) | Romifidine |
| Marketing Authorisation Holder | Boehringer Ingelheim Vetmedica GmbH,<br>Binger Strasse 173,<br>55216 Ingelheim am Rhein,<br>Germany |
| Legal basis of application | Article 5.10.a of Directive 81/851 |
| Date of Authorisation | 6th April 2001 |
| Target species | Horses |
| Indication for use | Sedative for use in horses to facilitate handling, examination, minor surgical interventions and manipulations, for use as a premedication agent prior to anaesthesia, and for use with synthetic opiates to provide profound sedation/analgesia |
| ATCvet code | QN05CM93 |

## PUBLIC ASSESSMENT REPORT

The Public Assessment Report reflects the scientific conclusion reached by the IMB 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 IMB 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 IMB 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 Sedivet 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 Sedivet 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 are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA's website.
This section contains information on significant changes made after approval which are important for the quality, safety or efficacy of the product.

**SCOPE**
Change to route of sale and supply. The IMB reference number for this change is CRN:7000969.
**SUMMARY OF CHANGE**
The route of sale and supply was changed from VSO (Veterinary Surgeon Only) to VPO (Veterinary Practitioner Only) to correspond with changes introduced in the Animal Remedies Regulations 2005 (S.I. 734 of 2005).
**DATE OF APPROVAL**
28th June 2006