

Report on Veterinary Drug Product

Brand Name: Ivomec Eprinex Pour-On

Generic Name: eprinomectin

DIN: 02237228 - 5 mg/ml

Patentee: Merial Canada Inc.

Indication (as per product monograph):

Ivomec Eprinex Pour-On is indicated for the treatment of parasitic infections in beef and dairy cattle caused by numerous species of gastrointestinal roundworms, lungworms, grubs, lice, mange mites, and horn flies; and in deer, gastrointestinal roundworms and lungworms.

Notice of Compliance: January 30, 1998

Date of First sale: September 1998

The first patent pertaining to Ivomec Eprinex Pour-On was issued on February 1, 2000 and it came under the PMPRB's jurisdiction at that time.

APPLICATION OF THE EXCESSIVE PRICE GUIDELINES: SPECIAL PROVISIONS FOR VETERINARY PATENTEES

The Special Provisions for Veterinary Patentees provide for an alternative means to review the price of patented veterinary medicines during the three-year trial complaints-driven process. In lieu of filing price and sales information, patentees must provide the proposed introductory price for any product that was not previously offered for sale in Canada. The Guidelines continue to be applied to the extent that they are appropriate.

See PMPRB's Compendium of Guidelines, Policies and Procedures for a more complete description of the Special Provisions for Veterinary Patentees.

Scientific Review:

The comparable medicines included in the Therapeutic Class Comparison (TCC) for Ivomec Eprinex are broad spectrum agents with activity against a number of different external and internal parasites which infect cattle. Ivomec Eprinex has a somewhat broader spectrum of action than the comparators identified, especially horn flies; it is also approved for dairy cattle and deer unlike the comparators. Ivomec Eprinex has a zero withholding time for meat and milk when used as indicated.

The products selected for the TCC are of the same topical dosage form. The comparable dosage regimens for Ivomec Eprinex Pour-On and the comparators listed are identical, i.e., 0.5 mg/kg of body weight, and are based on treatment of a 500 kg animal.

Price Review:

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the TCC test, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicine Regulations*. As a result of the Special Provisions for Veterinary Patentees, only the TCC test was carried out to review the price of Ivomec Eprinex Pour-On.

| Drug (Brand Name) | Strength | Comparable dosage regimen | Cost per day ¹ |
|--|----------|---|---------------------------|
| Ivomec Eprinex Pour-On (eprinomectin) | 5 mg/mL | 0.5 mg/kg body weight applied along the backline; use 50 mL | \$7.1500 |
| Ivomec Pour-On (ivermectin) | 5 mg/mL | 0.5 mg/kg body weight applied along the backline; use 50 mL | \$6.8150 |
| Dectomax Pour-On Solution (doramectin) | 5 mg/mL | 0.5 mg/kg body weight applied along the backline; use 50 mL | \$6.8150 |
| Cydectin Pour-On (moxidectin) | 5 mg/mL | 0.5 mg/kg body weight applied along the backline; use 50 mL | \$7.1500 |

¹ Drug cost based on publicly available prices in the CDMV (formerly known as the Centre de distribution de médicaments vétérinaires) price list.