

Report on Veterinary Drug Product

Brand Name: Fucithalmic Vet
Generic Drug: fusidic acid
DIN: 2231118 - 10 mg/gm
Patentee: Leo Pharma Inc.

Indication (as per product monograph):

Fusithalmic Vet is indicated for the treatment of conjunctivitis in dogs caused by pathogenic strains of Staphylococci sensitive to fusidic acid

Notice of Compliance: April 18, 1997

Date of First sale: January 29, 1999

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 comparators selected for the Therapeutic Class Comparison (TCC) are the more commonly used single entity products. Under the Guidelines, eye drops and eye ointments are considered to be comparable dosage forms therefore products of both formulations are included.

Since the recommended course of treatment is the same for all the comparators included in the TCC, daily dosage regimens can be compared. To calculate the total quantity of each product used each day, one drop was deemed to be equal to 0.05 mL (or 0.05 g in the case of Fucithalmic Vet); a 1/4 inch strip of ointment was assumed to be equal to 0.02 g.

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 Fucithalamic Vet.

Drug (Brand Name)	Strength	Comparable dosage regimen	Cost per day¹
Fucithalamic Vet (fucidic acid)	10 mg/g	1 drop twice daily (0.1 g)	\$0.17
Chloralean Drops (chloramphenicol)	4 mg/mL	1 drop four times daily (0.2 mL)	\$0.12
Chloramphenicol 1% Ointment	10 mg/g	1/4" strip four times daily (0.08 g)	\$0.07
Gentocin Ophthalmic (gentamicin SO ₄)	5 mg/mL	1/4" strip four times daily (0.08 g)	\$0.20
Tetracycline 1% (tetracycline HCl)	10 mg/g	1/4" strip four times daily (0.08 g)	\$0.11
Tobrex Ophthalmic (tobramycin)	3 mg/mL	1 drop four times daily (0.2 mL)	\$0.37
Tobrex Ophthalmic (tobramycin)	3 mg/g	1/4" strip four times daily (0.08 g)	\$0.21
Ciloxan (ciprofloxacin Hcl)	3.5 mg/mL	1 drop four times daily (0.2 mL)	\$0.32

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