

Obstaculos De La Investigacin

R Bogdan

Vimizim (elosulfase alfa) - Food and Drug Administration Evaluate the occurrence of serious infections associated with administration of a prophylactic immune tolerance regimen in a cohort of Morquio A syndrome patients treated with Vimizim... Drug Approval Package: Vimizim (Elosulfase Alfa) Feb 14, 2014 · Vimizim (Elosulfase Alfa) Company: BioMarin Pharmaceutical, Inc. Application No.: 125460 Approval Date: 2/14/2014 Persons with disabilities having problems accessing the PDF files below may... **125460Orig1s000 - accessdata.fda.gov** Since all of these drugs are ERTs (enzyme replacement therapies) that target GAGs in lysosomal storage sites for metabolic breakdown, the proposed EPC text phrase for elosulfase alfa is... **125460Orig1s000 - Food and Drug Administration** Elosulfase alfa was granted an orphan product designation on May 15, 2009. Therefore, the regulations that pertain to the Pediatric Research Equity Act (PREA) do not apply to elosulfase... *Food and Drug Administration* BioMarin Pharmaceutical Inc. 761052 Brineura cerliponase alfa 150MG/5ML (30MG/ML) Intraventricular April 27, 2017 LABEL - Food and Drug Administration The pharmacokinetics of elosulfase alfa were evaluated in 23 patients with MPS IVA who received intravenous infusions of Vimizim 2 mg/kg once weekly, over approximately 4 hours, for 22 weeks. **Search Orphan Drug Designations and Approvals** Jul 1, 2010 · *Exclusivity Protected Indications are shown for approvals from 01/01/2013 to the present. *Data for the Date Designation Withdrawn or Revoked field are shown for designations withdrawn or revoked after 08/12/2013. *Search Orphan Drug Designations and Approvals - Food and ...* May 15, 2009 · *Exclusivity Protected Indications are shown for approvals from 01/01/2013 to the present. *Data for the Date Designation Withdrawn or Revoked field are shown for designations withdrawn or revoked after 08/12/2013. **125460Orig1s000 - Food and Drug Administration** This memo documents my concurrence with the Division of Gastroenterology and Inborn Error Products' approval recommendation for Vimizim (elosulfase alfa) for the treatment of patients with... **label - Food and Drug Administration** The pharmacokinetics of elosulfase alfa were evaluated in 23 patients with MPS IVA who received intravenous infusions of Vimizim 2 mg/kg once weekly, over approximately 4 hours, for 22 weeks.

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