

New Drug Manufacturer Report

Section	Data element	NDC #1	NDC #2	NDC #3	NDC #4
1. Drug identification	National drug code (11-digit NDC)	71863-0119-60	71863-0120-60	71863-0121-60	71863-0122-60
	Drug name	Nitisinone Capsule 2 MG, 60 Each, Bottle	Nitisinone Capsule 5 MG, 60 Each, Bottle	Nitisinone Capsule 10 MG, 60 Each, Bottle	Nitisinone Capsule 20 MG, 60 Each, Bottle
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	The product was priced comparatively to other generics in the market. The company will market the bioequivalence to the brand and the patient support services offered by the company.	The product was priced comparatively to other generics in the market. The company will market the bioequivalence to the brand and the patient support services offered by the company.	The product was priced comparatively to other generics in the market. The company will market the bioequivalence to the brand and the patient support services offered by the company.	The product was priced comparatively to other generics in the market. The company will market the bioequivalence to the brand and the patient support services offered by the company.
	Estimated volume of patients who may be prescribed the drug	Less than 100 per year. This is a generic drug for a rare disease with incidence 1/100,000 to 1/120,000 globally	Less than 100 per year. This is a generic drug for a rare disease with incidence 1/100,000 to 1/120,000 globally	Less than 100 per year. This is a generic drug for a rare disease with incidence 1/100,000 to 1/120,000 globally	Less than 100 per year. This is a generic drug for a rare disease with incidence 1/100,000 to 1/120,000 globally
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	No	No	No	No
	Date and price of acquisition if the drug was not developed by the manufacturer	Date: 10/4/2023 & Price: \$650,000 plus 20% profit to original manufacturer.	Date: 10/4/2023 & Price: \$650,000 plus 20% profit to original manufacturer.	Date: 10/4/2023 & Price: \$650,000 plus 20% profit to original manufacturer.	Date: 10/4/2023 & Price: \$650,000 plus 20% profit to original manufacturer.