

NDC DRUG_PROD_DESC INTRODUCED_TO_MARKET_DATE WAC_AT_INTRODUCTION

42192-0619-16	Naproxen Suspension: 125 mg/5 mL (contains 39 mg sodium): Available in 1 pint (473 mL) light-resistant bottles; Type 0: Not a Combination Product	11/12/2020	837
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MARKETING_PRICING_PLAN

MARKETING_PRICING_NONPUBLIC

ESTIMATED_PATIENTS

Acella's pricing strategy for this and all of its products is based on market conditions. As a generic product, it is priced at least 25% below the branded RLD. In this case, as with most of Acella's products, there are multiple generic competitors. Acella set, and will maintain, its price to be competitive with these products.

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Acella Pharmaceuticals estimates 7250 patients nationally. This product has multiple indications for differing patients (i.e., adults versus children) with differing volumes and durations of use. Accordingly, Acella cannot accurately predict the number of patients that will use this product.

BREAKTHROUGH_THERAPY_INDICATOR

PRIORITY_REVIEW_INDICATOR

ACQUISITION_DATE

N	N	11/11/2020
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ACQUISITION_PRICE

ACQUISITION_PRICE_NONPUBLIC

ACQUISITION_PRICE_COMMENT

This product is a licensed Authorized Generic. There was no acquisition price paid by Acella, however, Acella does share revenues with the Licensor.

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Factors affecting the acquisition price are only know to a small group of individuals at Acella – namely the Commercial, Government Pricing, Compliance and Legal departments consisting of less than 10 people within those departments with access to that information.

GENERAL_COMMENTS

This product was not launched on November 12, 2020 as indicated in Medispan, the various compendiums and our recent New Drug Notice filed with OSHPD. While we did sign the license agreement to market this product on November 11, 2020, we did not have the labeling or inventory ready to market/sell until December 2, 2020. The incorrect Marketing Start Date listed in DailyMed and in the compendiums was a result of confusion in our regulatory department regarding the business realities of the execution of the license agreement versus truly marketing the product with available inventory. Our understanding is that the "introduced to market date" for OSHPD should be consistent with the FDA "Marketing Start Date" reported to the FDA and reflected in DailyMed and the compendiums.