# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 213801Orig1s000

# PROPRIETARY NAME REVIEW(S)

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

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|---|---|
| **Date of This Review:** | February 5, 2021 |
| **Application Type and Number:** | NDA 213801 |
| **Product Name and Strength:** | Myrbetriq Granules (mirabegron for Oral Suspension), 8 mg/mL after reconstitution[a] |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Astellas Pharma Global Development, Inc. (Astellas) |
| **Panorama #:** | 2020-43140108 |
| **DMEPA Safety Evaluator:** | Beverly Weitzman, PharmD |
| **DMEPA Team Leader (Acting):** | Celeste Karpow, PharmD, MPH |

[a] Each bottle contains 8.3 g of granules equivalent to 830 mg mirabegron prior to reconstitution.

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Myrbetriq Granules, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Astellas did not submit an external name study for this proposed proprietary name.

## 1.1 REGULATORY HISTORY

Myrbetriq (mirabegron) Extended-release tablets, 25 mg and 50 mg was approved under NDA 202611 on June 28, 2012 and is currently approved for the treatment of overactive bladder (OAB) in adults.

The Applicant proposes to expand the Myrbetriq product line to include a new dosage form, mirabegron (8 mg/mL) granules for oral suspension for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older.

The Applicant previously submitted the proposed proprietary name, Myrbetriq (b) (4) Granules under NDA 213801 for review on September 29, 2020. On December 18, 2020 we submitted an information request (IR) requesting the Applicant provide additional information or rationale to support the use of two modifiers (b) (4) and 'Granules' as part of the Sponsor's proposed proprietary name.[b] In response to our information request, the Applicant submitted a Proprietary Name Review amendment on December 22, 2020[c] to amend the proposed proprietary name to Myrbetriq Granules (i.e., to include only one modifier) which is the subject of this review.

In parallel, Astellas has submitted efficacy supplement (017) under NDA 202611 proposing the addition of the same pediatric indication (treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older) for the extended-release tablet dosage form.

## 1.2 PRODUCT INFORMATION

**Table 1. Relevant Product Information[d] for Myrbetriq Granules and Myrbetriq**

| **Product Name** | Myrbetriq Granules | Myrbetriq |
|---|---|---|
| **Intended Pronunciation** | meer-BEH-trick | meer-BEH-trick |
| **Application #** | NDA 213801 | NDA 202611 |

[b] Information request available in DARRTS via: https://darrts fda.gov/darrts/faces/ViewDocument?documentId=090140af805bce25&_afrRedirect=995617049672564

[c] PNR Amendment available in docuBridge via: \\CDSESUB1\evsprod\nda213801\0013\m1\us\1-12-4-proprietary-name-request-amendment.pdf

[d] Prescribing Information labeling proposed under NDA 213801 and NDA 202611/S-017 available in EDR via: \\CDSESUB1\evsprod\nda213801\0001\m1\us\myrbetriq-uspi-redline.doc

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|---|---|---|
| **Initial Approval Date** | N/A | June 28, 2012 |
| **Active Ingredient** | Mirabegron | Mirabegron |
| **Indication**[e] | For the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older. | For the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.<br>In combination with the muscarinic antagonist solifenacin succinate, is indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency. |
| **Route of Administration** | Oral | Oral |
| **Dosage Form** | for Oral Suspension | Extended-release tablet |
| **Strength** | Each bottle contains 8.3 g of granules equivalent to 830 mg mirabegron prior to reconstitution.<br>8 mg/mL after reconstitution | 25 mg and 50 mg |
| **Dose and Frequency**[e] | OAB Indication: N/A | OAB Indication:<br>• Recommended starting dose is 25 mg once daily, alone or in combination with solifenacin succinate 5 mg, once daily.<br>• Based on individual efficacy and tolerability, may increase dose to 50 mg once daily, alone or in combination with solifenacin succinate 5 mg, once daily.<br>• Patients with Severe Renal Impairment or Patients with Moderate Hepatic Impairment: Maximum dose is 25 mg MYRBETRIQ once daily<br>• Patients with End Stage Renal Disease (ESRD) or Patients with |

[e] NDA 202611/S-017 proposes to expand the indication of Myrbetriq extended-release tablets to include treatment of NDO in pediatric patients aged 3 years and older. S-017 is currently under review by the Agency.

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