CLINICAL UPDATE

Brand Name	Xtandi®
Generic Name	enzalutamide
Drug Manufacturer	Astellas Pharma US, Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Strength and Dosage Form (40 mg, 80 mg, oral tablet)

FDA APPROVAL DATE

August 04, 2020

LAUNCH DATE

March 01, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Type 3 - New Dosage Form, New Drug Application (NDA): 213674

DISPENSING RESTRICTIONS

Specialty

Overview

INDICATION(S) FOR USE

Xtandi® is an androgen receptor inhibitor indicated for the treatment of patients with:

- Castration-resistant prostate cancer.
- Metastatic castration-sensitive prostate cancer.

MECHANISMS OF ACTION

Enzalutamide is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. It has been shown to competitively inhibit androgen binding to androgen receptors; and consequently, inhibits nuclear translocation of androgen receptors and their interaction with DNA. A major metabolite, N-desmethyl enzalutamide, exhibited similar in vitro activity to enzalutamide. Enzalutamide decreased proliferation and induced cell death of prostate cancer cells in vitro, and decreased tumor volume in a mouse prostate cancer xenograft model.

DOSAGE FORM(S) AND STRENGTH(S)

- Oral capsule: 40 mg
- Oral tablet: 40 mg, 80 mg

CLINICAL UPDATE

DOSE & ADMINISTRATION

160 mg (two 80 mg tablets or four 40 mg tablets or four 40 mg capsules) administered orally once daily. Swallow capsules or tablets whole.
Patients receiving Xtandi® should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

EFFICACY

The steady-state pharmacokinetic profiles (AUC and Cmax) and efficacy profiles of enzalutamide and N-desmethyl enzalutamide are similar for Xtandi® tablet and Xtandi® capsule.