Casodex®
bicalutamide

Indication	• CASODEX 50 mg daily is indicated for use in combination therapy with a luteinizing hormone-releasing hormone (LHRH) analog for the treatment of Stage D2 metastatic carcinoma of the prostate. • CASODEX 150 mg daily is not approved for use alone or with other treatments.
Dosage Forms and Strengths	50 mg tablets
Dosage & Administration	• The recommended dose for CASODEX therapy in combination with an LHRH analog is one 50 mg tablet once daily (morning or evening), with or without food. • It is recommended that CASODEX be taken at the same time each day. • Treatment with CASODEX should be started at the same time as treatment with an LHRH analog. • If a dose of CASODEX is missed, take the next dose at the scheduled time. Do not take the missed dose and do not double the next dose.
Drug Class/ Mechanism of Action	• Non-steroidal androgen receptor inhibitor • Competitively inhibits the action of androgens by binding to cytosol androgen receptors in the target tissue
Half-Life	5.8 days (standard deviation 2.29)
Most Common Adverse Reactions	Adverse reactions that occurred in more than 10% of patients receiving CASODEX plus an LHRH-A were: • Hot flashes • Pain (including general, back, pelvic, and abdominal) • Asthenia • Constipation • Infection • Nausea • Peripheral edema • Dyspnea • Diarrhea • Hematuria • Nocturia • Anemia
Most Common Laboratory Abnormalities	Laboratory abnormalities including: elevated AST, ALT, bilirubin, BUN, and creatinine; and decreased hemoglobin and white cell count, have been reported in both CASODEX-LHRH analog treated and flutamide-LHRH analog treated patients.
Post Marketing Safety	The following adverse reactions have been identified during post-approval use of CASODEX: • Interstitial lung disease (some fatal) including interstitial pneumonitis and pulmonary fibrosis, most often at doses greater than 50 mg. • Increased PT/INR due to interaction between coumarin anticoagulants and CASODEX. Serious bleeding reported. • Photosensitivity
Warnings and Precautions	• Hepatitis • Hemorrhage with Concomitant Use of Coumarin Anticoagulant • Gynecomastia and Breast Pain • Reduction in Glucose Tolerance • Laboratory Test: Monitoring Prostate Specific Antigen (PSA) is recommended. Evaluate for clinical progression if PSA increases.
Contraindications	• Hypersensitivity • Women • Pregnancy

Sourced from: Casodex® (bicalutamide) Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2017.

Erleada™ (apalutamide) 60 mg tablets

Indication	ERLEADA™ is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.
Dosage Forms and Strengths	Tablets (60 mg): slightly yellowish to greyish green oblong-shaped film-coated tablets, debossed with "AR 60" on one side.
Dosage & Administration	• The recommended dose of ERLEADA is 240 mg (four 60 mg tablets) administered orally once daily. • Swallow the tablets whole. • ERLEADA can be taken with or without food. • Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy • Dose modifications may be required for patients experiencing ≥ Grade 3 toxicity or an intolerable side effect as outlined in the Prescribing Information.
Drug Class/ Mechanism of Action	• Apalutamide is an Androgen Receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. • Apalutamide inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription.
Half-Life	The mean effective half-life for apalutamide in patients was approximately 3 days at steady-state.
Most Common Adverse Reactions	The most common adverse reactions (≥10%): • Fatigue • Nausea • Hot flush • Hypertension • Weight decreased • Decreased appetite • Rash • Arthralgia • Fracture • Diarrhea • Fall • Peripheral edema • Additional clinically significant adverse reactions occurring in 2% or more of patients treated with ERLEADA included hypothyroidism (8.1% versus 2% on placebo), pruritus (6.2% versus 2% on placebo), ischemic heart disease (3.7% versus 2% on placebo), and heart failure (2.2% versus 1% on placebo). • Rash: In SPARTAN, rash associated with ERLEADA was most commonly described as macular or maculo-papular. The onset of rash occurred at a median of 82 days of ERLEADA treatment. Rash resolved in 81% of patients within a median of 60 days (range: 2 to 709 days) from onset of rash.
Most Common Laboratory Abnormalities	The most common all-grades laboratory abnormalities that occurred in ≥15% of patients, and more frequently (>5%) in the ERLEADA arm compared to placebo include: anemia, leukopenia, lymphopenia, hypercholesterolemia, hyperglycemia, hypertriglyceridemia and hyperkalemia.
Post Marketing Safety	—
Warnings and Precautions	• Falls and Fractures • Seizure
Contraindications	ERLEADA can cause fetal harm and potential loss of pregnancy.

Sourced from: Erleada® (apalutamide) tablets Prescribing Information. Horsham, PA: Janssen Products, LP; February 2018.

JEVTANA® (cabazitaxel) injection

Indication	JEVTANA® is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.
Dosage Forms and Strengths	JEVTANA (cabazitaxel) injection is supplied as a kit consisting of the following: • Cabazitaxel injection: 60 mg/1.5 mL; a clear yellow to brownish-yellow viscous solution • Diluent: 5.7 mL of 13% (w/w) ethanol in water; a clear colorless solution
Dosage & Administration	• The recommended dose of JEVTANA is based on calculation of the Body Surface Area (BSA), and is 20 mg/m^2 administered as a one-hour intravenous infusion every 3 weeks in combination with oral prednisone 10 mg administered daily throughout JEVTANA treatment. • A dose of 25 mg/m^2 can be used in select patients at the discretion of the treating healthcare provider. • Premedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity – Antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine) – Corticosteroid (dexamethasone 8 mg or equivalent steroid), – H2 antagonist (ranitidine 50 mg or equivalent H2 antagonist) • Antiemetic prophylaxis is recommended and can be given orally or intravenously as needed. • JEVTANA injection single-use vial requires two dilutions prior to administration.
Drug Class/ Mechanism of Action	• Microtubule inhibitor • Cabazitaxel binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly.
Half-Life	Following a one-hour intravenous infusion, plasma concentrations of cabazitaxel can be described by a three-compartment pharmacokinetic model with α-, β-, and γ- half-lives of 4 minutes, 2 hours, and 95 hours, respectively.
Most Common Adverse Reactions	The most common (≥10%) grade 1–4 adverse reactions occurring in patients treated with the combination of JEVTANA plus prednisone (TROPIC Trial) were: • Anemia • Thrombocytopenia • Nausea • Asthenia • Back pain • Pyrexia • Cough • Leukopenia • Diarrhea • Vomiting • Abdominal pain • Anorexia • Dyspnea • Arthralgia • Neutropenia • Fatigue • Constipation • Hematuria • Peripheral neuropathy • Dysgeusia • Alopecia
Most Common Laboratory Abnormalities	The most common all-grades adverse reactions and laboratory abnormalities (≥10%) with JEVTANA 20 mg/m^2 or 25 mg/m^2 are neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, and anorexia.
Post Marketing Safety	The following adverse reactions have been identified from clinical trials and/or postmarketing surveillance: • Gastritis • Interstitial pneumonia/pneumonitis, • Acute respiratory distress syndrome • Intestinal obstruction • Interstitial lung disease
Warnings and Precautions	• Neutropenia (BOXED WARNING) • Increased Toxicity in Elderly Patients • Renal Failure • Severe hypersensitivity (BOXED WARNING) • Hypersensitivity Reactions • Respiratory Disorders • Bone Marrow Suppression • Gastrointestinal Adverse Reactions • Use in Patients with Hepatic Impairment
Contraindications	Patients with: • Neutrophil counts of ≤1500/mm^3 • History of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80 • Severe hepatic impairment (total bilirubin >3 × ULN) • Pregnancy

Sourced from: Jevtana® (cabazitaxel) Prescribing Information. Bridgewater, NJ: sanofi-aventis U.S. LLC; September 2017.

Indication	• LUPRON DEPOT 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, and 45 mg for 6-month administration (leuprolide acetate) are indicated in the palliative treatment of advanced prostatic cancer. • LUPRON DEPOT is a Gonadotropin releasing hormone (GnRH) agonist.
Dosage Forms and Strengths	• 7.5 mg for 1-month administration • 22.5 mg for 3-month administration • 30 mg for 4-month administration • 45 mg for 6-month administration Each is supplied as a kit with prefilled dual chamber syringe.
Dosage & Administration	All doses: do not use concurrently a fractional dose, or combination of doses of any depot formulation due to different release characteristics. Lyophilized microspheres must be reconstituted and should be administered every 4 weeks as a single intramuscular injection. • 7.5 mg for 1-month administration – one injection every 4 weeks. • 22.5 mg for 3-month administration – one injection every 12 weeks. • 30 mg for 4-month administration – one injection every 16 weeks. • 45 mg for 6-month administration – one injection every 24 weeks.
Drug Class/ Mechanism of Action	Leuprolide acetate, a GnRH agonist, acts as an inhibitor of gonadotropin secretion.
Half-Life	Terminal elimination half-life was approximately 3 hours based on a two-compartment model.
Most Common Adverse Reactions	• LUPRON DEPOT 7.5 mg for 1-month administration: The most common adverse reactions (>10%) were general pain, hot flashes/sweats, GI disorders, edema, respiratory disorder, urinary disorder. • LUPRON DEPOT 22.5 mg for 3-month administration: The most common adverse reactions (>10%) were general pain, injection site reaction, hot flashes/sweats, GI disorders, joint disorders, testicular atrophy, urinary disorders. • LUPRON DEPOT 30 mg for 4-month administration: The most common adverse reactions (>10%) were asthenia, flu syndrome, general pain, headache, injection site reaction, hot flashes/sweats, GI disorders, edema, skin reaction, urinary disorders. • LUPRON DEPOT 45 mg for 6-month administration: The most common adverse reactions (>10%) were hot flush, injection site pain, upper respiratory infection, and fatigue.
Most Common Laboratory Abnormalities	LUPRON DEPOT 7.5 mg for 1-Month Administration: the following were recorded in ≥5% of patients at final visit: decreased albumin, decreased hemoglobin/hematocrit, decreased prostatic acid phosphatase, decreased total protein, decreased urine specific gravity, hyperglycemia, hyperuricemia, increased BUN, increased creatinine, increased liver function tests (AST, LDH), increased phosphorus, increased platelets, increased prostatic acid phosphatase, increased total cholesterol, increased urine specific gravity, leukopenia.

Post Marketing Safety	• Like other drugs in this class, mood swings, including depression, have been reported. There have been very rare reports of suicidal ideation and attempt. • Symptoms consistent with an anaphylactoid or asthmatic process have been rarely (incidence rate of about 0.002%) reported. Rash, urticaria, and photosensitivity reactions have also been reported. • Decreased bone density has been reported. • Rare cases of pituitary apoplexy (a clinical syndrome secondary to infarction of the pituitary gland) have been reported. In a majority of these cases, a pituitary adenoma was diagnosed. • Symptoms consistent with fibromyalgia (e.g., joint and muscle pain, headaches, sleep disorders, gastrointestinal distress, and shortness of breath). • Cardiovascular System – Hypotension, Myocardial infarction, Pulmonary embolism • Interstitial lung disease • Serious drug-induced liver injury • Decreased WBC • Central/Peripheral Nervous System - Convulsion, Peripheral neuropathy, Spinal fracture/paralysis • Diabetes • Tenosynovitis-like symptoms • Prostate pain
Warnings and Precautions	• Tumor Flare • Hyperglycemia and Diabetes • Cardiovascular Diseases • Effect on QT/QTc Interval • Convulsions • Laboratory Tests: Monitor serum levels of testosterone following injection of LUPRON DEPOT 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, or 45 mg for 6-month administration. In the majority of patients, testosterone levels increased above baseline, and then declined thereafter to castrate levels (<50 ng/dL) within 4 weeks.
Contraindications	• Hypersensitivity • Pregnancy

Sourced from: Lupron Depot® (leuprolide acetate for depot suspension) Prescribing Information. North Chicago, IL: AbbVie Inc.; June 2016.

PROVENGE®
(sipuleucel-T)

Indication	PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.
Dosage Forms and Strengths	Each dose contains a minimum 50 million autologous CD54+ cells activated with PAP-GM-CSF, suspended in 250 mL of Lactated Ringer's Injection, USP.
Dosage & Administration	• Recommended course of therapy – 3 complete doses, given at approximately 2-week intervals. • To minimize potential acute infusion reactions, pre-medicate orally with acetaminophen + antihistamine, such as diphenhydramine, approximately 30 minutes prior to administration of PROVENGE. • If patient is unable to receive a scheduled infusion patient will need to undergo an additional leukapheresis procedure prior to continuing treatment.
Drug Class/ Mechanism of Action	• Classified as an autologous cellular immunotherapy. • The precise mechanism of action is unknown. • Designed to induce an immune response targeted against PAP, an antigen expressed in most prostate cancers.
Most Common Adverse Reactions	The most common all-grade adverse reactions in clinical trials (≥15% of patients receiving PROVENGE): • Chills • Fatigue • Fever • Back pain • Nausea • Joint ache • Headache
Most Common Laboratory Abnormalities	—
Post Marketing Safety	• Nervous system disorders: syncope, transient ischemic attack, strokes • Hypotension • Myocardial infarction • Thromboembolic disorders: deep venous thrombosis and pulmonary embolism
Warnings and Precautions	• Acute Infusion Reactions • Thromboembolic Events • Vascular Disorders • Handling Precautions for Control of Infectious Disease • Concomitant Chemotherapy or Immunosuppressive Therapy • Product Safety Testing
Contraindications	None

Sourced from: Provenge® (sipuleucel-T) Prescribing Information. Seattle, WA: Dendreon Corporation; October 2014.

TAXOTERE® docetaxel

Indication	• TAXOTERE in combination with prednisone is indicated for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer. Additional Indications: • Breast Cancer: single agent for locally advanced or metastatic breast cancer after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer • Non-Small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced, or metastatic untreated NSCLC • Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction • Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN
Dosage Forms and Strengths	One vial TAXOTERE (Injection concentrate): TAXOTERE 20 mg/mL • TAXOTERE (docetaxel) Injection Concentrate 20 mg/1 mL: 20 mg docetaxel in 1 mL in 50/50 (v/v) ratio polysorbate 80/dehydrated alcohol TAXOTERE 80 mg/4 mL • TAXOTERE (docetaxel) Injection Concentrate 80 mg/4 mL: 80 mg docetaxel in 4 mL 50/50 (v/v) ratio polysorbate 80/dehydrated alcohol
Dosage & Administration	• For all indications, toxicities may warrant dosage adjustments, as outlined in the Prescribing Information. • For hormone-refractory metastatic prostate cancer, the recommended dose of TAXOTERE is 75 mg/m^2 every 3 weeks as a 1 hour intravenous infusion. Prednisone 5 mg orally twice daily is administered continuously. • Recommended premedication regimen is oral dexamethasone 8 mg at 12 hours, 3 hours, and 1 hour before TAXOTERE infusion Combination therapy with TAXOTERE for hormone-refractory metastatic prostate cancer: • TAXOTERE should be administered when the neutrophil count is ≥1500 cells/mm^3 • Patients who experience either febrile neutropenia, neutrophils <500 cells/mm^3 for more than one week, severe or cumulative cutaneous reactions, or moderate neurosensory signs and/or symptoms during TAXOTERE therapy should have the dosage of TAXOTERE reduced from 75 mg/m^2 to 60 mg/m^2. If the patient continues to experience these reactions at 60 mg/m^2, the treatment should be discontinued.
Drug Class/ Mechanism of Action	• Docetaxel is an antineoplastic agent, microtubule inhibitor that acts by disrupting the microtubular network in cells essential for mitotic and interphase cellular functions. • Binds to free tubulin and promotes assembly of tubulin into stable microtubules while simultaneously inhibiting their disassembly.
Half-Life	• Three-compartment pharmacokinetic model • Half-lives for the α, β, and γ phases of 4 min, 36 min, and 11.1 hr, respectively
Most Common Adverse Reactions	The most common adverse reactions (regardless of relationship) occurring in (≥10% of patients) of patients with hormone refractory prostate cancer who received TAXOTERE in combination with prednisone (TAX327): • Anemia • Alopecia • Fatigue • Nausea • Neutropenia • Diarrhea • Infection • Neuropathy sensory • Nail changes • Fluid retention • Stomatitis/Pharyngitis • Peripheral edema • Taste Disturbance • Vomiting • Anorexia • Dyspnea • Myalgia • Cough • Cardiac left ventricular function • Tearing • In patients treated with TAXOTERE every three weeks, the following treatment-emergent adverse reactions occurred at rates 10% higher in patients 65 years of age or greater compared to younger patients: anemia (71% vs 59%), infection (37% vs 24%), nail changes (34% vs 23%), anorexia (21% vs 10%), weight loss (15% vs 5%), respectively.

Most Common Adverse Reactions *(continued)*	The most common adverse reactions with TAXOTERE across all indications: • Infections • Hypersensitivity • Dyspnea • Fluid retention • Diarrhea • Alopecia • Neutropenia • Thrombocytopenia • Constipation • Asthenia • Vomiting • Skin reactions • Anemia • Neuropathy • Anorexia • Pain • Mucositis • Myalgia • Febrile neutropenia • Dysgeusia • Nail disorders • Nausea
Most Common Laboratory Abnormalities	—
Post Marketing Safety	• Body as a whole: diffuse pain, chest pain, radiation recall phenomenon. • Cardiovascular: atrial fibrillation, deep vein thrombosis, ECG abnormalities, thrombophlebitis, pulmonary embolism, syncope, tachycardia, myocardial infarction. • Cutaneous: very rare cases of cutaneous lupus erythematosus and rare cases of bullous eruptions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and Scleroderma-like changes usually preceded by peripheral lymphedema. Severe hand and foot syndrome and cases of permanent alopecia have been reported. • Gastrointestinal: abdominal pain, anorexia, constipation, duodenal ulcer, esophagitis, gastrointestinal hemorrhage, gastrointestinal perforation, ischemic colitis, colitis, intestinal obstruction, ileus, neutropenic enterocolitis and dehydration as a consequence to gastrointestinal events have been reported. • Hematologic: bleeding episodes. Disseminated intravascular coagulation (DIC), often in association with sepsis or multiorgan failure, has been reported. Cases of acute myeloid leukemia and myelodysplastic syndrome have been reported in association with docetaxel when used in combination with other chemotherapy agents and/or radiotherapy. • Hypersensitivity: rare cases of anaphylactic shock • Hepatic: rare cases of hepatitis • Neurologic: confusion, rare cases of seizures or transient loss of consciousness • Ophthalmologic: conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive tearing which may be attributable to lacrimal duct obstruction has been reported. Rare cases of transient visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions. Cases of cystoid macular edema (CME) have been reported in patients treated with docetaxel. • Hearing: rare cases of ototoxicity, hearing disorders and/or hearing loss • Respiratory: dyspnea, acute pulmonary edema, acute respiratory distress syndrome/pneumonitis, interstitial lung disease, interstitial pneumonia, respiratory failure, and pulmonary fibrosis have rarely been reported and may be associated with fatal outcome. Rare cases of radiation pneumonitis have been reported in patients receiving concomitant radiotherapy. • Renal: renal insufficiency and renal failure have been reported. • Metabolism and Nutritional Disorders: cases of hyponatremia
Warnings and Precautions	• Toxic Deaths (Breast Cancer and Non-Small Cell Lung Cancer) (BOXED WARNING) • Hepatic Impairment • Hepatotoxicity (BOXED WARNING) • Hematologic Effects • Neutropenia (BOXED WARNING) • Hypersensitivity Reactions (BOXED WARNING) • Fluid Retention (BOXED WARNING) • Acute Myeloid Leukemia • Cutaneous Reactions • Neurologic Reactions • Eye Disorders • Asthenia • Alcohol Content • Use in Pregnancy
Contraindications	• TAXOTERE is contraindicated in patients who have a history of severe hypersensitivity reactions to docetaxel or to other drugs formulated with polysorbate 80. Severe reactions, including anaphylaxis, have occurred. • TAXOTERE should not be used in patients with neutrophil counts of <1500 cells/mm^3.

Sourced from: Taxotere® (docetaxel) Prescribing Information. Bridgewater, NJ: sanofi-aventis; December 2015.

Indication	Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases, and no known visceral metastatic disease.
Dosage Forms and Strengths	Available in single-use vials containing 6 mL of solution at a concentration of 1,100 kBq/mL (30 microcurie/mL) at the reference date with a total radioactivity of 6,600 kBq/vial (178 microcurie/vial) at the reference date.
Dosage & Administration	• 55 kBq (1.49 microcurie) per kg body weight, given at 4-week intervals for 6 injections. • Safety and efficacy beyond 6 injections have not been studied. • Volume to be administered should be calculated using: – Body weight (kg) – Dosage level 55 kBq/kg body weight or 1.49 microcurie/kg body weight – Radioactivity concentration of the product (1100 kBq/mL; 30 microcurie/mL) at the reference date – Decay correction factor to correct for physical decay of radium-223 • Administer Xofigo by slow intravenous injection over 1 minute. • Flush the intravenous access line or cannula with isotonic saline before and after injection of Xofigo.
Drug Class/ Mechanism of Action	• Alpha particle-emitting radioactive therapeutic agent • The active moiety is the alpha particle-emitting isotope radium-223 (as radium Ra 223 dichloride), which mimics calcium and forms complexes with the bone mineral hydroxyapatite at areas of increased bone turnover, such as bone metastases. The high linear energy transfer of alpha emitters (80 keV/micrometer) leads to a high frequency of double-strand DNA breaks in adjacent cells, resulting in an anti-tumor effect on bone metastases.
Half-Life	Radium-223 half-life is 11.4 days.
Most Common Adverse Reactions	Most common adverse reactions ≥10% occurring in patients receiving Xofigo: • Nausea • Diarrhea • Vomiting • Peripheral edema
Most Common Laboratory Abnormalities	Most common hematologic laboratory abnormalities in Xofigo-treated patients (≥10%): • Anemia • Lymphocytopenia • Leukopenia • Thrombocytopenia • Neutropenia
Post Marketing Safety	—
Warnings and Precautions	Bone Marrow Suppression
Contraindications	Pregnancy

Sourced from: Xofigo® (radium Ra 223 dichloride). Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; May 2017.

Xtandi (enzalutamide) 40 mg capsules

Indication	XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).
Dosage Forms and Strengths	XTANDI 40 mg capsules are white to off-white oblong soft gelatin capsules imprinted in black ink with ENZ.
Dosage & Administration	• The recommended dose of XTANDI is 160 mg (four 40-mg capsules) administered orally once daily. • Can be taken with or without food • Swallow capsules whole. • Do not chew, dissolve, or open capsules. • Dose modifications may be required as outlined in the Prescribing Information.
Drug Class/ Mechanism of Action	• Androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway • Shown to competitively inhibit androgen binding to androgen receptors and inhibit androgen receptor nuclear translocation and interaction with DNA • Decreases proliferation and induced cell death of prostate cancer cells *in vitro* • Decreased tumor volume in a mouse prostate cancer xenograft model
Half-Life	• $t_{1/2}$ in patients after a single oral dose is 5.8 days (range 2.8 to 10.2 days) • Following a single 160-mg oral dose of enzalutamide in healthy volunteers, mean terminal $t_{1/2}$ for N-desmethyl enzalutamide is 7.8 to 8.6 days.
Most Common Adverse Reactions	The most common adverse reactions (≥10%) that occurred more commonly (≥2% over placebo) in patients receiving XTANDI from the two randomized, placebo-controlled clinical trials: • Asthenia/fatigue • Back pain • Decreased appetite • Constipation • Arthralgia • Diarrhea • Hot flush • Upper respiratory tract infection • Peripheral edema • Dyspnea • Musculoskeletal pain • Weight decreased • Headache • Hypertension • Dizziness/vertigo • In the two randomized, placebo-controlled clinical trials, falls including fall-related injuries occurred in 9% of patients treated with XTANDI compared to 4% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in patients treated with XTANDI and included nonpathologic fractures, joint injuries, and hematomas. • In the two randomized, placebo-controlled trials, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in <1% of patients in each arm.
Most Common Laboratory Abnormalities	Most common laboratory abnormalities occurring in the two, randomized placebo-controlled clinical trials: • Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI • Grade 1-4 thrombocytopenia occurred in 6% of patients treated with XTANDI • Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI • Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI
Post Marketing Safety	• Hypersensitivity (tongue edema, lip edema, and pharyngeal edema) • Vomiting • Posterior reversible encephalopathy syndrome (PRES) • Rash
Warnings and Precautions	• Seizure • PRES
Contraindications	Pregnancy: fetal harm and potential loss of pregnancy

Sourced from: Xtandi® (enzalutamide) Prescribing Information. Northbrook, IL: Astellas Pharma US Inc.; July 2017.

Yonsa® (abiraterone acetate)
125 mg tablets

Indication	Yonsa is indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).*
Dosage Forms and Strengths	Yonsa (abiraterone acetate) tablets, 125 mg, are white to off-white, oval-shaped tablets debossed with "125 FP" on one side.
Dosage & Administration	The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily. Important Administration Instructions: • To avoid medication errors and overdose, be aware that Yonsa (abiraterone acetate) tablets may have different dosing and food effects than other abiraterone acetate products. • Patients receiving Yonsa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. • Yonsa tablets can be taken with or without food. • The tablets should be swallowed whole with water. • Do not crush or chew tablets. • Dose modifications may be required as outlined in the Prescribing Information. • Do not use Yonsa in patients with severe hepatic impairment (Child-Pugh Class C).
Drug Class/ Mechanism of Action	Abiraterone acetate (Yonsa) is converted *in vivo* to abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α-hydroxylase/C17, 20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis.
Half-Life	• In patients with mCRPC, mean terminal half-life of abiraterone in plasma (mean ± SD) is 12 ± 5 hours • In subjects with mild hepatic impairment, approximately 18 hours • Moderate hepatic impairment, approximately 19 hours
Most Common Adverse Reactions	Most common adverse reactions (≥10%) reported in the two randomized clinical trials that occurred more commonly (>2%) in the abiraterone acetate arm were: • Fatigue • Joint swelling or discomfort • Edema • Hot flush • Diarrhea • Vomiting • Cough • Hypertension • Dyspnea • Urinary tract infection • Contusion • In the combined data for studies 1 and 2, cardiac failure occurred more commonly in patients treated with abiraterone acetate compared to patients on the placebo arm (2.1% versus 0.7%).
Most Common Laboratory Abnormalities	The most common laboratory abnormalities (>20%) reported in the two randomized clinical trials that occurred more commonly (≥2%) in the abiraterone acetate arm were anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.
Post Marketing Safety	• Non-infectious pneumonitis • Myopathy, including rhabdomyolysis • Fulminant hepatitis, including acute hepatic failure and death
Warnings and Precautions	• Hypertension, Hypokalemia and Fluid Retention due to Mineralocorticoid excess • Adrenocortical insufficiency • Hepatotoxicity
Contraindications	Can cause fetal harm and potential loss of pregnancy

* Yonsa is not A/B rated.

Sourced from: Yonsa™ (abiraterone acetate) Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2018.

Zytiga® (abiraterone acetate) 250 mg tablets

Indication	ZYTIGA is indicated in combination with prednisone for the treatment of patients with: • Metastatic castration-resistant prostate cancer (CRPC) • Metastatic high-risk castration-sensitive prostate cancer (CSPC)
Dosage Forms and Strengths	• 500 mg film-coated Tablets are supplied as purple, oval-shaped, film-coated tablets debossed with "AA" one side and "500" on the other side. • 250 mg film-coated Tablets are supplied as pink, oval-shaped, film-coated tablets debossed with "AA250" on one side.* • 250 mg Tablets are supplied as white to off-white, oval-shaped tablets debossed with "AA250" on one side.
Dosage & Administration	Recommended dose for metastatic CRPC: • 1,000 mg (two 500 mg tablets or four 250 mg tablets) orally once daily with prednisone 5 mg orally **twice** daily. Recommended dose for metastatic high-risk CSPC: • The recommended dose of ZYTIGA is 1,000 mg (two 500 mg tablets or four 250 mg tablets) orally once daily with prednisone 5 mg administered orally **once** daily. Important administration instructions: • Patients receiving ZYTIGA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. • ZYTIGA must be taken on an empty stomach, either one hour before or two hours after a meal. • Swallow tablets whole with water. • Do not crush or chew tablets. • Dose modifications may be required as outlined in the full Prescribing Information.
Drug Class/ Mechanism of Action	Abiraterone acetate is converted *in vivo* to abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α-hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and required for androgen biosynthesis.
Half-Life	• In patients with mCRPC, mean terminal half-life of abiraterone in plasma (mean ± SD) is 12 ± 5 hours • In subjects with mild hepatic impairment, approximately 18 hours • Moderate hepatic impairment, approximately 19 hours
Most Common Adverse Reactions	Most common adverse reactions (≥10%) reported in the pooled data of five randomized clinical trials that occurred more commonly (>2%) in the abiraterone acetate arm were: • Fatigue • Nausea • Hot flush • Urinary tract infection • Arthralgia • Edema • Diarrhea • Cough • Hypertension • Hypokalemia • Vomiting • Headache In the combined data of 5 randomized, placebo-controlled clinical studies, cardiac failure occurred more commonly in patients on the ZYTIGA arm compared to patients on the placebo arm (2.6% versus 0.9%).
Most Common Laboratory Abnormalities	The most common laboratory abnormalities (>20%) reported in the five randomized clinical trials that occurred more commonly (≥2%) in the abiraterone acetate arm were anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, and hypokalemia.
Post Marketing Safety	• Non-infectious pneumonitis • Myopathy, including rhabdomyolysis • Fulminant hepatitis, including acute hepatic failure and death.
Warnings and Precautions	• Hypertension, Hypokalemia and Fluid Retention due to Mineralocorticoid Excess • Adrenocortical insufficiency • Hepatotoxicity
Contraindications	Women who are or may become pregnant

* ZYTIGA 250 mg film-coated tablets are not commercially available in the United States.

Sourced from: ZYTIGA® (abiraterone acetate) Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; March 2018.