



FDA Approved Drugs – October 2015

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General Note



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ENSTILAR (CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE)

Company: LEO Pharmaceuticals; Approved by October 2015

Specific Treatments: psoriasis

General Information

Enstilar is specifically indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. It is supplied as a foam for topical administration. It should be applied to affected areas once daily for up to 4 weeks, and rubbed in gently. Discontinue use when control is achieved. No more than 60 g every 4 days should be used.

Mechanism of Action

Enstilar is a dual-action investigational aerosol foam containing calcipotriol, a vitamin D analog, and betamethasone dipropionate, a corticosteroid.

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Side Effects

Adverse effects associated with the use of Enstilar may include: application site irritation, application site pruritus, folliculitis, skin hypopigmentation, hypercalcemia, urticaria, exacerbation of psoriasis

IMLYGIC (TALIMOGENE LAHERPAREPVEC)

Company: Amgen; Approved by October 2015

Specific Treatments: unresectable recurrent melanoma

General Information

Imlygic is specifically indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. It is supplied as a suspension for intralesional injection. It should be administered by injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance. It is provided in single-use vials of 1 mL each in two different dose strengths: 10^6 (1 million) plaque-forming units (PFU) per mL (light green cap) – for initial dose only and 10^8 (100 million) PFU per mL (royal blue cap) – for all subsequent doses. The initial recommended dose is up to 4 mL at a concentration of 10^6 (1 million) PFU per mL. The recommended dose for subsequent administrations is up to 4 mL at a concentration of 10^8 (100 million) PFU per mL.

Mechanism of Action

Imlygic (talimogene laherparepvec) is a genetically modified oncolytic viral therapy. It was designed to replicate within tumors and to produce the immune stimulatory protein GM-CSF. Imlygic causes lysis of tumors, followed by release of tumor-derived antigens, which together with virally derived GM-CSF may promote an antitumor immune response.

Side Effects

Adverse effects associated with the use of Imlygic may include: fatigue, chills, pyrexia, nausea, influenza-like illness, injection site pain

ONIVYDE (IRINOTECAN LIPOSOME INJECTION)

Company: Merrimack; Approved by October 2015

Specific Treatments: metastatic pancreatic cancer

General Information

Onivyde is specifically indicated in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. It is supplied as an injection for intravenous infusion. Administer Onivyde prior to leucovorin and fluorouracil. The recommended dose of Onivyde is 70 mg/m² administered by intravenous infusion over 90 minutes every 2 weeks. Increase the dose of Onivyde to 70 mg/m² as tolerated in subsequent cycles.

Mechanism of Action

Onivyde (irinotecan liposome injection) is a topoisomerase inhibitor encapsulated in a lipid bilayer vesicle or liposome. Topoisomerase 1 relieves torsional strain in DNA by inducing single-strand breaks. Irinotecan and its active metabolite SN-38 bind reversibly to the topoisomerase 1-DNA complex and prevent re-ligation of the single-strand breaks, leading to exposure time-dependent double-strand DNA damage and cell death. In mice bearing human tumor xenografts, irinotecan liposome administered at irinotecan HCl-equivalent doses 5-fold lower than irinotecan HCl achieved similar intratumoral exposure of SN-38.

Side Effects

Adverse effects associated with the use of Onivyde may include: diarrhea, fatigue/asthenia, vomiting, nausea, decreased appetite, stomatitis, pyrexia, lymphopenia, neutropenia

STRENSIQ (ASFOTASE ALFA)

Company: Alexion; Approved by October 2015

Specific Treatments: hypophosphatasia

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General Information

Strensiq (asfotase alfa) is a tissue nonspecific alkaline phosphatase. It is specifically indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia. It is supplied as an injection for subcutaneous administration.

Mechanism of Action

Hypophosphatasia is caused by a deficiency in the tissue non-specific alkaline phosphatase (TNSALP) enzyme, which leads to elevations in several TNSALP substrates, including inorganic pyrophosphate (PPi). Elevated extracellular levels of PPi block hydroxyapatite crystal growth which inhibits bone mineralization and causes an accumulation of unmineralized bone matrix which manifests as rickets and bone deformation in infants and children and as osteomalacia (softening of bones) once growth plates close, along with muscle weakness. Replacement of the TNSALP enzyme upon Strensiq treatment reduces the enzyme substrate levels.

Side Effects

Adverse effects associated with the use of Strensiq may include: injection site reactions, lipodystrophy, ectopic calcifications, hypersensitivity reactions

PRAXBIND (IDARUCIZUMAB)

Company: Boehringer Ingelheim; Approved by October 2015

Specific Treatments: reversal of the anticoagulant effects of dabigatran

General Information

Praxbind is specifically indicated in patients treated with Pradaxa when reversal of the anticoagulant effects of dabigatran is needed: For emergency surgery/urgent procedures and /or in life-threatening or uncontrolled bleeding. It is supplied as a solution for intravenous injection.

Mechanism of Action

Praxbind (idarucizumab) is a humanized monoclonal antibody fragment (Fab) derived from an IgG1 isotype molecule, whose target is the direct thrombin inhibitor dabigatran. It binds to dabigatran and its acylglucuronide metabolites with higher affinity than the binding affinity of dabigatran to thrombin, neutralizing their anticoagulant effect.

Side Effects

Adverse effects associated with the use of Praxbind may include: headache, hypokalemia, delirium, constipation, pyrexia, pneumonia

VELTASSA (PATIROMER)

Company: Relypsa; Approved by October 2015

Specific Treatments: hyperkalemia

Veltassa is specifically indicated for the treatment of hyperkalemia. It should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. It is supplied as a suspension for oral administration. The recommended starting dose is 8.4 grams patiromer once daily. Monitor serum potassium and adjust the dose based on the serum potassium level and the desired target range. The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily. The dose can be up-titrated based on serum potassium level at 1-week or longer intervals, in increments of 8.4 grams. It binds to many orally administered medications, which could decrease their absorption and reduce their effectiveness. Administer other oral medications at least 6 hours before or 6 hours after Veltassa.

Mechanism of Action

Veltassa (patiromer) is a potassium binder. Veltassa increases fecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels.

Side Effects

Adverse effects associated with the use of Veltassa may include: constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort, flatulence

VIVLODEX (MELOXICAM)

Company: Iroko Pharmaceuticals; Approved by October 2015

Specific Treatments: osteoarthritis pain

General Information

Vivlodex is specifically indicated for the management of osteoarthritis pain. It is supplied as a capsule for oral administration. The recommended starting dose is 5 mg orally once daily. The dose may be increased to 10 mg in patients who require additional analgesia. Use the lowest effective dose for shortest duration consistent with individual patient treatment goals.

Mechanism of Action

Vivlodex (meloxicam) is a non-steroidal anti-inflammatory. It has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of Vivlodex like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).

Side Effects

Adverse effects associated with the use of Vivlodex may include: diarrhea, nausea, abdominal discomfort

BELBUCA (BUPRENORPHINE)

Company: Endo Pharmaceuticals; Approved by October 2015

Specific Treatments: severe pain

General Information

Belbuca is specifically indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It is supplied as a buccal film for oral administration. Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse. Initiate treatment in opioid naïve patients with a 75 mcg film once daily or, if tolerated, every 12 hours for at least 4 days, then increase dose to 150 mcg every 12 hours. Individual titration to a dose that provides adequate analgesia and minimizes adverse reactions should proceed in increments of 150 mcg every 12 hours, no more frequently than every 4 days. Doses up to 450 mcg every 12 hours were studied in opioid naïve patients in the clinical trials.

Mechanism of Action

Belbuca buccal film contains buprenorphine, a partial opioid agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.

Side Effects

Adverse effects associated with the use of Belbuca may include: nausea, constipation, headache, vomiting, dizziness, somnolence

YONDELIS (TRABECTEDIN)

Company: Janssen; Approved by October 2015

Specific Treatments: liposarcoma or leiomyosarcoma

General Information

Yondelis is specifically indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen. It is supplied as an injection for intravenous administration. The recommended dose is 1.5 mg/m² administered as an intravenous infusion over 24 hours through a central venous line every 21 days (3 weeks), until disease progression or unacceptable toxicity, in patients with normal bilirubin and AST or ALT less than or equal to 2.5 times the upper limit of normal.

Mechanism of Action

Yondelis (trabectedin) is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.

Side Effects

Adverse effects associated with the use of Yondelis may include: nausea, fatigue, vomiting, constipation, decreased appetite, diarrhea, peripheral edema, dyspnea, headache, neutropenia, increased ALT, thrombocytopenia, anemia, increased AST, increased creatine phosphokinase.