PharmNotes

Monthly Communications

September 2025

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Drug Safety Alert Notification

The Drug Safety Communications are provided by the U.S. Food and Drug Administration and are intended to offer important information to patients and health care providers about new safety issues regarding certain medications. This helps prescribers and health care professionals be informed so that decisions regarding the treatment of patients are made accordingly.

No Drug Safety Alert Notification was released during September.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Forzinity™ (elampretide) injection for subcutaneous use

FDA-Approved Indication

Indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30kg.

Dosage & Administration

40 mg subcutaneously once daily

Dosage Forms & Strengths

Injection: 280 mg/3.5 mL (80 mg/mL) solution for injection in single-patient use vials.

Contraindications

Serious hypersensitivity to any of the ingredients

Common Adverse Reactions

Injection site reactions.

Warnings & Precautions

- Benzyl alcohol toxicity

Clinical Studies

The approval was based on results from TAZPOWER, a randomized, double-blind, placebo-controlled, crossover trial. The study included 12 patients with genetically confirmed Barth syndrome. Results showed that there was an improved strength of the muscle used to straighten the leg at the knee, which is reasonably likely to predict patient benefit such as an ability to stand more easily or walk farther.

Place in Therapy

Barth syndrome is a rare, life-threatening disease that is caused by a mutation in the tafazzin gene, which results in altered mitochondrial function. Forzinity is the first treatment approved for Barth syndrome.

New FDA-Approved Drug Products

New Molecular Entity

Orphan Drug | Specialty

Palsonify™ (paltusotine) tablets for oral use

FDA-Approved Indication

For the treatment of adults with acromegaly who had an inadequate response to surgery and/ or for whom surgery is not an option.

Dosage & Administration

40 mg once daily.

Dosage Forms & Strengths

Tablets: 20 mg, 30 mg.

Contraindications

None

Common Adverse Reactions

Diarrhea, abdominal pain, nausea, decreased appetite, sinus bradycardia, hyperglycemia, palpitations, and gastroenteritis.

Warnings & Precautions

- Cholelithiasis and its complications
- Hyperglycemia and Hypoglycemia
- Cardiovascular Abnormalities
- Thyroid Function Abnormalities
- Steatorrhea and Malabsorption of Dietary Fats
- Vitamin B_{12} Deficiency

Drug Interactions

- Strong CYP3A4 Inducers
- Moderate CYP3A4 Inducers
- Proton Pump Inhibitors
- Cyclosporine

Clinical Studies

The approval was based on data from PATHFNDR-1 and PATHFNDR-2, two randomized, double-blind, parallel group, placebo-controlled, phase 3 trials. Results from PATHFNDR-1 showed that, at week 24, 56% of paltusotine-treated patients achieved biochemical control compared with 5% of those who received placebo. In the PATHFNDR-2 study, 83% of patients who were treated with paltusotine maintained biochemical control versus 4% of the placebo group.

Place in Therapy

Somatostatin analogs are the treatment option for patients in which surgery is not appropriate. Palsonify is the first once-daily, oral treatment approved for adults with acromegaly.

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Inluriyo™ (imlunestrant) tablets, for oral use

FDA-Approved Indication

For the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Dosage & Administration

400 mg orally once daily, on an empty stomach

Dosage Forms & Strengths

Tablets: 200 mg of imlunestrant

Contraindications

None

Common Adverse Reactions

Hemoglobin decreased, musculoskeletal pain, calcium decreased, neutrophils decreased, AST increased, fatigue, diarrhea, ALT increased, triglycerides increased, nausea, platelets decreased, constipation, cholesterol increased, and abdominal pain.

Warnings and Precautions

- Embryo-Fetal Toxicity

Drug Interactions

- Strong CYP3A Inhibitors
- Strong CYP3A Inducers

Clinical Studies

The approval was based on results from EMBER-3 trial, a Phase 3, randomized, open-label, active-controlled, multicenter study in 874 patients with ER-positive, HER2-negative locally advanced or metastatic breast cancer, who were previously treated with an aromatase inhibitor either alone or in combination with a CDK4/6 inhibitor. Results showed that, in the ESR1-mutant subgroup, imlunestrant improved median progression-free survival to 5.5 months versus 3.8 months with standard endocrine therapy. Results also demonstrated that the objective response rate 14.3% in the imlunestrant arm compared with 7.7% in the endocrine therapy arm.

Place in Therapy

Inluriyo joins the treatment landscape of ER-positive, HER2-negative, ESR1-mutated locally advanced or metastatic breast cancer, with direct competition being Orserdu (elacestrant).

New FDA-Approved Drug Products

New Molecular Entity

Specialty

Rhapsido® (remibrutinib) tablets for oral use

FDA-Approved Indication

For the treatment of chronic spontaneous urticaria in adult patients who remain symptomatic despite H1 antihistamine treatment.

Dosage & Administration

25 mg orally twice daily with or without food.

Dosage Forms & Strengths

Tablets: 25 mg

Contraindications

None

Common Adverse Reactions

Nasopharyngitis, bleeding, headache, nausea and abdominal pain.

Warnings & Precautions

- Risk of Bleeding
- Live Attenuated Vaccines

Drug Interactions

- Strong or Moderate CYP3A4 Inhibitors
- Strong or Moderate CYP3A4 Inducers
- P-gp Substrates
- Antithrombotic Agents

Use in Specific Populations

Mild, Moderate, or Severe Hepatic Impairment: Avoid use of Rhapsido.

Clinical Studies

The approval came from REMIX-1 and REMIX-2, two identical, 52-week, randomized, double-blind, placebo-controlled trials in adult patients with CSU inadequately controlled by H_1 antihistamines. Results showed that treatment with Rhapsido resulted in statistically significant improvement in itch and hives symptoms compared with placebo. In REMIX-1, the least squares (LS) mean differences in ISS7 (the sum of the daily itch severity scores [range: 0-3] recorded over a 7-day period) and HSS7 (the sum of the daily hive severity scores [range: 0-3] recorded over a 7-day period) at 12 weeks were -2.63 and -3.61, respectively. In REMIX-2, the LS mean differences were -3.23 and -4.47, respectively.

Place in Therapy

With this approval, Rhapsido is now the first oral and targeted BTK inhibitor for chronic spontaneous urticaria. Rhapsido joins the treatment landscape alongside Xolair and Dupixent.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Bosaya™ (denosumab-kyqq) injection, for subcutaneous use

FDA-Approved Indication

[1] Postmenopausal women with osteoporosis at high risk for fracture; [2] To increase bone mass in men with osteoporosis at high risk for fracture; [3] Glucocorticoid induced osteoporosis in men and women at high risk for fracture; [4] To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; [5] To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Dosage & Administration

60 mg every 6 months as a subcutaneous injection administered by a healthcare provider.

Dosage Forms & Strengths

Injection: 60 mg/mL solution in single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Pregnancy
- Know hypersensitivity to denosumab products

Common Adverse Reactions

Back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, cystitis, arthralgia, nasopharyngitis, hypertension, bronchitis, and headache.

Use in Specific Populations

- Pregnant women and females of reproductive potential: May cause fetal harm.
- Pediatric patients: Bosaya is not approved for use in pediatric patients.
- Renal impairment: No dose adjustment is necessary in patients with renal impairment.

Warnings & Precautions

- ***BBW:*** Severe Hypocalcemia in Patients with Chronic Kidney Disease
- Patients receiving Bosaya should not receive other denosumab products concomitantly
- Hypersensitivity including anaphylactic reactions may occur
- Osteonecrosis of the jaw
- Atypical femoral fractures
- Multiple vertebral fractures have been reported following treatment discontinuation
- Serious infections including skin infections
- Dermatological reactions
- Severe bones, joints, muscle pain may occur
- Suppression of bone turnover

Clinical Studies

The approval for Bosaya was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that Bosaya is highly similar to Prolia. The data demonstrated that there were no clinically meaningful differences between Bosaya and Prolia in terms of safety, efficacy, purity and potency.

Place in Therapy

Bosaya (denosumab-kyqq) is the sixth Prolia biosimilar to receive FDA-approval.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Aukelso™ (denosumab-kyqq) injection, for subcutaneous use

FDA-Approved Indication

[1] Multiple myeloma and bone metastasis from solid tumors; [2] Giant cell tumor of bone; [3] Hypercalcemia of malignancy.

Dosage & Administration

Refer to package insert for more information.

Dosage Forms & Strengths

Injection: 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial and in a single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Known clinically significant hypersensitivity to denosumab products

Common Adverse Reactions

Fatigue, asthenia, hypophosphatemia, nausea diarrhea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, headache, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, and constipation.

Use in Specific Populations

- Pediatric patients: Recommended only for treatment of skeletally mature adolescents with giant cell tumor of bone
- Renal impairment: Patients with creatinine clearance less than 30 mL/min or receiving dialysis are at risk for hypocalcemia.

Warnings & Precautions

- Patients receiving Aukelso should not receive other denosumab products concomitantly
- Hypersensitivity reactions including anaphylaxis
- Hypocalcemia
- Osteonecrosis of the jaw
- Atypical femoral fracture
- Hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons
- Multiple vertebral fractures following treatment discontinuation
- Embryo-fetal toxicity

Clinical Studies

The approval for Aukelso was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that Aukelso is highly similar to Xgeva. The data demonstrated that there were no clinically meaningful differences between Aukelso and Xgeva in terms of safety, efficacy, purity and potency.

Place in Therapy

Aukelso (denosumab-kyqq) is the sixth Xgeva biosimilar to receive FDA-approval.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Enoby™ (denosumab-qbde) injection, for subcutaneous use

FDA-Approved Indication

[1] Postmenopausal women with osteoporosis at high risk for fracture; [2] To increase bone mass in men with osteoporosis at high risk for fracture; [3] Glucocorticoid induced osteoporosis in men and women at high risk for fracture; [4] To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; [5] To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Dosage & Administration

60 mg every 6 months as a subcutaneous injection administered by a healthcare provider.

Dosage Forms & Strengths

Injection: 60 mg/mL solution in single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Pregnancy
- Know hypersensitivity to denosumab products

Common Adverse Reactions

Back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, cystitis, arthralgia, nasopharyngitis, hypertension, bronchitis, and headache.

Use in Specific Populations

- Pregnant women and females of reproductive potential: May cause fetal harm.
- Pediatric patients: Enoby is not approved for use in pediatric patients.
- Renal impairment: No dose adjustment is necessary in patients with renal impairment.

Warnings & Precautions

- ***BBW:*** Severe Hypocalcemia in Patients with Chronic Kidney Disease
- Patients receiving Enoby should not receive other denosumab products concomitantly
- Hypersensitivity including anaphylactic reactions may occur
- Osteonecrosis of the jaw
- Atypical femoral fractures
- Multiple vertebral fractures have been reported following treatment discontinuation
- Serious infections including skin infections
- Dermatological reactions
- Severe bones, joints, muscle pain may occur
- Suppression of bone turnover

Clinical Studies

The approval for Enoby was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that Enoby is highly similar to Prolia. The data demonstrated that there were no clinically meaningful differences between Enoby and Prolia in terms of safety, efficacy, purity and potency.

Place in Therapy

The FDA has approved Enoby, making it an additional Prolia biosimilar to join the market.

New FDA-Approved Drug Products

New Biosimilar Product

Specialty

Xtrenbo™ (denosumab-qbde) injection, for subcutaneous use

FDA-Approved Indication

[1] Multiple myeloma and bone metastasis from solid tumors; [2] Giant cell tumor of bone; [3] Hypercalcemia of malignancy.

Dosage & Administration

Refer to package insert for more information.

Dosage Forms & Strengths

Injection: 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial and in a single-dose prefilled syringe.

Contraindications

- Hypocalcemia
- Known clinically significant hypersensitivity to denosumab products

Common Adverse Reactions

Fatigue, asthenia, hypophosphatemia, nausea diarrhea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, headache, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, and constipation.

Use in Specific Populations

- Pediatric patients: Recommended only for treatment of skeletally mature adolescents with giant cell tumor of bone
- Renal impairment: Patients with creatinine clearance less than 30 mL/min or receiving dialysis are at risk for hypocalcemia.

Warnings & Precautions

- Patients receiving Xtrenbo should not receive other denosumab products concomitantly
- Hypersensitivity reactions including anaphylaxis
- Hypocalcemia
- Osteonecrosis of the jaw
- Atypical femoral fracture
- Hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons
- Multiple vertebral fractures following treatment discontinuation
- Embryo-fetal toxicity

Clinical Studies

The approval for Xtrenbo was based on a comprehensive package of analytical, nonclinical and clinical data, which confirmed that Xtrenbo is highly similar to Xgeva. The data demonstrated that there were no clinically meaningful differences between Xtrenbo and Xgeva in terms of safety, efficacy, purity and potency.

Place in Therapy

The FDA has approved Xtrenbo, making it an additional Xgeva biosimilar to join the market.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Zolymbus™ (bimatoprost) gel for topical ophthalmic use

FDA-Approved Indication

For the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Dosage & Administration

One drop in the affected eye(s) once daily in the evening.

Dosage Forms & Strengths

Ophthalmic gel: 0.01% bimatoprost in a single-dose container.

Contraindications

Hypersensitivity

Common Adverse Reactions

Conjunctival hyperemia and eye irritation.

Warnings & Precautions

- Pigmentation
- Eyelash Changes

Use in Specific Populations

Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

Clinical Studies

The approval was based on results from a 12-week clinical trial of patients with open-angle glaucoma or ocular hypertension with a mean baseline IOP of 23 to 24 mmHg, the IOP-lowering effect of Zolymbus once daily (in the evening) was non-inferior to preserved bimatoprost ophthalmic solution 0.01%.

Place in Therapy

The prostaglandin analogs are considered first-line for the treatment of glaucoma due to being the most effective, generally well-tolerated, administered once daily, and readily available as generics. The choice of the agent is based on tolerability, access, and cost.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Specialty

Inlexzo™ (gemcitabine) intravesical system

FDA-Approved Indication

For the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS) with or without papillary tumors.

Dosage & Administration

Inserted into the bladder, using the co-packaged urinary catheter and stylet, once every 3 weeks up to 6 months (8 doses), followed by once every 12 weeks (6 doses).

Dosage Forms & Strengths

One single-dose 225 mg gemcitabine intravesical system

Contraindications

- Perforation of the bladder
- Prior hypersensitivity reaction to gemcitabine or any component of the product

Common Adverse Reactions

Urinary frequency, urinary tract infection, dysuria, micturition urgency, decreased hemoglobin, increased lipase, urinary tract pain, decreased lymphocytes, hematuria, increased creatinine, increased potassium, increased AST, decreased sodium, bladder irritation, and increased ALT.

Warnings & Precautions

- Risks in Patients with Perforated Bladder
- Risk of Metastatic Bladder Cancer with Delayed Cystectomy
- Magnetic Resonance Imaging (MRI) Safety
- Embryo-Fetal Toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed.

Clinical Studies

The approval was based on results of the cohort 2 of the single-arm, phase 2b SunRISe-1 study, which included patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, who were ineligible for or elected not to undergo radical cystectomy. Of the 83 study participants, 82% achieved a complete resolution, and 51% of those responders maintained a complete resolution for at least 1 year.

Place in Therapy

Inlexzo is an intravesical gemcitabine-releasing system that sustains drug delivery over a 3-week period, avoiding the need for weekly instillations. Inlexzo offers an outpatient, bladder-sparing option for patients who decline or are ineligible for cystectomy.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Enbumyst™ (bumetadine) spray for nasal use

FDA-Approved Indication

For the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome in adults.

Dosage & Administration

0.5 mg to 2 mg administered once daily. Enbumyst is not intended for chronic use; replace with oral diuretics as soon as practical.

Dosage Forms & Strengths

Nasal spray: 0.5 mg bumetanide per 0.1 mL spray

Contraindications

- Anuria
- Hepatic Coma
- History of hypersensitive to bumetanide

Common Adverse Reactions

Hypovolemia, headache, muscle cramps, dizziness, hypotension, nausea and encephalopathy (in patients with pre-existing liver disease).

Warnings & Precautions

- Fluid, Electrolyte, and Metabolic Abnormalities
- Worsening Renal Function
- Ototoxicity
- Potential Altered Absorption in Patients with Nasal Mucosal or Structural Abnormalities

Drug Interactions

- Lithium
- Probenecid
- Indomethacin
- Drugs with ototoxic potential
- Drugs with nephrotoxic potential
- Antihypertensives

Use in Specific Populations

Lactation: A lactating woman treated with Enbumyst should monitor her infant for excessive urine output, dehydration, and lethargy.

Clinical Studies

The approval was based on results of a study that compared the absorption and efficacy of intranasal bumetanide with oral and intravenous (IV) bumetanide.

Place in Therapy

The pharmacologic treatment of HF is based upon the ACCF/AHA stage of HF and NYHA functional class and varies by type. Diuretics are usually used by patients alongside other drugs such as ARN inhibitors, ACE inhibitors or ARBs, mineralocorticoid receptor antagonists (MRA) or beta blockers, and SGLT-2 inhibitors. Enbumyst is a treatment option for patients that have trouble swallowing pills or don't have easy access to IV treatments.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Subvenite™ (lamotrigine) oral suspension

FDA-Approved Indication

[1] Adjunctive therapy in patients aged 2 years and older with partial-onset seizures, primary generalized tonic-clonic (PGTC) seizures, and generalized seizures of Lennox-Gastaut syndrome; [2] Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug; [3] Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy.

Dosage & Administration

Refer to package insert for administration instructions.

Dosage Forms & Strengths

Oral Suspension: 10 mg/mL

Contraindications

Hypersensitivity to the drug or its ingredients.

Common Adverse Reactions

Dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, rash, vomiting, infection, fever, accidental injury, diarrhea, abdominal pain, tremors, insomnia, back pain, fatigue, abdominal pain and xerostomia.

Warnings & Precautions

- ***BBW:*** Serious Skin Rashes
- Hemophagocytic lymphohistiocytosis
- Drug Reaction with Eosinophilia and Systemic Symptoms/Multiorgan Hypersensitivity
- Cardiac rhythm and conduction abnormalities
- Blood dyscrasias
- Suicidal behavior and ideation
- Aseptic meningitis
- Medication errors due to product name confusion

Drug Interactions

- Valproate
- Carbamazepine, phenytoin, phenobarbital, primidone, and rifampin
- Estrogen-containing oral contraceptives
- Protease inhibitors lopinavir/ritonavir and atazanavir/lopinavir
- Coadministration with organic cationic transporter 2 substrates with narrow therapeutic index

Use in Specific Populations

- Pregnancy: Based on animal data may cause fetal harm.
- Hepatic impairment: Dosage adjustments required in patients with moderate and severe liver impairment.
- Renal impairment: Reduced maintenance doses may be effective for patients with significant renal impairment.

Clinical Studies

The efficacy of Subvenite is based on the established effectiveness of lamotrigine oral tablets.

Place in Therapy

Lamotrigine is a widely prescribed medication that was only available as a solid oral dosage form. This new oral suspension is designed for patients who have difficulty swallowing tablets, those who require individualized dosing, or prefer liquid medication formulations.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Specialty

Keytruda Qlex™ (pembrolizumab and berahyaluronidase) injection for subcutaneous use

FDA-Approved Indication

Several including head and neck squamous cell cancer (HNSCC), melanoma, non-small cell lung cancer, ovarian cancer, gastric cancer, etc. (Not approved for hematologic malignancies, unlike the IV formulation).

Dosage & Administration

Refer to package insert for more information.

Dosage Forms & Strengths

Injection:

- 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg/2,000 units per mL) in a single-dose vial
- 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 4.8 mL (165 mg/2,000 units per mL) in a single-dose vial

Contraindications

In patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

Common Adverse Reactions

Several including fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism

Warnings & Precautions

- Immune-Mediated Adverse Reactions
- Hypersensitivity and Administration-Related Reactions
- Complications of Allogeneic HSCT
- Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials
- Embryo-Fetal toxicity

Use in Specific Populations

Lactation: Advise not to breastfeed

Clinical Studies

The effectiveness of Keytruda Qlex for its approved indications has been established based upon the evidence from the adequate and well-controlled studies conducted with intravenous pembrolizumab and additional data that demonstrated comparable pharmacokinetic, efficacy, and safety profiles between Keytruda Qlex and intravenous pembrolizumab.

Place in Therapy

This new formulation offers shorter, more convenient procedures that helps reduce time burden. With this approval, Keytruda Qlex joins two other SC checkpoint inhibitors: Tecentriq Hybreza and Opdivo Qvantig.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Bondlido™ (lidocaine) topical system

FDA-Approved Indication

Indicated in adults for relief of pain associated with post-herpetic neuralgia (PHN).

Dosage & Administration

Apply the prescribed number of topical systems (maximum of two) only once for up to 12 hours in a 24-hour period.

Dosage Forms & Strengths

Topical System: 10% lidocaine.

Contraindications

In patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

Common Adverse Reactions

Application site reactions such as irritation, erythema, and pruritus.

Warnings & Precautions

- Accidental Exposure
- Excessive Dosing
- Non-Intact Skin
- External Heat Sources
- Methemoglobinemia
- Application Site Reactions
- Hypersensitivity Reactions
- Eye Exposure

Drug Interactions

- Antiarrhythmic Drugs
- Local Anesthetics

Use in Specific Populations

Lactation: Lidocaine is excreted into human milk.

Clinical Studies

The safety and effectiveness of Bondlido were supported by clinical trial data from a different lidocaine topical system.

Place in Therapy

Lidocaine patches are widely used in the treatment of PHN. Bondlido uses a novel technology designed to increase the transdermal permeability of drugs.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Orphan Drug | Specialty

Clotic™ (clotrimazole) otic solution

FDA-Approved Indication

For the treatment of fungal otitis externa (otomycosis) due to *Aspergillus* species and *Candida* species in patients 18 years of age and older

Dosage & Administration

Instill the contents of one single-dose vial into the affected ear canal twice daily, morning and evening, preferably 12 hours apart for 14 consecutive days.

Dosage Forms & Strengths

Otic solution: Each single-dose vial of Clotic otic solution, 1%, delivers approximately 0.17 mL of solution equivalent to 1.7 mg of clotrimazole.

Contraindications

In patients with known hypersensitivity to clotrimazole.

Common Adverse Reactions

Headache, application site pain, tinnitus, tympanic membrane perforation, and paresthesia.

Warnings & Precautions

None

Clinical Studies

The approval was based on results of two randomized, double-blind, placebo-controlled studies in adult patients with a positive baseline fungal culture for Aspergillus species and/or Candida species (mycological intent-to-treat [MITT] population). In trial 1, therapeutic cure, defined as both clinical cure and mycological cure at the test of cure visit which occurred on day 24 to 26, was achieved in 58.5% and 27.8% of patients with Clotic and placebo, respectively. In trial 2, therapeutic cure was achieved in 78.7% and 22.9% of patients with Clotic and placebo, respectively.

Place in Therapy

With this approval, Clotic becomes the first FDA-approved treatment for fungal otitis externa in adult patients. Before the approval of this medication, other topical antifungals, which are considered first-line treatment options, were used off-label.

Other notable new approvals include:

Koselugo (selumetinib) oral granules

The Food and Drug Administration (FDA) has approved Koselugo (selumetinib) oral granules and capsules for pediatric patients aged 1 year and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). Previously Koselugo had only been available in a capsule formulation for patients aged 2 years and older.

Qivigy (immune globulin intravenous, human-kthm) 10% solution

Qivigy is indicated for treatment of adults with primary humoral immunodeficiency (PI). Qivigy is a ready-to-use, sterile, non-pyrogenic liquid solution of human immune globulin (IgG) for IV administration. This product represents another IVIG treatment option for patients.

New First-Time Generic Approvals

First-Time Generics are the first generic forms of brand name drugs. The generic version is formulated to work in the same way as the brand-name product and provides the same clinical benefit.

No New First- Time Generics were approved during September

New FDA-Approved Indications for Existing Drugs

The following table contains drugs that have gained FDA approval for the treatment of additional diseases or conditions.

Drug Name and Manufacturer	Previous Indication(s)	New Indication
Vonvendi™ (Von Willerbrand factor (recombinant) From: Takeda Pharmaceuticals	Indicated for adults with von Willebrand factor (VWD): [1] On-demand treatment and control of bleeding episodes; [2] Perioperative management of bleeding	Indicated for adults and pediatric patients with von Willebrand factor (VWD): [1] On-demand treatment and control of bleeding episodes; [2] Perioperative management of bleeding
Koselugo™ (selumetinib) From: AstraZeneca	For the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas	For the treatment of pediatric patients 1 year of age and older with neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas
Opzelura™ (ruxolitinib) From: Incyte Corp	The topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	The topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Evkeeza™ (evinacumab-dgnb) From: Regeneron Pharmaceuticals	As an adjunct to other low-density lipoprotein-cholesterol lowering therapies for the treatment of adult and pediatric patients, aged 5 years of age and older, with homozygous familial hypercholesterolemia	As an adjunct to diet and exercise and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies to reduce LDL-C in adults and pediatric patients, aged 1 year and older, with homozygous familial hypercholesterolemia

Pipeline

The goals of the NDA (or BLA) are to provide enough information to permit FDA approval of a new pharmaceutical for sale and marketing in the U.S.

Drug Name and Manufacturer	Indication(s)	Additional Information	Impact
Ensitrelvir *From: Shionogi & Co., Ltd*	Post-exposure Prophylaxis of COVID-19	NDA Acceptance	Low

Pipeline Generics

This section describes generics that may possibly be available on the market in the next month. Various legal factors may come into play, affecting the date.

Generic Name	Brand Name	Brand Manufacturer
Rilpivirine Hydrochloride	Edurant	Johnson & Johnson (Janssen)
Rilpivirine Hydrochloride	Edurant Ped	Johnson & Johnson (Janssen)