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PHARMNOTES

January 2024

urac
ACCREDITED
Pharmacy Benefit Management
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Drug Safety Alert Notification

Safety Alert	Date	Additional Information
Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity	1-11-2024	The U.S. Food and Drug Administration (FDA) has been evaluating reports of suicidal thoughts or actions in patients treated with glucagon-like peptide-1 receptor agonists. These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. The preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions.
FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab)	1-19-2024	Based on a completed U.S. Food and Drug Administration (FDA) review of available information, it has been concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia, very low blood calcium levels, in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death. As a result, we are revising the Prolia prescribing information to include a new Boxed Warning, FDA's most prominent warning, communicating this increased risk.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Zelsuvmi (berdazimer sodium)	Ligand Pharmaceuticals	1/5/2024

THERAPEUTIC CLASS
Nitric oxide releasing agent

FDA-APPROVED INDICATION(S)
For the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

DOSAGE AND ADMINISTRATION
- Supplied in a carton containing Tube A (berdazimer gel) and Tube B (hydrogel). Mix equal amounts of gel from Tube A and Tube B.
- Dispense equal amounts (0.5mL) of gel from both tubes. Mix and apply as an even thin layer once daily to each MC lesion for up to 12 weeks.

DOSAGE FORMS AND STRENGTHS
Topical gel: 10.3% berdazimer supplied as two tubes. Tube A contains berdazimer gel and Tube B contains hydrogel.

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- *Application Site Reactions*: Application site reactions, including allergic contact dermatitis, occurred. Discontinue Zelsuvmi and initiate appropriate therapy.

ADVERSE REACTIONS
- The most commonly reported adverse reactions (≥1%) are application site reactions, including pain (such as burning or stinging sensations), erythema, pruritus, exfoliation, dermatitis, swelling, erosion, discoloration, vesicles, irritation, and infection.

USE IN SPECIFIC POPULATIONS
- *Pregnancy*: There are no available data on Zelsuvmi use in pregnant women to evaluate for a drug associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- *Lactation*: There are no data on the presence of berdazimer or its metabolite in either human or animal milk, the effects on the breastfed infant, or the effects on milk production.
- *Pediatric use*: The safety and effectiveness of Zelsuvmi for the topical treatment of MC have been established in pediatric patients 1 year of age and older.

Orphan status: No

New Biosimilar Products

- No new biosimilar product was approved during the month of January.

New Formulations, Combination Products & Line Extensions

- No new formulation/combination/line extension was approved during the month of January.

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)
Nilotinib Hydrochloride Capsules 50mg (base), 150mg (base) and 200mg (base)	Apotex Corp	1/5/2024	Tasigna	BCR-ABL tyrosine kinase inhibitors	Chronic Myeloid Leukemia
Fidaxomicin Tablets 200 mg	Actavis Laboratories FL, Inc	1/16/2024	Dificid	Macrolides	Clostridioides difficile-Associated Diarrhea
Pimavanserin Tartrate Capsules 34 mg (base)	MSN Laboratories Private Limited; Zydus Pharmaceuticals USA Inc.	1/16/2024	Nuplazid Capsules	Atypical antipsychotics	Parkinson's Disease Psychosis
Pimavanserin Tartrate Tablets 10 mg (base)	Zydus Pharmaceuticals USA Inc.	1/16/2024	Nuplazid Tablets	Atypical antipsychotics	Parkinson's Disease Psychosis

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Hyqvia (immune globulin and hyaluronidase) From: Takeda Pharmaceuticals	Passive Immunizing and Treatment Agents	Primary immunodeficiency in adults and pediatric patients two years of age and older	Maintenance therapy in adults with chronic demyelinating polyneuropathy	1/12/2024
Keytruda (pembrolizumab) From: Merck	Antineoplastics	Various indications, including melanoma, non-small cell lung cancer, cervical cancer, renal cell carcinoma.	FIGO 2014 Stage III-IVA cervical cancer	1/12/2024
Casgevy (exagamglogene autotemcel) From: Vertex	Hematopoietic Agents	Treatment of sickle cell disease in patients 12 years and older with recurrent vaso occlusive crises	Transfusion dependent beta thalassemia in patients 12 years and older	1/16/2024
Gammagard Liquid (immune globulin infusion (human)) From: Takeda Pharmaceuticals	Passive Immunizing and Treatment Agents	[1] Primary immunodeficiency; [2] Multifocal motor neuropathy	Chronic inflammatory demyelinating polyneuropathy	1/26/2024

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
DFD-29 (minocycline hydrochloride) From: Journey Medical Corporation	1/5/2024	For the treatment of inflammatory lesions and erythema of rosacea in adults.	NDA submitted.	Moderate

References

- *New Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/newdrugs.html.
- *Latest Generic Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/generic-approvals.html.
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- *Drugs@FDA: FDA-Approved Drugs. Accessdata.FDA.gov. (2023).* *https://www.accessdata.fda.gov/scripts/cder/daf/.*