

New Drug Update



SERIES 46

MAY 2023

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FDA approved drugs

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1. Fecal Microbiota Spores, live- brpk

DATE OF APPROVAL : April 26, 2023

DRUG CLASS: Oral microbiome-based therapeutic

INDICATION: To prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI

DOSAGE FORM: Capsules for Oral use

2. Tofersen

DATE OF APPROVAL : April 25, 2023

DRUG CLASS: Antisense oligonucleotide

INDICATION: Treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene

DOSAGE FORM: Injection for Intrathecal use

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For Further Reading:

1. US Food and Drug Administration. Novel drug approvals; USA [Internet] 2023 [cited 2023 May 01]. Available from: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023>
2. Drugs.com. New drug approvals; New zealand [Internet] 2023 [cited 2023 May 01]. Available from: <https://www.drugs.com/newdrugs.html>

3. Omidubicel-only

DATE OF APPROVAL : April 17, 2023

DRUG CLASS: Nicotinamide (NAM) modified allogeneic hematopoietic progenitor cell

INDICATION: For use in patients with hematologic malignancies to reduce risk of infection following stem cell transplantation

DOSAGE FORM: Suspension for Infusion

4. Rizatriptan (Oral Film)

DATE OF APPROVAL: April 14, 2023

DRUG CLASS: Serotonin (5-HT) 1B/1D receptor agonist

INDICATION: Acute treatment of Migraine

DOSAGE FORM: Oral film

