PharmaFacts for Case Managers

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Sephience oral powder

- *Generic Name:* Sepiapterin
- *Company*: PTC Therapeutics, Inc.
- *Treatment For:* Hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU). SEPHIENCE is to be used in conjunction with a phenylalanine (Phe)-restricted diet.
- *Description:* Sephience contains the drug substance sepiapterin, a phenylalanine hydroxylase (PHA) activator. It is a yellow to orange powder with water solubility of ¼ mg/mL.
- *Drug Class:* Phenylalanine hydroxylase activator.
- *Dosing Information:* The recommended starting dose is based on the patient's age and is given once daily.
- *Side Effects:* Increased bleeding and hypophenylalaninemia.
- *Full Prescribing Information:* https://www.sephience.com/wp-content/uploads/prescribing-information.pdf

Vostally oral solution

- *Generic Name:* Ramipril oral solution
- *Company:* Rosemont Pharmaceuticals, Inc.
- *Treatment For:* 1) Hypertension in adults; 2) patients 55 years or older at high risk of developing a major cardiovascular event because of history of coronary artery disease, stroke, peripheral vascular disease, or diabetes that is accompanied by at least one other cardiovascular risk factor (hypertension, elevated total cholesterol levels, low high-density cholesterol levels, cigarette smoking, or documented microalbuminuria) to reduce the risk of myocardial infarction, stroke, or death from cardiovascular disease; 3) adult patients with post-myocardial infarction heart failure to reduce the risk of cardiovascular death and hospitalization for heart failure.
- *Description*: Vostally is an angiotensin-converting enzyme (ACE) inhibitor.
- *Drug Class:* Antihypertensive.
- *Dosing Information:* The starting dose of Vostally is 2.5 mg orally, twice daily.

Warning: Fetal Toxicity

- When pregnancy is detected, discontinue Vostally as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

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- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.
- *Side Effects:* Fetal toxicity.
- *Full Prescribing Information:* https://rosemontpharmaceuticals.com/wp-content/uploads/2025/07/Vostally_ramipril-PIL_final-1.pdf

Kirsty insulin aspart-xjhz

- *Generic Name:* Insulin aspart-xjhz injection
- *Company*: Bicon Biologics Inc.
- *Treatment For:* Improving glycemic control in adult and pediatric patients with diabetes mellitus.
- *Description*: Kirsty is a rapid-acting human insulin analog homologous with regular human insulin, with the exception of a single substitution of the amino acid proline by aspartic acid in position B28 and is produced by recombinant DNA technology utilizing Pichia pastoris.
- *Drug Class:* Antidiabetic.
- *Dosing Information:* Dosing is individualized based on patient needs. Kirsty is available in prefilled syringes and multidose vials.

- *Side Effects:* Hypoglycemia, hypoglycemia due to medication errors, hypersensitivity, and hypokalemia.
- *Full Prescribing Information:* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761188s001lbl.pdf

Ekterly tablets

- *Generic Name:* Sebetralstat
- *Company*: KalVista Pharmaceut icals Limited
- *Treatment For*: On-demand treatment for hereditary angioedema attacks in adults and pediatric patients ages 12 years and older.
- *Description*: A plasma kallikrein inhibitor tablet used for treatment of hereditary angioedema attacks.
- *Drug Class:* Plasma kallikrein inhibitor.
- *Dosing Information:* 600 mg at signs of first attack. If symptoms worsen, repeated in 3 hours. Not to exceed 1,200 mg in 24 hours.
- *Side Effects:* Headache.
- *Full Prescribing Information:* https://www.kalvista.com/ekterly-us-prescribing-information.pdf

Lynozyfic injection

- *Generic Name:* Linvoseltamab-gcpt
- *Company*: Regeneron Pharmaceuticals, Inc.
- *Treatment For:* Adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- *Description*: Linvoseltamab-gcpt, a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, is a recombinant human immunoglobulin (Ig)G4 antibody. Linvoseltamab-gcpt is produced by recombinant DNA technology in Chinese hamster ovary (CHO) cell suspension culture. The molecular weight of linvoseltamab-gcpt is approximately 146 kDa.
- *Drug Class:* Human immunoglobulin antibody.
- *Dosing Information:* LYNOZYFIC is administered intravenously according to the step-up schedule to reduce the incidence and severity of cytokine release syndrome.

Warning:

- Cytokine Release Syndrome and Neurological Toxicity including immune effector cell–associated neurotoxicity syndrome, infections, neutropenia, and hepatotoxicity.

- *Side Effects:* Musculoskeletal pain, cytokine release syndrome, neurological toxicity, cough, upper respiratory tract infection, diarrhea, fatigue, dyspnea, pneumonia, nausea and headache.
- *Full Prescribing Information:* https://www.regeneron.com/downloads/lynozyfic_fpi.pdf

Zegfrovy tablets

- *Generic Name:* Sunvozertinib
- *Company*: Dizal (Jiangsu) Pharmaceuticals Co., Ltd.
- *Treatment For:* Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.
- *Description*: Zegfrovy is a kinase inhibitor of EGFR that binds to and inhibits EGFR exon 20 insertion mutations at similar concentrations as wild-type EGFR.
- *Drug Class:* Kinase inhibitor.
- *Dosing Information:* The recommended dosage of Zegfrovy is 200 mg orally once daily with food until disease progression or unacceptable toxicity. Tablets should be swallowed whole and not split, crushed, chewed, or dissolved. Zegrovy is taken at the same time each day.
- *Side Effects:* Interstitial lung disease/pneumonitis, gastrointestinal adverse reactions, dermatologic adverse reactions, ocular toxicity.
- *Full Prescribing Information:* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219839s000lbl.pdf

The FDA is now requiring new labeling for all opioid pain medication to address risks.

- The labeling changes will include the following updates:
- *Clearer Risk Information:* A summary of study results showing the estimated risks of addiction, misuse, and overdose during long-term use.

- *Dosing Warnings:* Stronger warnings that higher doses come with greater risks, and that those risks remain over time.
- *Clarified Use Limits:* Removing language that could be misinterpreted to support using opioid pain medications over indefinitely long duration.
- *Treatment Guidance:* Labels will reinforce that long-acting or extended-release opioids should only be considered when other treatments, including shorter-acting opioids, are inadequate.
- *Safe Discontinuation:* A reminder not to stop opioids suddenly in patients who may be physically dependent, as it can cause serious harm.
- *Overdose Reversal Agents:* Additional information on medicines that can reverse an opioid overdose.
- *Drug Interactions:* Enhanced warning about combining opioids with other drugs that slow down the nervous system—now including gabapentinoids.
- *More Risks with Overdose:* New information about toxic leukoencephalopathy—a serious brain condition that may occur after an overdose.
- *Digestive Health:* Updates about opioid-related problems with the esophagus.