WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 8/1/25 – 8/31/25

FDA Drug Safety Communications & Drug Information Updates:

Unapproved Thyroid Medications (animal-derived thyroid medication, desiccated thyroid extract) 8/7/25
The FDA issued a statement regarding use and availability of unapproved thyroid medications (desiccated thyroid extract, animal-derived thyroid medication) sold by prescription. Animal derived thyroid products were grandfathered in after the Food, Drug, and Cosmetic Act of 1938, which required evidence of safety for new drugs, but did not address drugs already on the market. Since 2006, the FDA has been addressing these unapproved drugs, using risk-based assessment to mediate the process of removing unapproved drugs. The FDA noted concerns with the safety and effectiveness of the unapproved thyroid medications, which have not been FDA reviewed for safety, purity, potency, or efficacy. Patients and prescribers are strongly encouraged to transition to FDA-approved synthetic thyroid (levothyroxine or liothyronine), as this is the guideline-recommended treatment of hypothyroidism, although the FDA is not taking immediate action against manufacturers to give patients time to transition therapy. The thyroid medication announcement can be found here. Additional information on unapproved drugs can be found on the FDA's Unapproved Drugs page.

Skysona (elivaldogene autotemcel) Labeling Changes – Increased Risk Hematologic Malignancy 8/7/25
Following investigation of reports of hematologic malignancies following treatment of early, active cerebral adrenoleukodystrophy patients with Skysona, the FDA has received reports of hematologic malignancies in 10 of 67 (15%) clinical trial participants. The FDA has required updates to the boxed warning, indications, warnings and precautions, and adverse reactions sections of the prescribing information and medication guide. The revised indication restricts use to patients without an available human leukocyte antigen (HLA)-matched allogeneic hematopoietic stem cell donor.

Ixchiq (Chikungunya vaccine, live) – FDA Suspends Biologics License 8/22/25
The FDA's Center for Biologics Evaluation and Research (CBER) suspended the biologics license for Ixchiq (Chikungunya vaccine, live) due to serious adverse events consistent with chikungunya-like illness and a death directly related to the vaccine. Additional information can be found on the FDA site.

Clozapine REMS Program Discontinued – Drug Safety Communication 8/27/25
The FDA issued a Drug Safety Communication announcing removal of the clozapine risk evaluation and mitigation strategy (REMS) for clozapine effective June 13, 2025. Prescribers are reminded to continue to monitor patients' absolute neutrophil count as described in the prescribing information to mitigate risk of severe neutropenia.

Updated Labeling for Alzheimer's Drug Leqembi (lecanemab) to Include Earlier MRI Monitoring 8/28/25
Leqembi (lecanemab) infusion for slowing Alzheimer's disease progression comes with a recommendation to monitor for amyloid-related imaging abnormalities with edema (ARIA-E) via MRI before the 5th, 7th, and 14th infusions. The FDA identified serious and fatal outcomes earlier in treatment, prompting a recommendation for MRI monitoring prior to the 3rd infusion for earlier identification of ARIA-E.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

t:slim X2 Insulin Pump, Tandem Diabetes Care: Device Correction – Error Discontinues Insulin Delivery 8/7/25
Tandem Diabetes Care has issued a medical device correction for select t:slim X2 insulin pumps to address a speaker-related issue that can trigger an error which results in discontinuation of insulin delivery. Notices were sent to impacted customers in July 2025 with instructions on what to do for a Malfunction 16 alarm. Additional information can be found on the FDA site.

DermaRite Industries Products: Recall –Contamination 8/9/25 & 8/29/25

DermaRite Industries expanded the July recall of DermaKleen, DermaSarra, KleenFoam, and PeriGiene to include additional hand sanitizers, cleansers, skin protectants, and deodorants due to potential contamination with *Burkholderia Cepacia* Complex (BCC). The company advises destroying all products associated with this recall. The affected products, item numbers, lots and additional recommendations can be found on the FDA site.

Novum IQ Infusion Pumps, Baxter: Early Alert -- Urgent Medical Device Correction 8/15/25

Baxter has issued a device correction for Novum IQ Large Volume Pumps (LVP) and Novum IQ Syringe Pumps (SP) for software issues that can affect drug infusion therapy. The alert is for all serial numbers of the Novum IQ LVP product code 40700BAXUS/UDI-DI #05413765851797 and Novum IQ SP product code 40800BAXUS/UDI-DI #05413765852428. Instructions for continued use of these pumps if alternatives are not available can be found on the FDA site.

Lactated Ringers USP and 0.9% Sodium Chloride Injection USP, B. Braun Medical: Recall - Particulate 8/19/25

One lot of lactated ringers injection USP 1000 mL (NDC 0264-7750-07; lot # J4S807) and one lot of 0.9% sodium chloride injection USP 1000 mL (NDC 0264-7800-09; lot # V3K770) from B. Braun Medical were recalled due to the presence of particulate matter inside the container. Both were distributed nationwide in boxes of 12 each.

Cyclobenzaprine Hydrochloride Tablets 10 mg, Unichem Pharmaceuticals: Recall – Mislabeling 8/27/25

One lot (number GMML24026A, expiry Sept 2027) labeled as cyclobenzaprine 10 mg tablets from Unichem Pharmaceuticals (NDC 29300-415-19) was recalled after discovery that the cyclobenzaprine label had been placed on bottles containing meloxicam 7.5 mg tablets.

Plum Duo Infusion System, ICU Medical Inc: Correction (Recall) – Software Update 8/28/25

ICU Medical advises users to quarantine the Plum Duo Infusion System with Software Version 1.1.3 and earlier (model M3335400021, UDI 400020401) if possible until a patch is available to correct a software issue that may result in the pump becoming unresponsive. If continued use is necessary, risk mitigation strategies are provided.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Green Lumbar (counterfeit products that are missing lot numbers)	Sexual enhancement	Tadalafil
Pain Flex	Joint pain	Dexamethasone, methocarbamol

New Product Shortages (per FDA or ASHP)	***Date Initially Posted***
Fluocinolone acetonide intravitreal implant	8/4/25
Valproate Sodium Injection	8/13/25
Dextran Low Molecular Weight (Dextran 40), 10% Injection	8/13/25
Dimenhydrinate Injection	8/14/25
Methylprednisolone Acetate Injection	8/25/25
Sodium Ferric Gluconate Complex	8/26/25
Mometasone Furoate and Formoterol Fumarate Inhalation Aerosol	8/29/25

ASHP Drug Shortages List contains up to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Palivizumab injection (Synagis, Swedish Oprhan Biovitrum AB) manufacturing discontinued and will no longer be available as of 12/31/25; nirsevimab and clesrovimab are preferred	8/13/25
Methotrexate injection (Otrexup, Assertio Specialty Pharmaceutical): discontinue of manufacturing, other methotrexate injectable formulations remain available	8/29/25

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Dordaviprone/Modeyso/Jazz Pharmaceuticals, Inc.	Protease activator for systemic therapy for H3 K27M-mutant diffuse midline glioma for adults and pediatric patients 1 year of age and older	8/6/25
Zongertinib/Hernexeos/Boehringer Ingelheim Pharmaceuticals, Inc.	Tyrosine kinase inhibitor for treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations and who have received prior systemic therapy	8/8/25
Brensocatib/Brinsupri/Insmed, Inc.	Dipeptidyl peptidase 1 inhibitor for the treatment of non-cystic fibrosis bronchiectasis in patients ages 12 years and older	8/12/25
Zopapogene imaadenovec-drba/Papzimeos/Precigen, Inc.	Adenoviral vector based immunotherapy for treatment of recurrent respiratory papillomatosis in adult patients	8/14/25
Donidalorsen/Dawnzera/Ionis Pharmaceuticals, Inc.	Prekallikrein directed antisense oligonucleotide for prophylaxis of hereditary angioedema attacks in pediatric and adult patients 12 years of age and older	8/21/25
Rilzabrutinib/Wayrilz/Genzyme Corporation	Bruton's tyrosine kinase inhibitor for the treatment of adults with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment	8/29/25

New Indications:	***Description***	***Date Approved***
Dasatinib/Phyrago/Handa Therapeutics	Treatment of pediatric patients 1 year and older with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase or newly diagnosed Ph+ acute lymphoblastic leukemia in combination with chemotherapy	8/1/25
Fremanezumab-vfrm/Ajovy/Teva Pharmaceuticals	Indication expanded to include preventive treatment of episodic migraine in pediatric patients (6-17 years) who weigh at least 45 kg	8/5/25
Tocilizumab/Actemra/Genentch, Inc.	Indication expanded to include treatment of COVID-19 in hospitalized patients 2 years and older who are receiving systemic steroids and require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)	8/8/25
Semaglutide/Wegovy/Novo Nordisk	Treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (stage F2 to F3 fibrosis) in adults	8/15/25

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Articaine/Cykix/American Genomics	Ophthalmic solution 8%: for ocular surface anesthesia prior to ocular procedures and/or intraocular injections in adults and pediatric patients	8/15/25
Cyclobenzaprine/Tonimya/Tonix	Sublingual tablet 2.8 mg: for the treatment of fibromyalgia	8/15/25
Leuprolide mesylate/Camcevi ETM/Foresee Pharmaceuticals, Ltd.	Injectable emulsion, 21 mg: for subcutaneous administration every 3 months in the treatment of adult patients with advanced prostate cancer	8/27/25
Apremilast/Otezla XR/Amgen	Extended-release tablets 75 mg: for the treatment of active psoriatic arthritis, plaque psoriasis, oral ulcers associated with Behcet's disease	8/29/25
Escitalopram/Almatica Pharma	Capsules 15 mg; for treatment of major depressive disorder in patients 12 to 65 years of age and generalized anxiety disorder in adults younger than 65 years of age	8/29/25
Lecanemab/Leqembi Iqlik/Eisai	Single-dose prefilled autoinjector 360 mg/1.8 mL: for subcutaneous administration once weekly as maintenance therapy following 18 months of biweekly IV lecanemab	8/29/25

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Dordaviprone/Modeyso/Jazz Pharmaceuticals, Inc.	
Generic Name/Brand Name/Company	Dordaviprone/Modeyso/Jazz Pharmaceuticals, Inc.
Date of approval	8/6/25
Drug Class (Mechanism of Action if novel agent)	Imipridones: protease activator of the mitochondrial caseinolytic protease P (ClpP) and inhibitor of dopamine D2 receptor (DRD2, a type of G protein-coupled receptor, GPCR)
Indication	Systemic therapy for H3 K27M-mutant diffuse midline glioma in adults and pediatric patients at least 1 year of age with progressive disease following prior therapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Capsules: 125 mg
Common Dose/sig	Adults: 625 mg PO once weekly Pediatrics age 1-17 weighing at least 10 kg: start at 125 mg once weekly and increase dose by 125 mg for specific body weight thresholds. See prescribing information for more details.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Doxorubicin
Clinical Use Evaluation	
Common Adverse Effects	Fatigue (34%), headache (32%), vomiting (24%), nausea (24%), and musculoskeletal pain (20%)
Severe Adverse Effects	Hydrocephalus (5%), vomiting (4.3%), headache (3.2%), seizure (2.4%), and muscular weakness (2.1%). Fatal adverse reactions: cardiac arrest (0.5%), intercranial hemorrhage (0.3%), and encephalopathy (0.3%).
Severe Drug-Drug Interactions	Avoid use of moderate and strong CYP3A4 inducers and inhibitors, adjust dordaviprone dose if concomitant use with strong or moderate CYP3A4 inhibitors cannot be avoided. Avoid use with QTc prolonging products.
Severe Drug-Food Interactions	Food decreases maximum concentration.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor electrolytes before initiation and periodically as indicated
Used in Pediatric Areas	At least 1 year old and weighing at least 10 kg (actual body weight)
Renal or Hepatic Dosing	No dose adjustments based on renal or hepatic function
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: -hypersensitivity: discontinue if anaphylaxis occurs -QTc prolongation: monitor ECG at baseline and periodically as indicated; interrupt or reduce dose if QT prolongation and permanently discontinue if arrythmia occurs -May cause fetal harm
Special administration technique or considerations	Take on an empty stomach at least 1 hour before eating or 3 hours after. Swallow capsule whole or open capsule and combine with 1-2 tbsp of sports drink, apple juice, lemonade, or water.
Prepared by	Alex Hatkoff
Source	Modeyso (dordaviprone) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2025.

Zongertinib/Hernexeos/Boehringer Ingelheim Pharmaceuticals, Inc.	
Generic Name/Brand Name/Company	Zongertinib/Hernexeos/Boehringer Ingelheim Pharmaceuticals, Inc.
Date of approval	8/8/25
Drug Class (Mechanism of Action if novel agent)	Tyrosine kinase inhibitor of human epidermal growth factor receptor 2 (HER2)
Indication	Treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations and who have received prior systemic therapy
Comparative agent – Therapeutic interchange?	Antibody-drug conjugate fam-trastuzumab deruxtecan; no therapeutic interchange
Dosage forms/strengths	Tablet: 60 mg
Common Dose/sig	2-3 tablets daily based on weight (120 mg is for patients <90 kg; 180 mg is for patients ≥90 kg)
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Herzuma
Clinical Use Evaluation	
Common Adverse Effects	Symptoms: (≥ 20%) are diarrhea, hepatotoxicity, rash, fatigue, and nausea. Labs: (≥ 2%; Grade 3 or 4 laboratory abnormalities) decreased lymphocytes, increased alanine aminotransferase, increased aspartate aminotransferase, decreased potassium, and increased gamma glutamyl transferase
Severe Adverse Effects	Hepatotoxicity, left ventricular dysfunction, interstitial lung disease/pneumonitis
Severe Drug-Drug Interactions	Avoid use with strong CYP3A inducers, or if use cannot be avoided, increase therapeutic dose. This medication is a BCRP inhibitor.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status. ALT, AST, and bilirubin at baseline, every 2 weeks for 12 weeks, then monthly afterwards as clinically necessary.
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dose adjustments based on renal or hepatic impairment; not evaluated in moderate to severe renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: Hepatotoxicity- discontinue based on severity Left ventricular dysfunction- monitor at baseline and regular intervals Interstitial lung disease- monitor for signs of interstitial lung disease (cough, dyspnea, fever); discontinue or disrupt based on severity Embryo-fetal toxicity- advise the use of contraception in females of child-bearing potential
Special administration technique or considerations	Do not split, crush, or chew tablets. If vomited, do not take an additional dose. See prescribing information for dose reductions for adverse reactions.
Prepared by	Alex Hatkoff
Source	Hernexeos (Zongertinib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; August 2025.

Brensocatib/Brinsupri/Insmed Inc.	
Generic Name/Brand Name/Company	Brensocatib/Brinsupri/Insmed Inc.
Date of approval	8/12/25
Drug Class (Mechanism of Action if novel agent)	Dipeptidyl peptidase 1 (DPP1) inhibitor
Indication	Treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 10 mg and 25 mg
Common Dose/sig	10 or 25 mg by mouth once daily
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Breztri
Clinical Use Evaluation	
Common Adverse Effects	(≥ 2%): upper respiratory tract infection, headache, rash, hypertension
Severe Adverse Effects	Gingival and periodontal adverse reactions, dermatologic reactions
Severe Drug-Drug Interactions	Concentration raised over 50% when administered with moderate and strong CYP3A4 and P-gp inhibitors. Concentration decreased by 15% when administered with strong CYP3A4 inducers. Avoid use of live vaccines.
Severe Drug-Food Interactions	No effect: may be taken with or without food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Established in patients 12 and older
Renal or Hepatic Dosing	No adjustments or precautions
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: dermatologic, gingival, and periodontal adverse reactions. Concomitant use with live attenuated vaccines has not been evaluated.
Special administration technique or considerations	None
Prepared by	Alex Hatkoff
Source	Brinsupri (brensocatib) [prescribing information]. Bridgewater, NJ: Insmed Incorporated; August 2025.

Zopapogene imaadenovec-drba/Papzimeos/Precigen, Inc.	
Generic Name/Brand Name/Company	Zopapogene imaadenovec-drba/Papzimeos/Precigen, Inc.
Date of approval	8/14/25
Drug Class (Mechanism of Action if novel agent)	Non-replicating adenoviral vector-based immunotherapy
Indication	Treatment of recurrent respiratory papillomatosis in adult patients; initiated following surgical debulking, to maintain residual disease during treatment visible papilloma lesions should be removed prior to the third and fourth dose
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Suspension for subcutaneous injection: $5x10^{11}$ PU/mL concentration in a single dose vial
Common Dose/sig	$5x10^{11}$ PU injected subcutaneously 4 times over a 12-week interval with the second dose occurring 2 weeks after the first, the third dose 4 weeks after the second, and the fourth dose 6 weeks after the third.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	N/A
Clinical Use Evaluation	
Common Adverse Effects	Study consisting of 38 patients: Injection site reactions (97%), fatigue (74%), chills (66%), fever (63%), myalgia (29%), nausea (26%)
Severe Adverse Effects	Tachycardia, blurred vision
Severe Drug-Drug Interactions	None reported
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: injection site reactions – monitor thrombotic events - monitor
Special administration technique or considerations	Following universal biosafety precautions for handling and for disposal of vials, syringes, and dressings. Must be rapidly thawed in a water bath before use and may remain at room temperature for up to 60 minutes; do not place thawed vial in refrigerator, freezer, or on dry ice. Inject subcutaneously to a lateral region of the upper arm or thigh. Monitor patients for local site reactions for at least 30 minutes after the initial treatment.
Prepared by	Alex Hatkoff
Source	Papzimeos (zopapogene imaadenovec-drba) [prescribing information]. Germantown, MD: Precigen, Inc.; August 2025.

Donidalorsen/Dawnzera/Ionis Pharmaceuticals, Inc.	
Generic Name/Brand Name/Company	Donidalorsen/Dawnzera/Ionis Pharmaceuticals, Inc.
Date of approval	8/21/25
Drug Class (Mechanism of Action if novel agent)	Prekallikrein-directed antisense oligonucleotide; lowers prekallikrein concentration preventing excessive bradykinin production
Indication	Hereditary angioedema attack prophylaxis for patients 12 years and older
Comparative agent – Therapeutic interchange?	Therapeutic interchange: none Comparative prophylactic agents: Cinryze (C1 esterase inhibitor [human]), Takhzyro (lanadelumab-flyo), Orladeyo (berotralstat), Andembry (garadacimab)
Dosage forms/strengths	Injection: 80 mg/0.8 mL in single-dose autoinjector
Common Dose/sig	80 mg subcutaneously every 4 weeks, or 80 mg subcutaneously every 8 weeks
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Donepezil, donislecel
Clinical Use Evaluation	
Common Adverse Effects	(>5%): mild injection site reactions, upper respiratory tract infection, urinary tract infection, abdominal discomfort
Severe Adverse Effects	Hypersensitivity reactions, anaphylaxis
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Established in patients 12 and older
Renal or Hepatic Dosing	Renal impairment: no dose adjustment in mild renal impairment; not studied in moderate or severe renal impairment Hepatic impairment: no dose adjustment in mild hepatic impairment; not recommended in patients with moderate to severe hepatic impairment (total bilirubin >1.5 x ULN)
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of serious hypersensitivity reaction to donidalorsen or any product ingredients Warnings: risk of hypersensitivity and anaphylaxis
Special administration technique or considerations	Remove from refrigerator 30 minutes before injecting and allow to warm to room temperature.
Prepared by	Alex Hatkoff
Source	Dawnzera (donidalorsen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; August 2025.

Rilzabrutinib/Wayrilz/Genzyme Corporation	
Generic Name/Brand Name/Company	Rilzabrutinib/Wayrilz/Genzyme Corporation
Date of approval	8/29/25
Drug Class (Mechanism of Action if novel agent)	Bruton's tyrosine kinase (BTK) inhibitor
Indication	Treatment of persistent or chronic immune thrombocytopenia (ITP) in adults who have had an insufficient response to a previous treatment
Comparative agent – Therapeutic interchange?	Therapeutic interchange: none Comparative agents: Thrombopoietin receptor agonists (TPO-RA), Tavalisse (fostamatinib)
Dosage forms/strengths	Tablets: 400 mg
Common Dose/sig	400 mg orally twice daily
DEA Schedule	N/A
Date of market availability	September 2025
Similar Medication Names	Rilpivirine, ibrutinib
Clinical Use Evaluation	
Common Adverse Effects	(>10%): diarrhea, nausea, headache, abdominal pain, COVID-19
Severe Adverse Effects	Infections, drug-induced liver injury
Severe Drug-Drug Interactions	Avoid administering with moderate or strong CYP3A inducers and inhibitors. Avoid using PPIs. Administer rilzabrutinib at least 2 hours before an antiacid or H2 antagonist.
Severe Drug-Food Interactions	Avoid consumption of grapefruit, starfruit, and Seville oranges, and products containing these fruits
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status. Bilirubin and transaminases at baseline and when clinically indicated
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Renal impairment: no dose adjustment in mild or moderate impairment; avoid use in severe impairment. Hepatic impairment: no dose adjustment in mild (Child-Pugh class A) impairment. Avoid use in patients with moderate-severe (Child-Pugh class B-C) impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: serious infection, hepatotoxicity, fetal toxicity
Special administration technique or considerations	Should be taken at approximately the same time each day with or without food. Taking with food may improve gastrointestinal tolerability. Swallow tablets whole.
Prepared by	Alex Hatkoff
Source	Wayrilz (rilzabrutinib) [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2025.