Bilastine (United States: Not available): Drug information

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For additional information see "Bilastine (United States: Not available): Patient drug information" and "Bilastine (United States: Not available): Pediatric drug information"

For abbreviations, symbols, and age group definitions show table

Brand Names: Canada

APO-Bilastine; AURO-Bilastine; Blexten; GLN-Bilastine; JAMP-Bilastine; M-Bilastine; MAR-Bilastine; NRA-Bilastine; SANDOZ Bilastine

Pharmacologic Category

Histamine H_1 Antagonist; Histamine H_1 Antagonist, Second Generation; Piperidine Derivative

Dosing: Adult

Allergic rhinitis

Allergic rhinitis: Oral: 20 mg once daily (maximum: 20 mg/day).

Urticaria, chronic spontaneous

Urticaria, chronic spontaneous: Oral: Initial: 20 mg once daily. If symptom control is inadequate after 2 weeks, may increase to 40 mg once daily; if symptoms remain uncontrolled after an additional 2 weeks, may increase to 80 mg once daily (Ref). Periodically reevaluate necessity for continued treatment (Ref).

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

Dosing: Kidney Impairment: Adult

No dosage adjustment necessary.

Dosing: Liver Impairment: Adult

No dosage adjustment necessary.

Dosing: Older Adult

Refer to adult dosing.

Dosing: Pediatric

(For additional information see "Bilastine (United States: Not available): Pediatric drug information")

Allergic rhinitis, seasonal

Allergic rhinitis, seasonal:

Children ≥4 to 11 years weighing ≥16 kg: Oral: 10 mg once daily.

Children ≥12 years and Adolescents: Oral: 20 mg once daily.

Urticaria, chronic spontaneous

Urticaria, chronic spontaneous: Note: Considered first-line therapy for management of chronic urticaria; if response inadequate after 2 to 4 weeks of therapy or symptoms intolerable, consider increasing the dose of bilastine (as age and weight permit) as second-line treatment rather than changing therapy (Ref).

Children ≥4 to 11 years weighing ≥16 kg: Oral: 10 mg once daily.

Children ≥12 years and Adolescents: Oral: 20 mg once daily.

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

Dosing: Kidney Impairment: Pediatric

Altered kidney function: Children ≥4 years weighing ≥16 kg and Adolescents: Oral: No dosage adjustment necessary.

Dosing: Liver Impairment: Pediatric

Children ≥4 years weighing ≥16 kg and Adolescents: Oral: No dosage adjustment necessary.

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Reported adverse reactions are for adolescents and adults, unless otherwise noted.

1% to 10%:

Gastrointestinal: Upper abdominal pain (1%)

Nervous system: Dizziness (1%), drowsiness (4%), headache (children, adolescents, adults: 2% to 4%)

<1%:

Cardiovascular: Chest discomfort, ECG abnormality (including abnormal T waves on ECG, inversion T wave on ECG, prolonged QT interval on ECG, ST segment changes on ECG, widened QRS complex on ECG), premature ventricular contractions, right bundle branch block, sinoatrial nodal rhythm disorder, sinus bradycardia, syncope (children)

Dermatologic: Acneiform eruption, eczema (children), papular rash, pruritus, urticaria (children, adolescents, adults)

Endocrine & metabolic: Increased thirst, menstrual disease (delayed)

Gastrointestinal: Abdominal pain, constipation, diarrhea (children, adolescents, adults), dysgeusia, dyspepsia, eructation, gastritis, increased appetite, motion sickness, nausea (children, adolescents, adults), oral herpes simplex infection, stomach discomfort, vomiting, xerostomia (including dry tongue)

Hematologic & oncologic: Anemia

Hypersensitivity: Swelling of lips (children)

Nervous system: Anxiety, asthenia, disturbance in attention, fatigue (children, adolescents, adults), hypersomnia, insomnia, jitteriness, loss of consciousness (children), malaise, myasthenia, nightmares, pain, vertigo

Neuromuscular & skeletal: Back pain, myalgia

Ophthalmic: Eye irritation (children), eye pain

Otic: Tinnitus

Respiratory: Dry nose, dyspnea, epistaxis, nasal discomfort, pharyngitis, throat irritation

Miscellaneous: Fever

Frequency not defined:

Endocrine & metabolic: Hypercholesterolemia, increased serum triglycerides, weight gain, weight loss

Hepatic: Increased gamma-glutamyl transferase, increased serum alanine aminotransferase, increased serum aspartate aminotransferase, increased serum bilirubin

Postmarketing (any population):

Cardiovascular: Palpitations, tachycardia

Hypersensitivity: Hypersensitivity reaction (including anaphylaxis, angioedema)

Contraindications

Hypersensitivity to bilastine or any component of the formulation; history of QT prolongation and/or torsades de pointes, including congenital long QT syndromes.

Warnings/Precautions

Disease-related concerns:

- QT interval prolongation: QTc interval prolongation has been reported with use; use is contraindicated in patients with a history of QT prolongation and/or Torsade de pointes, including congenital long QT syndromes. Use caution in patients with a history of cardiac arrhythmia, significant bradycardia, a family history of sudden cardiac death, electrolyte abnormalities (eg, hypokalemia, hypomagnesemia), or with concomitant use of other QTc-prolonging drugs.

Product Availability

Not available in the United States.

Generic Equivalent Available: US

No

Dosage Forms: Canada

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution, Oral:

- Blexten: 2.5 mg/mL (120 mL) [contains methylparaben, propylparaben]

Tablet, Oral:

- Blexten: 20 mg
- Generic: 20 mg

Tablet Disintegrating, Oral:

- Blexten: 10 mg

Administration: Adult

Oral: Administer with water 1 hour before or 2 hours after intake of food or fruit juices.

Administration: Pediatric

Oral: Administer with water 1 hour before or 2 hours after intake of food or fruit juices.

- Oral dispersible tablet: Place on tongue to allow tablet to dissolve so it can be easily swallowed. May also disperse in water prior

to administration.

Oral solution: Administer with an accurate measuring device (dosing cup provided); do not use a household teaspoon (overdosage may occur).

Use: Labeled Indications

Note: Not approved in the United States.

Allergic rhinitis: Relief of symptoms associated with seasonal allergic rhinitis in patients ≥4 years of age and weighing ≥16 kg.

Chronic spontaneous urticaria: Symptomatic treatment of chronic spontaneous urticaria (eg, pruritus, hives) in patients ≥4 years of age and weighing ≥16 kg.

Medication Safety Issues

High alert medication:

The Institute for Safe Medication Practices (ISMP) includes this medication among its list of drugs (pediatric liquid medications requiring measurement) which have a heightened risk of causing significant patient harm when used in error (High-Alert Medications in Community/Ambulatory Care Settings).

The Institute for Safe Medication Practices (ISMP) includes this medication among its list of drugs (chemotherapeutic agent, parenteral and oral; contraindicated in pregnancy) which have a heightened risk of causing significant patient harm when used in error (High-Alert Medications in Acute Care and Community/Ambulatory Care Settings).

Metabolism/Transport Effects

Substrate of P-glycoprotein (Major with inhibitors), P-glycoprotein (Minor with inducers); **Note:** Assignment of Major/Minor substrate status based on clinically relevant drug interaction potential

Drug Interactions

(For additional information: Launch drug interactions program)

Note: Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the drug interactions program by clicking on the "Launch drug interactions program" link above.

Amezinium: Antihistamines may increase stimulatory effects of Amezinium. *Risk C: Monitor*

Asciminib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Benzylpenicilloyl Polylysine: Coadministration of Antihistamines and Benzylpenicilloyl Polylysine may alter diagnostic results. Management: Suspend systemic H1 antagonists for benzylpenicilloyl-polylysine skin testing and delay testing until systemic antihistaminic effects have dissipated. A histamine skin test may be used to assess persistent antihistaminic effects. *Risk D: Consider Therapy Modification*

Betahistine: Antihistamines may decrease therapeutic effects of Betahistine. Betahistine may decrease therapeutic effects of Antihistamines. *Risk C: Monitor*

Certoparin: Antihistamines may increase therapeutic effects of Certoparin. *Risk C: Monitor*

Elacestrant: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Erdafitinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Management: If coadministration with these narrow therapeutic index/sensitive P-gp substrates is unavoidable, separate erdafitinib administration by at least 6 hours before or after administration of these P-gp substrates. *Risk D: Consider Therapy Modification*

Gilteritinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Grapefruit Juice: May decrease serum concentrations of Bilastine. *Risk C: Monitor*

Haloperidol: QT-prolonging Agents (Indeterminate Risk - Caution) may increase QTc-prolonging effects of Haloperidol. *Risk C: Monitor*

Hyaluronidase: Antihistamines may decrease therapeutic effects of Hyaluronidase. *Risk C: Monitor*

Lasmiditan: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk X: Avoid*

Levacetylleucine: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Lonafarnib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (High risk with Inhibitors). *Risk C: Monitor*

Loop Diuretics: May increase QTc-prolonging effects of Bilastine. *Risk C: Monitor*

Lumacaftor and Ivacaftor: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (High risk with Inhibitors or Inducers). Lumacaftor and Ivacaftor may decrease serum concentrations of P-glycoprotein/ABCB1 Substrates (High risk with Inhibitors or Inducers). *Risk C: Monitor*

Mitapivat: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

P-glycoprotein/ABCB1 Inhibitors: May increase serum concentrations of Bilastine. Management: Consider alternatives, as product labeling states that the use of bilastine with P-gp inhibitors is not recommended. Bilastine therapy should be strictly avoided in patients with moderate to severe renal insufficiency receiving P-gp inhibitors. *Risk D: Consider Therapy Modification*

Pacritinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Pitolisant: Antihistamines may decrease therapeutic effects of Pitolisant. *Risk X: Avoid*

Pretomanid: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Primaquine: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

QT-prolonging Agents (Highest Risk): QT-prolonging Agents (Indeterminate Risk - Caution) may increase QTc-prolonging effects of QT-prolonging Agents (Highest Risk). Management: Monitor for QTc interval prolongation and ventricular arrhythmias when these

agents are combined. Patients with additional risk factors for QTc prolongation may be at even higher risk. *Risk C: Monitor*

Remibrutinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Rilzabrutinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Sotorasib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Management: Consider avoiding use of sotorasib and narrow therapeutic index/sensitive P-gp substrates. If combined use is unavoidable, monitor for increased toxicities of the substrate and consider a decrease in the substrate dosage. *Risk D: Consider Therapy Modification*

Sparsentan: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk X: Avoid*

Taurursodiol: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk X: Avoid*

Venetoclax: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Management: Avoid concomitant use of venetoclax and oral p-glycoprotein (P-gp) substrates if possible. If combined use is unavoidable, administer the P-gp substrate at least 6 hours before venetoclax to minimize the potential for an interaction. *Risk D: Consider Therapy Modification*

Vimseltinib: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (High risk with Inhibitors). Management: Avoid concomitant use of vimseltinib and P-gp

substrates when possible. If combined, administer vimseltinib at least 4 hours before the P-gp substrate. *Risk D: Consider Therapy Modification*

Xanomeline: May increase serum concentrations of P-glycoprotein/ABCB1 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). *Risk C: Monitor*

Food Interactions

Food: Decreases bioavailability by 33%. Management: Administer 1 hour before or 2 hours after intake of food.

Grapefruit juice: Decreases bioavailability by 30%. This effect may also apply to other fruit juices. Management: Administer 1 hour before or 2 hours after intake of grapefruit juice or other fruit juices.

Pregnancy Considerations

Outcome data related to the use of bilastine in pregnancy are limited. Based on the limitations of available data, second-generation antihistamines are considered acceptable for use during pregnancy, with preference given to agents with more study (EAACI [Zuberbier 2022]).

Algorithms are available for the treatment of acute rhinitis and urticaria. When treatment with a second-generation oral antihistamine is recommended, agents other than bilastine are preferred for use during pregnancy (AAAAI/ACAAI [Dykewicz 2020], BAD [Sabroe 2022], EAACI [Zuberbier 2022]).

Breastfeeding Considerations

It is not known if bilastine is present in breast milk.

Drowsiness and irritability have been reported in breastfed infants

exposed to antihistamines (Ito 1993). In general, second-generation antihistamines are less sedating as compared to their first-generation counterparts. Infants exposed to a second-generation antihistamine via breast milk should be monitored for irritability, jitteriness, or drowsiness (Butler 2014).

According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother. Use of a second-generation antihistamine is preferred when an oral antihistamine is needed in lactating patients (Butler 2014, EAACI [Zuberbier 2022]).

Monitoring Parameters

Relief of symptoms

Mechanism of Action

Histamine antagonist with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors.

Pharmacokinetics (Adult Data Unless Noted)

Onset: 1 hour

Duration: 26 hours

Absorption: Rapid

Protein binding: 84% to 90%

Metabolism: Minimal (~5% of dose)

Bioavailability: ~61%

Half-life elimination: ~14.5 hours

Time to peak: 1.13 hours

Excretion: Feces (67%, as unchanged bilastine); Urine (28%, as unchanged bilastine)

Brand Names: International

International Brand Names by Country
For country code abbreviations (show table)

(AE) United Arab Emirates: Bilaxten; (AR) Argentina: Bilidren; (AT) Austria: Olisir | Rhinolibre; (AU) Australia: Allertine; (BD) Bangladesh: Allertin | Bilamin | Bilan | Bilanex | Bilargo | Bilasi | Bilastin | Bilfast | Bilista | Bilista kids | Billi | Biltin | Bilxen | Bislor | Blast | Byloza | Mylastin | Tinabil | Zilas; (BE) Belgium: Bellozal | Bilastine ab | Bilastine eg | Bilastine eurogenerics | Ilexel; (BF) Burkina Faso: Bilaxten; (BG) Bulgaria: Bilergia | Fortecal | Fortecal children | Fortecal for children; (BR) Brazil: Alektos | Alektos ped | Allep | Allep pediatrico | Bilargos | Bilastina | Bilastina ems | Bilastina neo quimica | Bixlyn | Hisbila | Naire | Tynna; (CH) Switzerland: Bilastin axapharm | Bilastin mepha | Bilastin spirig hc | Bilastin zentiva | Bilaxin | Bilaxten; (CI) Côte d'Ivoire: Bilaxten; (CL) Chile: Bilastina | Bilidren | Blaxitec | Blaxitec odt | Naire; (CO) Colombia: Bilaxten; (CR) Costa Rica: Bilasnor | Bilaxten | Blaxitec; (CZ) Czech Republic: Bilastin teva | Bilastine glenmark | Nestibil | Xados; (DE) Germany: Allegra | Bitosen; (DO) Dominican Republic: Bilaxten | Blaxitec; (EC) Ecuador: Alerin | Bilaxten | Bilazap | Blemed | Naire; (EE) Estonia: Bilastine stada | Bilastine zentiva | Opexa; (EG) Egypt: Bilastigec | Bilastomed | Pharmabilast; (ES) Spain: Abisax | Abrilia | Bilamax flas | Bilastina alter | Bilastina aristo | Bilastina aurovitas | Bilastina cinfa | Bilastina Kern Pharma | Bilastina mylan | Bilastina Normon | Bilastina pensa | Bilastina ratiopharm | Bilastina sandoz | Bilastina stada | Bilastina tecnigen | Bilastina teva | Bilastina vivanta

| Bilastine combix | Bilaxten | Ibis | Obalix; (FI) Finland: Revitelle; (FR) France: Bilaska | Bilastine arrow | Bilastine biogaran | Bilastine eg | Bilastine teva | Bilastine viatris | Bilastine zentiva | Bilastine zydus | Inorial; (GB) United Kingdom: Ilaxten; (GR) Greece: Bilargen | Bilaz; (GT) Guatemala: Blascan; (HK) Hong Kong: Labixten; (HR) Croatia: Nixar; (HU) Hungary: Bilastine stada | Bilastine teva | Bilergin | Lendin | Lendin neo; (IE) Ireland: Drynol; (IN) India: Actv 24 | Akubliss | Allerblis | Antegy | Ata | Belatin | Belaxid | Beltas | Beltas forte | Bil1 | Bilabest | Bilacad | Bilacalm | Bilachek | Bilacip | Biladerm | Biladoz | Bilafav | Bilafem od | Bilagra | Bilahenz | Bilahist | Bilajoy | Bilambic | Bilamed | Bilamove | Bilanair | Bilanix | Bilanta | Bilaset | Bilashine | Bilashine dt | Bilast | Bilastero | Bilastibel | Bilasure | Bilatex | Bilatide | Bilatop | Bilaxta | Bilaxten | Bilazap | Bilazest | Bilazest kids | Bilazo | Bilbay | Bilkwik | Billacare | Billargic | Billasi | Bilmegh | Bilten | Bilvaz | Bistadin | Bl 24 | Blson | Blst | Bularid I | Byloza | Cosome ar | Elbel | Histabil | Ilastin | Mastowell | Maxstine | Nilhist | Nohives | Prucros | Prulastin | Ubil | Unilastine; (IT) Italy: Arynal | Ayrinal | Bilastina aristo | Bilastina aurobindo | Bilastina doc | Bilastina eg | Bilastina mylan | Bilastina sandoz | Bilastina tecnigen | Bilatina zentiva | Bysabel | Olisir | Robilas; (JO) Jordan: Bilaxten | Lesstab; (JP) Japan: Bilanoa | Bilanoa od; (KE) Kenya: Ilaxten; (KW) Kuwait: Bilaxten; (LB) Lebanon: Labixten; (LT) Lithuania: Bilastine stada | Opexa; (LU) Luxembourg: Bellozal | Bilastine eg | Bilastine eurogenerics; (LV) Latvia: Opexa; (MA) Morocco: Labixten; (MX) Mexico: Blaxitec | Labixten; (MY) Malaysia: Bilaxten; (NO) Norway: Zilas; (NZ) New Zealand: Labixten; (PA) Panama: Bilasnor | Bilaxten | Blaxitec; (PE) Peru: Bilaxten | Bilergy; (PH) Philippines: Bilaxten; (PL) Poland: Adablix | Allertec effect | Bellix | Bilaflex | Bilagra | Bilagra oro | Bilant | Bilargena | Bilastine aristo | Bilastyna hitaxa | Bilaxten | Clabilla | Clatexo | Clatra | Verpyllo; (PT) Portugal: Aelardis | Bilastina alter | Bilastina aristo | Bilastina azevedos | Bilastina bluepharma | Bilastina ciclum | Bilastina farmoz | Bilastina pharmakern | Bilastina teva | Bilastina tolife | Bilastina zentiva | Bilaxten | Lergonix | Zenayr allergo; (PY) Paraguay: Bilaxten; (QA) Qatar: Bilaxten; (RO)

Romania: Borenar; (RU) Russian Federation: Nixar; (SA) Saudi Arabia: Bilaxten; (SE) Sweden: Bilaxten; (SG) Singapore: Bilaxten; (SI) Slovenia: Bilador; (SK) Slovakia: Abisax | Bilastin stada | Nestibil | Omarit; (TH) Thailand: Bilaxten; (TR) Turkey: Bilaxten | Lasirin; (TW) Taiwan: Labixten; (UA) Ukraine: Bilagis | Nixar; (UG) Uganda: Ilaxten; (UY) Uruguay: Bilamin; (VE) Venezuela, Bolivarian Republic of: Labixten; (VN) Viet Nam: Bilazin | Bv lastin | Timbivo; (ZA) South Africa: Ilaxten

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