Product Monograph

Including Patient Medication Information

PrBLEXTEN®

bilastine ophthalmic solution

For ophthalmic use

6 mg/mL of bilastine

Histamine H1-Receptor Antagonist

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Date of Authorization:
2025-10-01

Control Number: 290817

Recent Major Label Changes

None at time of the most recent authorization

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Health Professional Information

1 Indications

BLEXTEN (bilastine) ophthalmic solution, 6 mg/mL, is indicated for:

- the treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis in adults.

1.1 Pediatrics

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (> 65 years of age): No dosage adjustments are necessary in patients over 65 years of age (see 10 Clinical Pharmacology, 4 Dosage and Administration).

2 Contraindications

BLEXTEN is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing of ingredients and components see 6 Dosage Forms, Strengths, Composition and Packaging.

4 Dosage and Administration

4.1 Dosing Considerations

No special dosing considerations are necessary for BLEXTEN.

4.2 Recommended Dose and Dosage Adjustment

The recommended daily dosage in adults is one drop in the affected eye(s) once daily.

Once symptomatic improvement has been established, therapy should be continued for as long as needed to sustain continued improvement. Therapy should not be used for more than 8 weeks without seeking medical advice.

No dosage adjustment is required in hepatic or renal impairment.

4.4 Administration

For ophthalmic use.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids,

surrounding areas or other surfaces with the dropper tip of the bottle. The tip of the nozzle should be wiped with a clean tissue after use to remove any residual liquid.

Patients should be instructed to remove contact lenses before administration of the BLEXTEN eye drops and to wait at least 15 minutes before putting their contact lenses back in.

If using other eye drops, patients should wait at least 5 minutes between putting in BLEXTEN Ophthalmic solution and the other drops. Eye ointments should be applied last.

4.5 Missed Dose

If a dose is missed, the next scheduled dose should be taken. An extra dose should not be taken.

5 Overdose

No specific reactions after ocular overdose are known and with ocular use, overdose reactions are not anticipated as excessive fluid will flow out of the eye quickly.

In phase I clinical trials with oral formulations tested at doses up to 11 times (single dose) and up to 10 times (multiple dose) the human recommended oral dose, dizziness, headache and nausea were the most frequently reported adverse events, with no serious adverse events reported.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6 Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths and Composition

Route of Administration	Dosage Form/Strength/ Composition	Non-Medicinal Ingredients
ophthalmic	ophthalmic solution, 6 mg/mL.	glycerol, hydroxypropyl β-cyclodextrin, methyl cellulose, sodium hyaluronate, sodium hydroxide 1 N (for pH-adjustment), water for injection

Description

BLEXTEN ophthalmic solution is a clear, colorless solution. Each drop contains 0.2 mg bilastine.

Packaging

BLEXTEN 6 mg/mL ophthalmic solution is packaged in a multi-dose LDPE bottle (5 mL preservative free solution) and white HDPE nozzle with tamper evident screw-cap. Pack size contains 1 x 5 mL bottle.

7 Warnings and Precautions

General

For ophthalmic use only. Not for injection or oral use.

Driving and Operating Machinery

After dropping BLEXTEN ophthalmic solution into the conjunctival sac of the eye, the visual acuity can deteriorate for a few minutes due to the formation of streaks.

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient should be advised to wait until the vision clears before driving or using machinery.

Ophthalmologic

Bilastine is an antiallergic/antihistaminic active substance and, although administered topically, it is absorbed systematically. If signs of serious reactions or hypersensitivity occur, treatment should be discontinued.

Administration site reactions

If adverse events at the administration site, such as eye irritation, pain, redness or change in vision occur or if the patient's condition is worsened, discontinuation of the treatment should be considered.

Reproductive Health

- **Fertility**

No impairments of fertility have been observed in rats (see 16 Non-Clinical Toxicology). Regarding human fertility, no effects are anticipated since systemic exposure to bilastine after ocular administration is negligible (see 10 Clinical Pharmacology).

7.1 Special Populations

7.1.1 Pregnancy

There are no or limited data from the oral or ocular use of bilastine in pregnant women.

Reproductive toxicity in animals was only observed at oral exposures more than 1000-fold higher than human levels after ocular dosing (see 16 Non-Clinical Toxicology).

No effects during pregnancy are therefore anticipated since systemic exposure to bilastine after ocular administration is negligible. BLEXTEN ophthalmic solution can be used during pregnancy.

7.1.2 Breastfeeding

The excretion of bilastine in milk has not been studied in humans.

Considering the low systemic absorption of bilastine after ocular administration (see 10 Clinical Pharmacology), no effects on the breastfed newborn/infant are anticipated after ocular administration in humans. BLEXTEN ophthalmic solution can be used during breast-feeding.

7.1.3 Pediatrics

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

No dosage adjustments are recommended in subjects over 65 years of age (see 10 Clinical Pharmacology and 4 Dosage and Administration).

8 Adverse Reactions

8.1 Adverse Reaction Overview

In Phase II and Phase III clinical studies involving bilastine 6 mg/mL eye drops, solution, 682 patients participated, with 340 receiving bilastine 6 mg/mL eye drops of which 218 were treated for up to 8 weeks. Overall, the incidence of treatment emergent adverse event (TEAE) was balanced between the groups. Approximately 9.7% of subjects receiving bilastine 6 mg/mL eye drops and 13.6% of subjects in the vehicle group reported at least 1 TEAE. Most of the TEAEs reported in the phase II and III studies were mild and there were no severe or serious adverse events.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

No treatment-related adverse drug reactions occurred at an incidence ≥ 1%.

8.3 Less Common Clinical Trial Adverse Reactions

Overall, most of the related TEAEs (ADRs) were ocular and most of the events were reported in the long-term study. Only one event (mild headache) in the phase II study and none in the phase III efficacy study was considered to be related to study medication.

Table 2 Related Treatment-Emergent Adverse Reactions Reported in ≥ 0.1% of Patients Treated with Bilastine 6 mg/mL eye drops in the Phase II and Phase III Ocular Studies

Body System / AE	BLEXTEN 6 mg/mL N=340	Vehicle N=192
Eye disorders		
Dry eye	2	2
Eye discharge	2	0
Eye irritation	1	1
Lacrimation increased	1	0
Ocular discomfort	1	0
Nervous system disorders		
Dysgeusia	1	0
Headache	1	0

In the long-term study (8 weeks treatment), all TEAEs were classified as mild or moderate. The number of ocular adverse events considered as related to treatment was low, with 7 adverse events in 6 patients (2.8%) for the bilastine group, and 5 adverse events in 5 patients (4.3%) in the vehicle group.

8.5 Post-Market Adverse Reactions

During post-marketing experience with oral bilastine formulations, hypersensitivity reactions have been observed with frequency not known.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

No interaction studies have been performed. Considering the low systemic exposure to bilastine after ocular administration, no clinically relevant interaction with other medicinal products is expected.

9.3 Drug-Behavioural Interactions

The interaction of BLEXTEN with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4 Drug-Drug Interactions

- Topical Ocular Products

In case of concomitant therapy with other topical ocular medicinal products, an interval of 5 minutes should be allowed between successive applications. Eye ointments should be administered last.

- Contact lenses

Physical compatibility with contact lenses has been demonstrated *in vitro*. Patients can continue using

contact lenses during treatment with this medicinal product.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 Clinical Pharmacology

10.1 Mechanism of Action

Bilastine is a non-sedating, second-generation histamine antagonist with selective peripheral H_1 receptor affinity and no apparent affinity for muscarinic receptors. Bilastine antagonises histamine, stabilizes mast cells and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells, and thus prevents itching, vasodilation and vascular leak leading to ocular redness, chemosis and blepharitis.

10.2 Pharmacodynamics

Bilastine 6 mg/mL ophthalmic solution is designed to be locally applied and locally acting at the conjunctiva. Pharmacodynamic studies were previously performed for the oral formulations, and no new clinical pharmacodynamic studies were performed for the ophthalmic solution.

Cardiac Electrophysiology: At the oral therapeutic dose of 20 mg/day and a supratherapeutic dose of 100 mg/day administered to healthy volunteers, bilastine was associated with a concentration-related prolongation of the QTcF interval. However, QTcF interval prolongation is not expected with Blexten ophthalmic solution due to the low systemic exposure of bilastine following ocular administration (See 10.3 Pharmacokinetics).

10.3 Pharmacokinetics

Bilastine pharmacokinetic properties have been extensively studied with the oral formulation. The pharmacokinetic properties of bilastine 6 mg/ml ophthalmic solution, were evaluated in a phase I study of twelve healthy subjects who received one drop into each eye per day (0.42 mg/day) for 5 days.

Table 3 – Summary of bilastine 6 mg/mL ophthalmic solution pharmacokinetic parameters in healthy volunteers following once-daily administration for 5 days.

	$C_{max,ss}$ (ng/mL)	T_{max} (h)	$t_{½}$ (h)	$AUC_{(0-\tau)ss}$ (h*ng/mL)	CL_{SS} (L/h)	**Vc/F** (L)	**Vp/F** (L)
Steady state Mean	2.7	2.52 h	7.88 h	19.5	21.5	59.2	30.2

Absorption

Bilastine is rapidly absorbed into the blood stream after ocular application. At steady state, bilastine reached maximum blood levels of 2.7 ng/ml within 2.52 hours after administration, i.e., about 1.5% of C_{max} at steady state following oral administration of bilastine 20 mg tablets.

Distribution

Bilastine is 84-90% bound to plasma proteins in humans, over the concentration range of 0.2 µg/ml to 1 µg/ml, which includes the plasma levels observed at therapeutic doses following oral administration of bilastine tablets. The apparent central distribution volume (Vc/F) was 59.2 L and the apparent peripheral distribution volume (Vp/F) was 30.2 L.

Metabolism

Little or no metabolism was observed *in vitro* and *in vivo* for bilastine after oral administration. Bilastine did not induce or inhibit activity on CYP 450 isoenzymes in *in vitro* studies. No hepatic enzyme inhibition or induction by bilastine was detected.

Elimination

In a mass balance study performed in healthy adult volunteers, after administration of a single oral dose of 20 mg ^{14}C-bilastine, almost 95% of the administered dose was recovered in urine (28.3%) and feces (66.5%) as unchanged bilastine. The mean elimination half-life following oral administration was 14.5 h, while after ocular administration was 7.88 h.

Linearity

Bilastine presents linear pharmacokinetics in the dose range studied (5 to 220 mg oral administration), with a low interindividual variability.

Special Populations and Conditions

Pediatrics: Effectiveness in pediatric patients has not been established.

Geriatrics: Only limited pharmacokinetic data are available in subjects older than 65 years. No statistically significant differences have been observed with regard to PK of bilastine in subjects aged over 65 years compared to adult population aged between 18 and 35 years.

Hepatic Impairment: There are no pharmacokinetic data in subjects with hepatic impairment. Bilastine is not significantly metabolized in humans. Results of a renal impairment study indicate renal elimination to be a major contributor in the elimination of bilastine; therefore, biliary excretion is expected to be only marginally involved. Changes in liver function are not expected to have a clinically relevant influence on bilastine pharmacokinetics.

Renal Impairment: The pharmacokinetics of bilastine (oral administration, 20 mg tablets) in renally-impaired subjects demonstrated that the same dose and dosing interval of oral bilastine can be

administered to subjects independently of the severity of renal impairment in a safe and efficacious manner. Therefore, due to lower systemic exposure compared to oral bilastine 20 mg tablets, no dose adjustment is recommended for bilastine ophthalmic solution for patients with renal impairment.

11 Storage, Stability, and Disposal

Recommended storage conditions: Store between 15°C – 30°C. Do not use BLEXTEN ophthalmic solution if the bottle has been opened for longer than 2 months.

Keep out of reach and sight of children.

Part 2: Scientific Information

13 Pharmaceutical Information

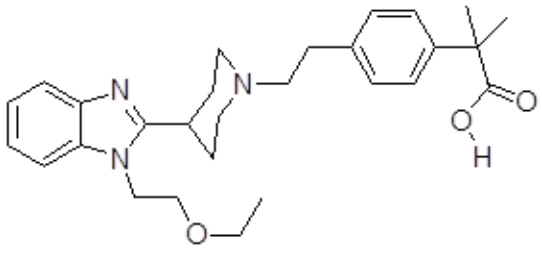
Drug Substance

Non-proprietary name of the drug substance: bilastine

Chemical name: 2-[4-(2-(4-(1-(2-ethoxyethyl)-1H-benzimidazol-2-yl)piperidin-1-yl)ethyl)phenyl]-2-methylpropionic acid
or
p-[2-[4-[1-(2-ethoxyethyl)-2-benzimidazolyl]piperidino]ethyl]-α-methylhydratropic acid

Molecular formula and molecular mass: $C_{28}H_{37}N_3O_3$ and 463.61 g/mol

Structural formula:



Physicochemical properties:

Physical Form: White, crystalline powder

Solubility:

Practically insoluble	acetonitrile
Very slightly soluble	water, buffer pH=6, buffer pH=4.5, buffer pH=8, acetone and isopropyl alcohol, glycerin
Slightly soluble	NaOH 0.01N, ethanol, methanol and dimethylsulfoxide (DMSO), 1,2-propylene glycol
Sparingly soluble	dimethylformamide (DMF), 0.1N hydrochloric acid (HCl) and buffer pH=3.5
Freely soluble	chloroform, HCl 1N and NaOH 1N

pKa Value: 4.15 ± 0.06, when determined by ultraviolet spectrophotometry and 4.18 by HPLC.

Hygroscopicity: Bilastine is not hygroscopic tested under ambient temperature (25.1 ± 0.1 °C) and relative humidity (85 % RH) conditions.

14 Clinical Trials

14.1 Clinical Trials by Indication

Allergic conjunctivitis

Table 3 - Summary of patient demographics for BOFT-0218 in Allergic Conjunctivitis

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
BOFT-0218/AC-CAC	Double-blind, randomized, parallel, vehicle and active drug controlled, pivotal study	bilastine ophthalmic solution 6 mg/mL,	91	45.9 (18-72)	M/F 33/58
		ketotifen ophthalmic solution 0.025%	90	41.7 (18-65)	M/F 37/53
		Vehicle	47	45.1 (18-87)	M/F 22/25
		One drop in each eye on Day 1 and Day 8 (0.21 mg/eye/treatment day)			
		Ocular use			
		2 treatments within 8 days			

Pivotal Efficacy Study

The efficacy and safety of bilastine 6 mg/ml ophthalmic solution was demonstrated in a Phase lll multi-center, double-blind, randomized, parallel-group, vehicle- and active-controlled study in 228 subjects using the Conjunctival Allergen Challenge (CAC) Model. The primary endpoint was defined as ocular itching evaluated by the subject at 3, 5 and 7 minutes after CAC performed 16 hours post-treatment on Day 1 and 15 minutes post-treatment on Day 8. This study employed a hierarchical analysis where significance was determined by stepwise comparison of bilastine versus vehicle. To demonstrate efficacy for ocular itching, bilastine ophthalmic solution needed to show clinical superiority over vehicle by at least 0.5 units of a 5-point scale for all three (3) post-CAC time points: 3(±1), 5(±1), and 7(±1) minutes post-CAC and at least 1 unit for the majority (2:3) of these post-CAC time points on both Day 1 and Day 8.

For the primary endpoint, bilastine 6 mg/mL met the criteria established by the hierarchical paradigm: all ocular itch measures, at both 15 minutes and 16 hours post-treatment were statistically significantly lower for bilastine than for the vehicle. Further, bilastine 6 mg/mL reduced itching by > 1 unit as compared to vehicle at 15 minutes post-treatment at all 3 time points, and by > 0.75 units in 2 out of 3 time points at 16 hours post-treatment (see Table 4).

Table 4: ANCOVA LS Mean Ocular Itch Responses to Bilastine 6 mg/mL Ophthalmic Solution in BOFT-0218

Challenge time	16 hours post-treatment			15 minutes post-treatment		
Ocular Itch Assessment	3 minutes	5 minutes	7 minutes	3 minutes	5 minutes	7 minutes
Vehicle	2.262	2.532	2.570	1.856	2.030	1.953
Bilastine 6 mg/mL	1.595	1.736	1.732	0.664	0.822	0.818
Difference[1]	-0.667	-0.796	-0.839	**-1.192**	**-1.208**	**-1.134**
P-value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

[1]Bilastine – Vehicle Note: Bolded differences indicate clinical efficacy.

For the secondary endpoint of conjunctival redness, bilastine ophthalmic solution demonstrated improvement over vehicle (P <0.05) at 15 minutes post-treatment but not at 16 hours post-treatment.

Long-Term Safety Study

A multi-centre, randomised, double blind, vehicle-controlled, parallel-group, phase III, long-term study was conducted to assess the safety, tolerability and efficacy of bilastine 6 mg/mL ophthalmic solution when used up to 8 weeks. BLEXTEN ophthalmic solution was found to be well tolerated and effective when used for up to 8 weeks in 218 adult patients.

15 Microbiology

No microbiological information is required for this drug product.

16 Non-Clinical Toxicology

General Toxicology: Non-clinical data with bilastine reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

Reproductive and Developmental Toxicology: In reproduction toxicity studies, no effect on male and female fertility or pre- and postnatal development was detected at oral bilastine dose up to 1000 mg/kg bodyweight in rats. In embryo-foetal development studies with oral bilastine administration, slightly increased pre- and post-implantation losses in rats as well as delayed ossification and growth retardation in rabbits were only observed at more than 1000-fold in excess of the human exposure at the recommended ocular dose.

Special Toxicology: In a lactation study, bilastine was identified in the milk of nursing rats administered a single oral dose (20 mg/kg). Concentrations of bilastine in milk were about half of those in maternal plasma. Considering the low systemic absorption of bilastine after ocular administration (see 10 Clinical Pharmacology), lower levels of bilastine in human breast milk may therefore be expected.

17 Supporting Product Monographs

BLEXTEN (bilastine), orodispersible tablets (10 mg), tablets (20 mg), oral solution (2.5 mg/mL) Control #241318, Product Monograph, Aralez Pharmaceuticals Canada Inc.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]BLEXTEN®

bilastine ophthalmic solution

This patient medication information is written for the person who will be taking **BLEXTEN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BLEXTEN**, talk to a healthcare professional.

What BLEXTEN is used for:

BLEXTEN ophthalmic solution is used to treat the signs and symptoms of eye disorders which you get with seasonal and perennial allergic conjunctivitis in adults.

How BLEXTEN works:

BLEXTEN is an antihistamine - it blocks the action of histamine and relieves the signs and symptoms of eye disorders such as itchiness due to allergic conjunctivitis.

The ingredients in BLEXTEN are:

Medicinal ingredient: bilastine

Non-medicinal ingredients: glycerol, hydroxypropyl β-cyclodextrin, methyl cellulose, sodium hyaluronate, sodium hydroxide 1 N (for pH-adjustment), water for injection

BLEXTEN comes in the following dosage form:

Ophthalmic solution (eye drops): 1 mL ophthalmic solution contains 6 mg bilastine. One drop contains 0.2 mg bilastine. BLEXTEN is clear and colorless, filled in a multi-dose LDPE bottle containing 5 mL of preservative free solution, having a white HDPE nozzle with tamper evident screw-cap.

Pack size: 1 x 5 mL bottle.

Do not use BLEXTEN if:

- You are allergic (hypersensitive) to bilastine or any of the other ingredients of BLEXTEN.

Other warnings you should know about:

Doing tasks that require special attention:

Driving and using machines. Temporary blurred vision or other visual disturbances affecting the ability to drive or use machines may occur after instillation of this medicine. Please wait until the vision clears before driving or using machinery.

Contact lenses. The use of this medicine does not affect the properties of the contact lenses. You can continue wearing contact lenses during use of this medicine. Remove contact lenses before administration of the eye drops and wait at least 15 minutes before putting contacts back in.

In the event of inflammation, including allergic conjunctivitis, ask your ophthalmologist whether you can wear contact lenses despite the symptoms.

BLEXTEN ophthalmic solution (6 mg/mL) is not suitable for use by patients less than 18 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BLEXTEN:

- Other medicinal products for ophthalmic use. Wait at least 5 minutes between putting BLEXTEN and other eye drops. Eye ointments should be administered last.

How to administer BLEXTEN:

1. Always wash your hands and dry them with a clean towel first before administering this medicine.
2. Gently clean the eyelids if they are crusty with discharge by wiping the lid from the inner corner to the outer corner with the eye closed using a cotton ball dampened with warm water.
3. Open the bottle and avoid touching the dropper tip against your eye or anything else - eyedrops and droppers must be kept clean.
4. Tilt back the head, or lie down, and look upward (Figure 1). Using your finger, gently pull the lower eyelid downward (Figure 2).
5. Look up and squeeze one eye drop into the eye.
6. Release your lower eye lid and keep your eye closed to spread the drop across the surface of your eye (Figure 3).
7. Repeat the above for the other eye if necessary.

Figure 1

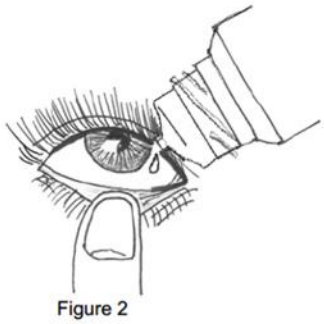


Figure 2

Figure 3

To avoid contamination during the use of this medicine do not touch any surfaces (eyelids, surrounding areas of the eye, or other surfaces) with the dropper tip and clean the tip of the nozzle with a clean tissue after use to remove any residual liquid.

Usual dose:

Adults: one drop in each affected eye(s) once daily.

The treatment with this medicine should be done regularly if possible until a relief of symptoms is reached and should be continued as long as needed to maintain symptom relief. This medicine can be used for up to 8 weeks. If you stop using BLEXTEN ophthalmic solution while you are still exposed to the allergen(s), you have to expect that the typical allergic symptoms will return.

If you have any further questions on the use of this medicine, ask your healthcare professional. Your healthcare professional will decide and advise on how long you should use it based on your condition.

Overdose:

If you use more BLEXTEN ophthalmic solution than you should, you can rinse it out with warm water.

If you think you, or a person you are caring for, have taken too much BLEXTEN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget to apply the drop on time, apply the forgotten dose as soon as possible and then go back to your regular dosing schedule. Do not use a double dose to make up for a forgotten dose.

Possible side effects from using BLEXTEN:

These are not all the possible side effects you may have when taking BLEXTEN. If you experience any side effects not listed here, tell your healthcare professional.

- Eye problems such as:
  - Eye Pain
  - Redness of the eyes
  - Change in vision
  - Condition becomes worse
  - Dry eye
  - Eye discharge
  - Eye irritation
  - Increased tearing
  - Eye discomfort
- Distortion of the sense of taste
- Headache
- Dizziness

- Nausea

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C - 30°C.

Do not use BLEXTEN after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle: do not use this medicine if the bottle has been opened for longer than 2 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of reach and sight of children.

If you want more information about BLEXTEN:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website (https://www.searchlightpharma.com/), or by calling 1-855-331-0830.

This leaflet was prepared by Aralez Pharmaceuticals Canada Inc.

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