

PATIENT MEDICATION INFORMATION :

BLEXTEN® 

bilastine

Histamine H1-Receptor Antagonist

Aralez/dba Miravo

Date of Revision: August 10, 2021

Patient Medication Information: Tablets:

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Read this carefully before you start taking **BLEXTEN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BLEXTEN**.

What is BLEXTEN used for?

BLEXTEN tablets are used to relieve the symptoms of:

- **Seasonal Allergic Rhinitis:** Hayfever (sneezing, itchy, runny, blocked-up nose, red and watery eyes) in patients 12 years of age and older.
- **Chronic Spontaneous Urticaria:** Hives and itching in patients 12 years of age and older.

How does BLEXTEN work?

BLEXTEN is an antihistamine - it blocks the action of histamine and relieves hayfever symptoms, itchiness and hives.

What are the ingredients in BLEXTEN?

Medicinal ingredient: bilastine

Non-medicinal ingredients: colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

BLEXTEN comes in the following dosage forms:

Tablets: 20 mg

BLEXTEN is also available as a 10 mg orodispersible tablet and a 2.5 mg/mL oral solution for use in children 4 to 11 years of age, weighing at least 16 kg.

Do not use BLEXTEN if:

- You are allergic (hypersensitive) to bilastine or any of the other ingredients of BLEXTEN.
- You have a history of irregular heartbeat.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BLEXTEN. Talk about any health conditions or problems you may have, including if you:

- have kidney problems.
- have heart problems or a family history of heart problems.
- are pregnant or planning to becoming pregnant.
- are breastfeeding.

Other warnings you should know about:

Driving and using machines:

While taking BLEXTEN you may experience a feeling of tiredness, which can affect your ability to drive or use machines. If you experience tiredness, do not drive or operate machinery.

BLEXTEN tablets (20 mg) are not suitable for use by children under 12 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:

- ketoconazole (used to treat fungal infections)
- erythromycin and rifampicin (used to treat bacterial infections)
- diltiazem (used to treat heart problems)
- cyclosporine (used to suppress the immune system)
- ritonavir (used to treat HIV/AIDS)
- grapefruit and other fruit juices

How to take BLEXTEN:

- Swallow the tablet with water.
- Take BLEXTEN on an empty stomach, one hour before eating or drinking or two hours after. Food and fruit juice will lower the amount of medicine available to treat your symptoms.
- Do not take more BLEXTEN than your healthcare professional has told you to. If your symptoms do not improve, consult your healthcare professional.

Usual dose:

Seasonal Allergic Rhinitis:

Patients 12 years of age and older: 1 tablet (20 mg) once daily.

Chronic Spontaneous Urticaria:

Patients 12 years and older: 1 tablet (20 mg) once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much BLEXTEN, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are 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.

- headache
- sleepiness
- dizziness
- stomach pain

BLEXTEN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Heart problems: heart racing or slowing, cold sweats, feeling faint, feeling your heart beat, light headed, nausea, shortness of breath			√
UNKNOWN			
Allergic reactions: difficulty in breathing, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

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](#) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health 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 carton and the blisters after EXP. The expiry date refers to the last day of that month.

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 this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.miravohealthcare.com, or by calling 1-866-391-4503.

This leaflet was prepared by Aralez Pharmaceuticals Canada Inc.*

*Doing business as (d/b/a) Miravo Healthcare

Patient Medication Information: Orodispersible Tablets:

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Read this carefully before your child starts taking **BLEXTEN** and each time you get a refill for your child's prescription. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your child's medical condition and treatment and ask if there is any new information about **BLEXTEN**.

What is BLEXTEN used for?

BLEXTEN orodispersible tablets are used to relieve the symptoms of:

- **Seasonal Allergic Rhinitis:** Hayfever (sneezing, itchy, runny, blocked-up nose, red and watery eyes) in patients 4 to 11 years old, weighing at least 16 kg.
- **Chronic Spontaneous Urticaria:** Hives and itching in patients 4 to 11 years old, weighing at least 16 kg.

How does BLEXTEN work?

BLEXTEN is an antihistamine - it blocks the action of histamine and relieves hayfever symptoms, itchiness and hives.

What are the ingredients in BLEXTEN?

Medicinal ingredient: bilastine

Non-medicinal ingredients: croscarmellose sodium, mannitol, red grape flavour, sodium stearyl fumarate, sucralose (E955)

BLEXTEN comes in the following dosage forms:

Orodispersible Tablets: 10 mg

Do not use BLEXTEN if:

- Your child is allergic (hypersensitive) to bilastine or any of the other ingredients of BLEXTEN.
- Your child has a history of irregular heartbeat.

To help avoid side effects and ensure proper use, talk to your child's healthcare professional before your child starts taking BLEXTEN. Talk about any health conditions or problems your child may have, including if your child has:

- kidney problems.
- heart problems or a family history of heart problems.

Other warnings you should know about:

Doing tasks that require special attention:

BLEXTEN is not likely to affect your child's ability to do tasks. However, when they first start treatment, see how BLEXTEN affects their ability to do tasks such as riding a bicycle or using a machine.

BLEXTEN orodispersible tablets (10 mg) are not suitable for use by children under 4 years of age or weighing under 16 kg.

Tell your child's healthcare professional about all the medicines your child is using or receiving, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BLEXTEN:

- ketoconazole (used to treat fungal infections)
- erythromycin and rifampicin (used to treat bacterial infections)
- diltiazem (used to treat heart problems)
- cyclosporine (used to suppress the immune system)
- ritonavir (used to treat HIV/AIDS)
- grapefruit and other fruit juices

How to take BLEXTEN:

- The orodispersible tablet is for oral use.
- Place the orodispersible tablet in the mouth of your child. It will disperse rapidly in saliva and can then be easily swallowed.
- The tablet should **not** be taken with food or any fruit juices. Give your child the tablet one hour before or two hours after your child takes food or fruit juice.
- Alternatively, you may disperse the orodispersible tablet in a teaspoon of water before giving it to your child. Make sure that none of the orodispersible tablet remains in the spoon.
- **Only use water for dispersion**, do not use grapefruit juice or any other fruit juices.
- Do not give your child more BLEXTEN than your child's healthcare professional has told you to give them. If your child's symptoms do not improve, talk to your child's healthcare professional.

Usual dose:

Seasonal Allergic Rhinitis:

Patients 4-11 years of age, weighing at least 16 kg: 1 orodispersible tablet (10 mg) once daily.

Chronic Spontaneous Urticaria:

Patients 4-11 years of age, weighing at least 16 kg: 1 orodispersible tablet (10 mg) once daily.

Overdose:

If you think your child has taken too much BLEXTEN, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using BLEXTEN?

These are not all the possible side effects your child may have when taking BLEXTEN. If your child experiences any side effects not listed here, tell your child's healthcare professional.

- headache
- stomach pain
- eye irritation
- nasal irritation
- diarrhea
- nausea
- lip swelling
- fatigue
- eczema or hives

BLEXTEN can cause abnormal blood test results. Your child's healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Syncope (temporary loss of consciousness)			√
RARE			
Heart problems: heart racing or slowing, cold sweats, feeling faint, feeling your heartbeat, lightheaded, nausea, shortness of breath			√
UNKNOWN			
Allergic reactions: difficulty in breathing, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin			√

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your child's daily activities, tell your child's healthcare professional.

Reporting Side Effects

Reporting Side Effects

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

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- Calling toll-free at 1-866-234-2345.

Note: Contact your health 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 carton and the blisters after EXP. The expiry date refers to the last day of that month.

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 this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.miravohealthcare.com, or by calling 1-866-391-4503.

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Patient Medication Information: Oral Solution:

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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What is BLEXTEN used for?

BLEXTEN oral solution is used to relieve the symptoms of:

- **Seasonal Allergic Rhinitis:** Hayfever (sneezing, itchy, runny, blocked-up nose, red and watery eyes) in patients 4 to 11 years old, weighing at least 16 kg.
- **Chronic Spontaneous Urticaria:** Hives and itching in patients 4 to 11 years old, weighing at least 16 kg.

How does BLEXTEN work?

BLEXTEN is an antihistamine - it blocks the action of histamine and relieves hayfever symptoms, itchiness and hives.

What are the ingredients in BLEXTEN?

Medicinal ingredient: bilastine

Non-medicinal ingredients: betadex, hydrochloric acid 37% (for pH-adjustment), hydroxyethylcellulose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water, raspberry flavour, sodium hydroxide (for pH-adjustment), sucralose (E955)

BLEXTEN comes in the following dosage forms:

Oral solution: 2.5 mg bilastine in one milliliter of the oral solution

Do not use BLEXTEN if:

- Your child is allergic (hypersensitive) to bilastine or any of the other ingredients of BLEXTEN.
- Your child has a history of irregular heartbeat.

To help avoid side effects and ensure proper use, talk to your child's healthcare professional before your child starts taking BLEXTEN. Talk about any health conditions or problems your child may have, including if your child has:

- kidney problems.
- heart problems or a family history of heart problems.

Other warnings you should know about:

Doing tasks that require special attention:

BLEXTEN is not likely to affect your child's ability to do tasks. However, when they first start treatment, see how BLEXTEN affects their ability to do tasks such as riding a bicycle or using a machine.

BLEXTEN oral solution (2.5 mg/mL) is not suitable for use by children under 4 years of age or weighing under 16 kg.

Tell your healthcare professional about all the medicines your child is using or receiving, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BLEXTEN:

- ketoconazole (used to treat fungal infections)
- erythromycin and rifampicin (used to treat bacterial infections)
- diltiazem (used to treat heart problems)
- cyclosporine (used to suppress the immune system)
- ritonavir (used to treat HIV/AIDS)
- grapefruit and other fruit juices

How to take BLEXTEN:

- The oral solution is accompanied by a dosing cup with a mark of 4 mL, which will help you to pour the right amount of oral solution
- Fill the cup with 4 mL of oral solution and give the medicine to your child by mouth, directly from the cup
- Wash the cup after use
- BLEXTEN should **not** be taken with food or any fruit juices. Give your child the oral solution one hour before or two hours after your child takes any food or fruit juice.
- Your healthcare professional will determine how long to give your child BLEXTEN

Usual dose:

Seasonal Allergic Rhinitis:

Patients 4-11 years of age, weighing at least 16 kg: 4 mL of oral solution (equal to 10 mg bilastine) once daily

Chronic Spontaneous Urticaria:

Patients 4-11 years of age, weighing at least 16 kg: 4 mL of oral solution (equal to 10 mg bilastine) once daily

Overdose:

If you think your child has taken too much BLEXTEN, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to give your child the daily dose on time, give your child the dose as soon as possible, and then go back to your child's regular dosing schedule. Do not give your child a double dose to make up for a forgotten dose.

What are possible side effects from using BLEXTEN?

These are not all the possible side effects your child may have when taking BLEXTEN. If your child experiences any side effects not listed here, tell your child's healthcare professional.

- headache
- stomach pain
- eye irritation
- nasal irritation
- diarrhea
- nausea
- lip swelling
- fatigue
- eczema or hives

BLEXTEN can cause abnormal blood test results. Your child's healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Syncope (temporary loss of consciousness)			√
RARE			
Heart problems: heart racing or slowing, cold sweats, feeling faint, feeling your heartbeat, lightheaded, nausea, shortness of breath			√
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: difficulty in breathing, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin			√

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your child's daily activities, tell your child's healthcare professional.

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Note: Contact your health 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 carton after EXP. The expiry date refers to the last day of that month.

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 this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.miravohealthcare.com, or by calling 1-866-391-4503.

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