

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

BAQSIMI®
glucagon nasal powder

Read this carefully before you start taking BAQSIMI 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 BAQSIMI.

Show your family and friends where you keep BAQSIMI and explain when and how to use it. They need to know how to use it before you need it. Each BAQSIMI device comes with a package leaflet. **Keep them together at all times.** The package leaflet contains **all** the information needed to correctly give and use BAQSIMI.

Serious Warnings and Precautions

BAQSIMI should only be given when the person is unable to swallow sugar such as candy or orange juice. After giving BAQSIMI call for medical help right away. Patients usually respond to BAQSIMI within 15 minutes. Wait for medical assistance. They may need to give the person glucose in their veins (intravenously). When the person responds, get them to eat as soon as they are able to safely swallow.

BAQSIMI will not help if the person does not have enough glucose stored in the liver. Intravenous (IV) glucose must be given in these cases. This can occur if they have:

- not been eating for a long time.
- an illness that prevents them from making enough hormones from the adrenal gland (called adrenal insufficiency).
- chronic low blood sugar.

What is BAQSIMI used for?

BAQSIMI is a medicine used to treat severe low blood sugar. This is called severe hypoglycemia. It is used in adults and children who are older than 4 that take insulin for diabetes. It is used when the person is unable to swallow sugar.

How does BAQSIMI work?

BAQSIMI helps to increase blood sugar. It does this by releasing stored glucose (glycogen) from the liver to the blood.

What are the ingredients in BAQSIMI?

Medicinal ingredients: glucagon

Non-medicinal ingredients: betadex and dodecylphosphocholine

BAQSIMI comes in the following dosage forms:

BAQSIMI is a **single use** device. It is only for use in the nose. Each device contains 3 mg of glucagon nasal powder.

BAQSIMI comes in both a single and a two pack. Each BAQSIMI device comes with a package leaflet. **Keep them together at all times.**

Do not use BAQSIMI if you:

- are allergic to glucagon, or to any of the other ingredients.
- have a tumor in the gland on top of your kidneys called the adrenal gland. This tumor is called pheochromocytoma.
- have a tumor in your pancreas called insulinoma.

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

BAQSIMI may not work if the person does not have enough glucose stored in the liver. This can occur with fasting, chronic low blood sugar or underactive adrenal glands. BAQSIMI may not work if the person drinks too much alcohol.

Other warnings you should know about:

- Pregnant or plan to become pregnant. Talk with your doctor about the potential benefit for the mother. Decide if using BAQSIMI is justified based on the unknown risks to the mother and unborn baby.
- Breastfeeding or plan to breastfeed. It is not known if BAQSIMI passes into your breast milk.

Driving and using Machines:

If you have low blood sugar, your ability to concentrate and react may be impaired. After taking BAQSIMI you should wait until you know your blood sugar levels are in normal range before doing tasks. Low blood sugar can return after taking BAQSIMI.

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 BAQSIMI:**

- beta-blockers
- indomethacin
- warfarin
- insulin
- sulfonylureas: these are drugs to treat patients with type 2 diabetes. It is not recommended to take BAQSIMI if you take this kind of drug.

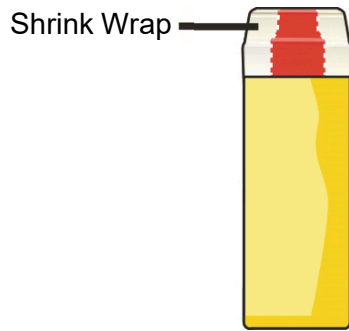
How to take BAQSIMI:

- Show your family and friends where you keep BAQSIMI and the package leaflet. Explain how to use it by sharing these instructions. **They need to know how to use it before you need it.**

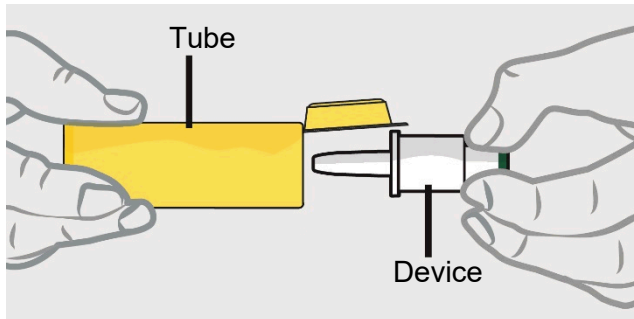
Important Points

- Keep BAQSIMI in the shrink wrapped Tube until ready to use.
- If the Tube has been opened, BAQSIMI may have been exposed to moisture. **This could cause BAQSIMI to not work as expected.**
- Each single device of BAQSIMI contains 1 dose of glucagon nasal powder and can only be used once. **Do not test before use.**
- Only use BAQSIMI in the nose.
- BAQSIMI will work even if you have a cold or are taking cold medicine.

Preparing the Dose

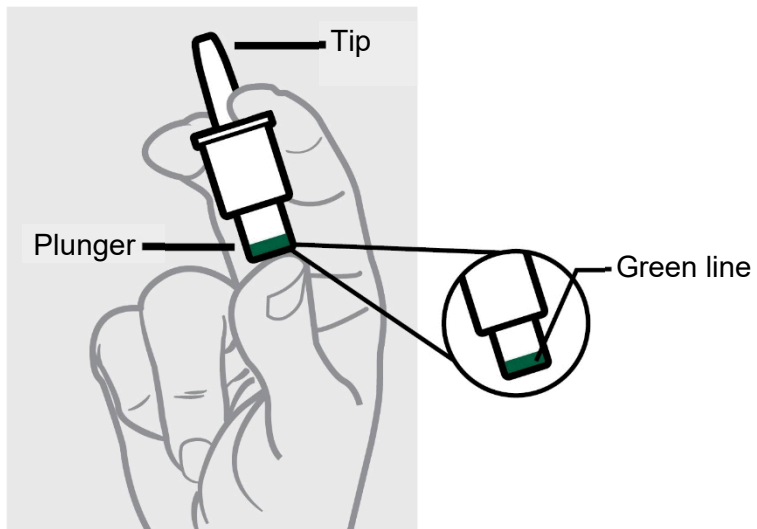


- Remove the Shrink Wrap by pulling on red stripe.



- Open the lid and remove the Device from the Tube.

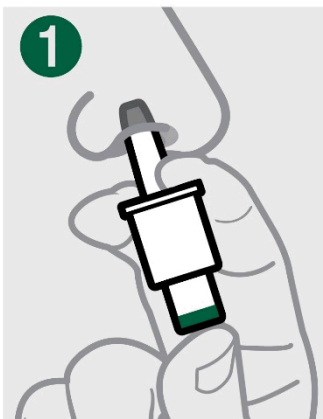
Do not test before use.



- Hold the Device between fingers and thumb.

Caution: Do not press the Plunger until ready to give the dose.

Giving the Dose



- Insert the Tip gently in one of the nostrils **until finger(s) touch the outside of the nose.**



- Push the Plunger all the way in.
- The dose is complete **when the Green Line is no longer showing.**

After Giving the Dose

- Remove the Tip from nose. **Throw away the used Device and Tube.**
- **Call for medical help right away.**
- If the person is unconscious, turn them on their side.
- Patients usually respond to BAQSIMI within 15 minutes. **Encourage the person to eat as soon as they can safely swallow.** Give the person a fast-acting source of sugar, such as juice or regular soda. Then give the person a long-acting source of sugar, such as crackers and cheese, peanut butter, or a meat sandwich.
- Tell your doctor each time you use BAQSIMI. Your doctor may need to adjust your dose of drugs for diabetes.

Caution: Replace the used BAQSIMI right away so you will have a new BAQSIMI in case you need it.

Usual adult and pediatric (4 years and older) dose:

3 mg given into one nostril (intranasal). Each device contains a single dose.

Overdose:

If you think you have taken too much BAQSIMI contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms. They may include nausea, vomiting, diarrhea, or slowing down of your gut. An increase in blood pressure and pulse rate can also occur.

What are possible side effects from using BAQSIMI?

These are not all the possible side effects you may feel when taking BAQSIMI. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Nausea, vomiting, abdominal pain or discomfort
- Upper respiratory tract irritation which includes sneezing, runny or stuffy nose, nose bleed or discomfort, cough, sore throat
- Headache, weakness, fatigue, sleepiness
- Watery, red or itchy eyes
- Ear, face or neck pain
- Change in sense of taste or smell
- Lack of attention, confusion, anxiety
- Itchy skin, increased sweating
- Increased heart rate and blood pressure

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 Allergic reaction (anaphylaxis): wheezing or difficulty breathing or swallowing. Sweating, rash, hives, swollen face, lips tongue or throat. Rapid heartbeat, collapse and low blood pressure.			✓

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

Reporting Side Effects

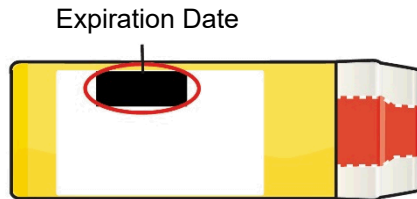
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 BAQSIMI in the shrink wrapped tube at temperatures up to 30°C (86°F).
- Only use BAQSIMI before the expiration date printed on the carton or tube.
- Replace BAQSIMI before the expiration date.



Keep out of reach and sight of children.

If you want more information about BAQSIMI:

- 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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

You may need to read this package leaflet again. Please do not throw it away until you have finished your medicine.

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