

RELiZORB[®] 
(IMMOBILIZED LIPASE) CARTRIDGE

Patient Guide



www.relizorb.com

RELiZORB is indicated for use in pediatric patients (ages 2 years and above) and adult patients to hydrolyze fats in enteral formula.

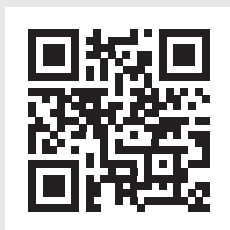
RELiZORB should only be used as directed by your physician.

Please see **Instructions for Use** at www.relizorb.com

Table of Contents



Scan now to learn more
about RELiZORB



www.relizorb.com | 1-844-632-9271

RELiZORB Overview

Glossary of Terms	4
Introduction	6
Indications for Use.....	6
Contraindications.....	6
Device Description	7
Warnings and Cautions	8
Risks and Benefits	10
Operating Information	11
RELiZORB Product Use	12

Setup Instructions

RELiZORB Setup Instructions.....	13
Enteral feeding with pump for up to 500 mL using 1 single RELiZORB cartridge.....	14
Enteral feeding with pump for greater than 500 mL and up to 1000 mL using tandem RELiZORB configuration	16
Bolus feeding with RELiZORB by syringe push for up to 250 mL using a single RELiZORB cartridge	18
Troubleshooting	20

Glossary of Terms

Bolus feeding: A type of feeding that can be used to deliver enteral formula through a feeding tube. Bolus feeding is intended to be provided as a replacement for snacks or meals and is completed in a short time, usually approximately 15-30 minutes, and can be administered with an enteral pump (at an increased flow rate) or using an enteral syringe.

Continuous feeding: A type of enteral feeding that can be used to deliver enteral formula through a feeding tube. Continuous feeding is administered with an enteral pump and is completed over several hours or up to a full day.

Digest (digesting; digestion): Breaking down food so it can be used (absorbed) by the body.

Digestive enzyme (enzyme): Substance made by the body that breaks down food so it can be absorbed.

ENFit®: ENFit is a standard connector designed for use in enteral feeding. Many enteral feeding supplies including pump sets, syringes, tubing, and patient extension sets have ENFit inlets and outlets designed to connect with a gentle twisting motion.

Enteral feeding pump set: Enteral feeding supply set that includes feeding tube and feeding tube bag. An enteral feeding pump set is threaded through the enteral pump and connects to the inlet of RELIZORB.

Enteral syringe: A type of syringe designed specifically for delivering enteral formula through a feeding tube. An enteral syringe has an ENFit connector outlet that is compatible with ENFit enteral feeding supplies.

Enteral tube feeding: A way to provide food through a tube placed in the nose, stomach or small intestine. The enteral feeding tube can be a G (gastrostomy) or J (jejunostomy) tube that is surgically placed in the patient's body.

Glossary of Terms

Fats: A type of nutrient in food. The body uses fat as an energy source (calories).

Fatty acids; monoglycerides: The forms of fat that the body can absorb and use for energy and other health benefits/functions.

Fat hydrolysis: The breakdown of fats (triglycerides) into forms that the body can absorb.

iLipase®: The combination of the lipase enzyme bound to the white beads in RELIZORB.

Lipase: A digestive enzyme that breaks down fats into absorbable fatty acids and monoglycerides.

Patient caregiver: Parent, relative, family member or friend responsible for assisting patient with use of RELIZORB.

Patient extension set (enteral feeding set): The tubing that connects the RELIZORB outlet to the enteral feeding port (low-profile button) on the patient's body.

Transition connector (or stepped connector or adapter): A device that is used for connecting enteral feeding sets (with ENFit connectors) to legacy (non-ENFit) feeding tubes and extension sets.

Introduction

Your doctor believes you or a patient you provide care for may need help breaking down (hydrolyzing) fats from your enteral tube feeding formula.

Read through this RELIZORB Patient Guide completely before you or a person you care for starts using RELIZORB. Reread the RELIZORB Patient Guide each time you get a new supply of RELIZORB in case there is new information in the guide.

Use RELIZORB as directed by your doctor or healthcare provider. Do not make changes to the feeding care plan for you or a patient you provide care for without first speaking with your doctor or healthcare provider.

Indications for Use

RELIZORB is indicated for use in pediatric patients (2 years and above) and adult patients to hydrolyze (break down) fats in enteral formula.

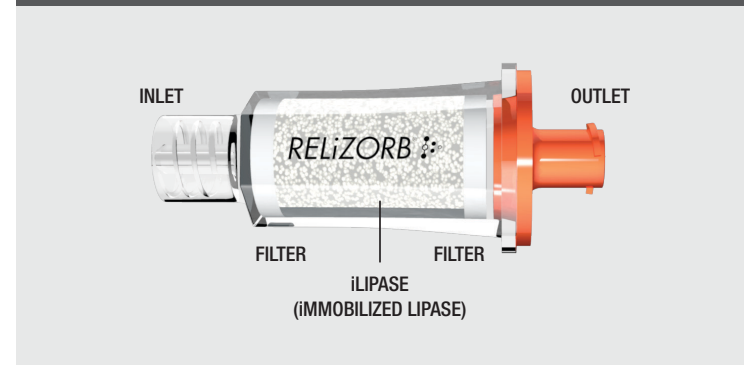
RELIZORB is designed for use by people who have trouble breaking down (digesting) fats and need enteral tube feeding. People who may benefit from RELIZORB cannot properly make digestive enzymes or may not be able to efficiently hydrolyze and absorb fats from nutrition. If fats are not broken down, you can have stomach pain, gas, oily or foul-smelling stools, an unusually full feeling in the stomach or feel like throwing up. Fats that are not broken down (digested) could result in getting fewer calories, weight loss, shortage of key fats (omega-3 fats), and lower levels of some vitamins.

Contraindications

There are no contraindications associated with RELIZORB.

Device Description

Figure 1: RELIZORB and its major components



RELIZORB is a digestive enzyme cartridge that contains the enzyme lipase. RELIZORB is used with enteral tube feeding to help break down the fats in tube feeding formulas. Lipase is an enzyme that is normally made in the body to break down (digest) fats into an absorbable form (fatty acids and monoglycerides). RELIZORB uses the enzyme lipase bound to white beads inside the cartridge, called iLipase, which is visible through the sides of the cartridge. The RELIZORB cartridge is shown in **Figure 1**.

A detailed listing of enteral formulas and enteral feeding supplies compatible with RELIZORB can be found at www.relizorb.com/compatibility.

Warnings and Cautions

WARNINGS: Using RELIZORB other than as directed may result in RELIZORB not working properly or may cause serious injury.

- DO NOT connect RELIZORB to IV (intravenous) or other non-enteral tubes or lines. RELIZORB is ONLY for use with enteral tube feeding.
- DO NOT place medicines, flushes, or non-enteral formula materials through the RELIZORB device. RELIZORB is for use with enteral formulas only. Passing medicines through RELIZORB may change how the medicine works or how RELIZORB breaks down fats. If medicines or flush solutions are accidentally added before RELIZORB, then the RELIZORB cartridge must be thrown away. Restart feeding using a new RELIZORB. Medicines may only be added to the enteral feed line after RELIZORB. Medicines may be added to the side port of a Y-connector extension set located between RELIZORB and the patient using an appropriately sized syringe.

CAUTIONS: Using RELIZORB other than as directed may result in RELIZORB not working properly.

- Do not reuse RELIZORB. Each RELIZORB should only be used once. At the end of the feeding, throw away RELIZORB. RELIZORB may not break down fats properly or could cause potential microbial contamination if reused.
- Do not break or place excess pressure on any part of RELIZORB. Any cracks or breaks may cause RELIZORB to not connect properly to enteral feeding supplies and may lead to formula leaking.
- Do not use blenderized enteral tube feeding formulas with RELIZORB as this may clog the cartridge. A detailed listing of enteral formulas compatible with RELIZORB can be found at www.relizorb.com/compatibility.

Warnings and Cautions

- If using RELIZORB with an enteral feeding pump, you should use a pump with a low flow/no flow alarm. If you use a pump system without a low flow/no flow alarm, you may not notice if the flow of the feeding slows down or stops.
- Do not use more than 6 RELIZORB cartridges in a day.
- For all feedings, follow guidance from your doctor on how long it should take you to complete your feeding.
- RELIZORB has been tested for up to a 1-hour stop during a continuous feeding and shown not to change flow rate or how well RELIZORB breaks down fat.
- Store RELIZORB in its pouch either refrigerated or at room temperature (2°C to 27°C; 36°F to 80°F) until you are ready to use it. Storing RELIZORB in a hot place (greater than 27°C or 80°F) may affect how well RELIZORB breaks down fat.
- Do not use RELIZORB after the “use by” date marked on the pouch. If RELIZORB is used after the “use by” date, RELIZORB may not break down fats as well.

Risks and Benefits

Risks

In clinical studies with RELiZORB, the most common complaints were stomach related symptoms that are typical in people who have trouble breaking down fats and need enteral tube feeding. The most commonly reported symptoms were stomach pain and gas.

Benefits

RELiZORB helps break down fats in enteral tube feeding formula before it goes into the body, allowing the fats in the formula to enter your body in an absorbable form. In clinical studies, RELiZORB was shown to increase the amount of fat that the body absorbs from enteral tube feeding formulas, including omega-3 fats, which are key fatty acids that provide energy and are important for normal development and growth. RELiZORB may help reduce gastrointestinal (GI) symptoms associated with fat malabsorption.



Operating Information

RELiZORB has ENFit compatible connectors on both ends to connect to enteral feeding supplies, including enteral feeding pumps, enteral syringes, and patient extension sets. More details on RELiZORB setup for continuous and bolus feeding are provided beginning on page 13. RELiZORB can also be used with tubing and patient extension sets that use a stepped connector (not ENFit compatible).

For a complete list of compatible formulas and enteral feeding supplies, visit www.relizorb.com/compatibility.

RELiZORB is designed to hydrolyze (break down) the fats in your enteral formula. Enteral formulas do not contain pre-hydrolyzed fats (fats that are broken down), because fats that are broken down into their absorbable form are not stable and spoil quickly. RELiZORB uses the enzyme lipase bound to white beads inside the cartridge, called iLipase. As enteral formula passes through RELiZORB, it makes contact with the iLipase and the fat in the formula is broken down to its absorbable form (fatty acids and monoglycerides). The iLipase stays inside RELiZORB as the enteral formula flows through the cartridge. As a result, you do not consume (or ingest) the lipase. You or the person you care for consumes (or ingests) the formula with the absorbable fats that the lipase has broken down.

Storage

Store RELiZORB in its pouch either refrigerated or at room temperature (2°C to 27°C; 36°F to 80°F) until you are ready to use it. Storing RELiZORB in a hot place (greater than 27°C or 80°F) may affect how well RELiZORB breaks down fat.

Disassembly and Disposal



When feeding is complete, disconnect the RELiZORB from the enteral feeding supplies.


Throw away the RELiZORB after use in your trash.

RELIZORB Product Use

RELIZORB has been evaluated with specifications and enteral pump flow rates listed below:

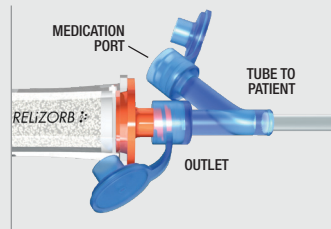
A maximum of 6 RELIZORB cartridges can be used per day, either in single or tandem configuration

Feeding with an Enteral Pump*		
	Single RELIZORB 	Tandem RELIZORB 
Enteral Formula Volume	Up to 500 mL	500-1000 mL
Enteral Pump Flow Rate	10-400 mL/hr	24-150 mL/hr

Bolus Feeding with an Enteral Syringe	
	Single RELIZORB for enteral syringe push 
Enteral Formula Volume	Up to 250 mL

*For continuous feeding, do not exceed use for more than 24 hours in either single or tandem configuration.

WARNING: DO NOT place medicines, flushes, or non-enteral formula materials through RELIZORB. RELIZORB is for use with enteral formulas only. Medicines must be added after RELIZORB, between the RELIZORB and the patient.



RELIZORB Setup Instructions

There are 3 different setup procedures depending on the feeding administration type and feeding formula volume:

- A** Enteral feeding with pump for up to 500 mL using 1 single RELIZORB cartridge (pages 14-15)
- B** Enteral feeding with pump for greater than 500 mL and up to 1000 mL using tandem RELIZORB configuration (pages 16-17)
- C** Bolus feeding with RELIZORB by syringe push for up to 250 mL using 1 single RELIZORB cartridge (pages 18-19)

IMPORTANT: When connecting RELIZORB to enteral feeding supplies or another RELIZORB, gently twist, do not overtighten. It usually needs just a quarter-turn to be secure. Avoid getting formula in the ENFit connections.

Note: Ensure all inlet and outlet connectors on RELIZORB and enteral feeding supplies are clean and dry prior to making connections.

When setting up RELIZORB, remove RELIZORB from its carton. Examine the RELIZORB pouch. **Do not use RELIZORB if the pouch seal is broken, or the current date is past the expiration date shown on the pouch.**

When opening the RELIZORB pouch, tear the pouch open from either end and remove the RELIZORB from its pouch. **Do not use RELIZORB if RELIZORB is damaged or RELIZORB has been previously used.**

Feeding with an Enteral Pump

A

Enteral feeding with pump for up to 500 mL using 1 single RELIZORB cartridge

- 1 Open RELIZORB as described on page 13.
- 2 Set up the enteral pump and feeding tube set according to the pump manufacturer's instructions.
- 3 Connect RELIZORB to the end of the enteral feeding tube set by inserting the outlet fitting from the tube set into the clear inlet of RELIZORB. Use a gentle twisting motion until the connection is tight, as shown in **Figure 2**. **Note:** Ensure all inlet and outlet connectors on RELIZORB and enteral feeding supplies are clean and dry prior to making connections. Do not apply excessive force. Gently twist to secure.

Figure 2: Securing RELIZORB inlet to outlet fitting from pump tubing



- 4 Prime the enteral formula through the tube set according to the pump manufacturer's instructions.

- 5 Connect the RELIZORB outlet to the inlet of the patient extension set or feeding tube that connects to the patient, as shown in **Figure 3**.

Figure 3: Connecting RELIZORB outlet to inlet fitting of patient extension set or enteral feeding tube that connects to patient



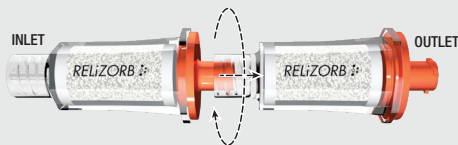
- 6 Manually prime the enteral formula through RELIZORB up to the outlet by holding the prime button on the enteral feeding pump. **Note:** Ensure formula does not come out of the RELIZORB outlet. If formula spills out, wipe away excess formula.
- 7 If a patient extension set is being used, follow the pump manufacturer's instructions to prime the enteral formula to the end of the patient extension set. Connect the patient extension set to the enteral feeding port (button).
- 8 Set the pump to the prescribed flow rate between 10 and 400 mL/hr and proceed with feeding.

Feeding with an Enteral Pump

B Enteral feeding with pump for greater than 500 mL and up to 1000 mL using tandem RELIZORB configuration

- 1 Open two RELIZORBs as described on page 13.
- 2 Connect the 2 RELIZORBs by inserting the orange outlet fitting from the first RELIZORB into the clear inlet of the second RELIZORB with a gentle twisting motion until secure as shown in **Figure 4**. **Note:** When connecting RELIZORB to another RELIZORB, gently twist, do not overtighten. It usually needs just a quarter-turn to be secure. Avoid getting formula in the ENFit connections.

Figure 4: Connecting RELIZORB cartridges together to form a tandem RELIZORB



- 3 Set up the enteral pump and feeding tube set according to the pump manufacturer's instructions.
- 4 Connect tandem RELIZORB configuration to the end of the enteral feeding tube set by inserting the outlet fitting from the tube set into the clear inlet of the first RELIZORB. Use a gentle twisting motion until the connection is tight, as shown in **Figure 5**.

Figure 5: Securing tandem RELIZORB inlet to outlet fitting from pump tubing



- 5 Prime the enteral formula through the tube set according to the pump manufacturer's instructions.
- 6 Manually prime the enteral formula through the tandem RELIZORB configuration up to the outlet of the second RELIZORB by holding the prime button on the enteral feeding pump. **Note:** Ensure formula does not come out of the RELIZORB outlet. If formula spills out, wipe away excess formula.
- 7 Connect the RELIZORB outlet to the inlet of the patient extension set or feeding tube that connects to the patient, as shown in **Figure 6**.

Figure 6: Connecting tandem RELIZORB outlet to inlet fitting of tube that connects to patient



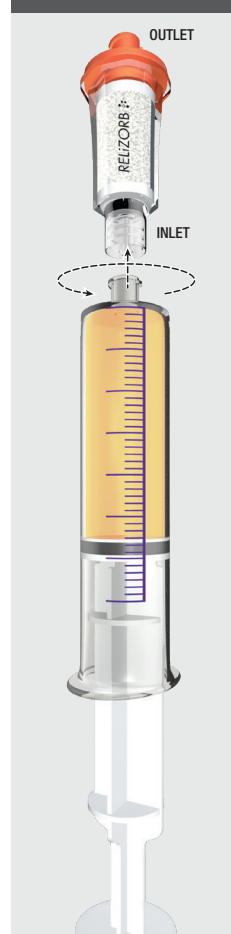
- 8 If a patient extension set is being used, follow the pump manufacturer's instructions to prime the enteral formula to the end of the patient extension set. Connect the patient extension set to the enteral feeding port (button).
- 9 Set the pump to the prescribed flow rate between 24 and 150 mL/hr and proceed with feeding.

Bolus Feeding with an Enteral Syringe

C Bolus feeding with RELiZORB by syringe push for up to 250 mL using a single RELiZORB cartridge

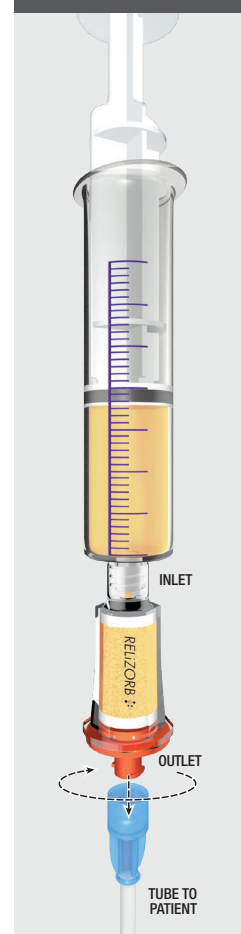
- 1 Flush the feeding tube with water using an enteral syringe. Clamp the feeding tube and remove the enteral syringe.
- 2 Pour the prescribed amount of enteral formula into a clean container. **Note:** When using RELiZORB, approximately 2 mL of formula stays in the RELiZORB during bolus feeding. Consult with your healthcare provider on the correct amount of formula to use for bolus feeds.
- 3 Use the enteral syringe to draw the enteral formula up into the syringe. Wipe the outlet of the enteral syringe clear of any formula.
- 4 Open RELiZORB as described on page 13.
- 5 Connect the clear inlet of RELiZORB to the outlet of the enteral syringe using a gentle twisting motion until the connection is tight as shown in **Figure 7**.

Figure 7: Enteral syringe filled with formula facing upward attached to RELiZORB



- 6 Gently press the syringe plunger to prime the formula through RELiZORB and push out excess air. **Note:** Ensure formula does not come out of the RELiZORB outlet. If formula spills out, wipe away excess formula.
- 7 Connect the orange outlet fitting of RELiZORB into the inlet fitting of the feeding tube set using a gentle twisting motion until the connection is tight as shown in **Figure 8**. If a patient extension set is being used, prime the feeding formula to the end of the patient extension set. Connect the patient extension set to the enteral feeding port (button).
- 8 Unclamp the feeding tube and gently push the plunger for the formula to flow through the feeding tube. **Note:** Do not rush the feed. Consult with your healthcare provider on how long the bolus feeding should take.
- 9 Once the syringe is empty, clamp your feeding tube. If you need more enteral formula based on the prescribed feeding volume, remove the syringe, refill it with formula, and repeat the process until you have reached your prescribed amount of formula.

Figure 8: Connecting RELiZORB outlet to inlet fitting of tube that connects to patient





Troubleshooting

SYMPTOM	FEEDING TYPE	PROBABLE CAUSE(S)	CORRECTION(S)
Flow Error Alarm	Continuous or bolus feeding with a pump	See pump instructions for probable cause	If none of the corrective actions offered by the pump instructions correct the Flow Error Alarm, remove the RELiZORB and replace it with a new RELiZORB
Leakage from RELiZORB connections	All	Improper connection of inlet or outlet fitting	Disconnect and reconnect RELiZORB with a twisting motion until secure. RELiZORB is designed for use with ENFit syringes and patient extension sets. Confirm that the syringe and patient extension set/tubing are clean and dry prior to connecting, and that they are connected properly. When connecting RELiZORB to enteral feeding supplies or another RELiZORB, gently twist, do not overtighten. It usually needs just a quarter-turn to be secure. Avoid getting formula in the ENFit connections
Incomplete priming	Continuous or bolus feeding with a pump	Auto prime may not pump formula completely through the cartridge	Use manual prime to completely prime the RELiZORB and patient extension set

If you have questions, talk to your doctor or healthcare professional. For more information, or to report a problem with RELiZORB, visit www.relizorb.com or call 1-844-632-9271



Alcresta Therapeutics, Inc.
130 Turner Street
Waltham, MA 02453

ENFit® is a registered trademark of GEDSA. RELiZORB, iLipase, the Alcresta capstone, and Alcresta Therapeutics are registered trademarks of Alcresta Therapeutics, Inc. Patents: <http://www.alcresta.com/patents>

©2024 Alcresta Therapeutics, Inc. All rights reserved. 1/2024 900715 Rev. A