RELIZORB
(iMMOBILIZED LIPASE) CARTRIDGE

Patient Guide

ENFit® Compatible
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GLOSSARY OF TERMS

**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.

**Enteral feeding pump tubing set**—The tubing set that is connected to the enteral tube feeding bag. An enteral feeding pump tubing set is threaded through the enteral tube feeding pump and connects to the inlet of RELiZORB.

**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.

**Exocrine pancreatic insufficiency**—A health condition where the body does not produce enough digestive enzyme or produces enzyme that does not work properly.

**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 easily absorb and use for energy and other health benefits/functions.

**Fibrosing colonopathy**—Rare bowel disease where thickening can form in the large intestine.

**iLipase™**—The combination of the lipase enzyme attached to the white beads in RELiZORB.

**Lipase**—A digestive enzyme that breaks down fats (triglycerides) into absorbable fatty acids and monoglycerides.

**Omega-3 and omega-6 fats**—Important fats that provide energy (calories) and other important health benefits. Omega-3 fatty acids are key for normal development and growth. Omega-3 fats include DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid). Omega-6 fats include AA (arachidonic acid).

**Pancreas**—An organ in the body that produces digestive enzymes, which are needed to break down food.

**Patient caregiver**—Parent, relative, family member or friend responsible for assisting patient with use of RELiZORB.

**Patient extension set (enteral tubing set)**—The tubing that connects RELiZORB outlet to the enteral feeding port (low-profile button) on the patient’s body.

**Triglycerides**—The form of fat that is used in enteral feeding formulas. The body cannot absorb this form of fat until enzymes break the fats down into fatty acids and monoglycerides.
INTRODUCTION

Your doctor believes that you or a patient you provide care for might benefit from RELiZORB because you or a patient you provide care for may need help breaking down (digesting) fats from your enteral tube feeding formula.

Read all of this RELiZORB Patient Guide 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 the patient you provide care for without first speaking with your doctor or healthcare provider.

WHAT IS RELiZORB?

RELiZORB is a digestive enzyme cartridge that contains the enzyme lipase. RELiZORB is used with enteral tube feeding to help break down the fats. Lipases are enzymes that are normally made in the body to break down (digest) fats (triglycerides) into an absorbable form (fatty acids and monoglycerides). The lipase enzyme used in RELiZORB is attached to the white beads (iLipase), which are visible through the side of the cartridge. The RELiZORB cartridge is shown in Figure 1.
HOW DOES RELIZORB CONNECT INTO MY FEEDING PUMP?

RELiZORB connects to your enteral feeding pump tubing setup and the patient extension set or enteral feeding tube as shown below (Figure 2). The tube from the enteral pump tubing set (left) connects to the inlet of RELiZORB. The patient extension set or enteral feeding tube to patient (right) connects to the outlet of RELiZORB. More details are provided in the RELiZORB Set-up Procedure and Use section at the end of this Patient Guide.
WHO IS RELIZORB DESIGNED FOR?

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. 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.

WHAT MUST YOU BE AWARE OF WHEN USING RELIZORB TO AVOID INJURY?

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 in the enteral tube feeding bag or anywhere else before the RELiZORB cartridge. 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 and all tubing and formula must be thrown away. Restart feeding using a new RELiZORB and enteral feeding pump tubing set and patient extension set (if used).
Medicines or saline flushes 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 as shown below in Figure 3.

**FIGURE 3** Medications may be added between RELiZORB and patient.
Fibrosing colonopathy is a rare bowel disease. The chance of having fibrosing colonopathy could increase with use of high dose pancreatic enzyme replacement therapy (PERT). PERTs are usually tablets or capsules that contain enzymes and are ingested orally. RELiZORB contains a digestive enzyme lipase which is not the same as in PERT. The lipase in RELiZORB stays attached to the white bead (iLipase) so it remains in the cartridge and does not enter the body with the enteral tube feeding formula. Follow your healthcare provider’s instructions on PERT product dosing when used with RELiZORB. Fibrosing colonopathy is a serious problem that may require surgery. Call your healthcare provider right away if you have any unusual or severe stomach area pain.
**WHAT ARE POTENTIAL RISKS WITH USE OF RELIZORB?**

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.

**WHAT MUST I DO TO AVOID DAMAGING RELIZORB AND USE IT CORRECTLY?**

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 the RELiZORB. RELiZORB may not break down fats properly if reused.

- Do not break or place excess pressure on any part of the RELiZORB cartridge. Any cracks or breaks may cause RELiZORB to not connect properly to the enteral feeding pump tubing set or patient extension set or enteral feeding tube and may lead to formula leaking.

- Do not use enteral tube feeding formulas containing insoluble fiber as insoluble fiber may block the cartridge. Check the label of your feeding formula for something called insoluble fiber.
• Use RELiZORB only with a pump that has a low flow or no flow alarm. RELiZORB has not been tested for use with gravity feed systems (systems that have no pumps). 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 two (2) RELiZORBs in a day (a 24-hour period). You can use two (2) RELiZORBs, one right after the other, or space out the timing of their use.

• Each RELiZORB may be used for up to 500 mL of enteral tube feeding formula. Do not use one RELiZORB for more than 500 mL in a feeding, as it may not work as well to break down all the fat. If you use less than 500 mL of formula in a feeding, you must throw away the RELiZORB after use.

• Use only with flow rates from 24 to 120 mL/hr when using RELiZORB. RELiZORB has not been tested using flow rates greater than 120 mL/hr or less than 24 mL/hr. Using a flow rate outside of this flow rate range may affect how well RELiZORB breaks down fat.

• RELiZORB has been tested for up to a 1 hour stop in feeding and shown not to change flow rate or how well RELiZORB breaks down fat.

• Do not freeze RELiZORB. 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.

HOW WILL USING RELIZORB HELP WITH ENTERAL FEEDING?

You or the patient you care for may need enteral tube feeding to gain or maintain weight because of trouble breaking down (digesting) and absorbing the fats needed. During laboratory testing, RELiZORB has been shown to break down fats in enteral tube feeding formulas. RELiZORB may help to break down fats in enteral tube feeding formula before it goes into the body, so the fats are absorbable. In clinical studies, RELiZORB was shown to increase the amount of fat that the body absorbs from enteral tube feeding formulas, particularly omega-3 fats, which are described in Section 13 on page 11.
WHY DOESN’T MY ENTERAL TUBE FEEDING FORMULA CONTAIN ABSORBABLE FATS?

Fats that are broken down into their absorbable form are not stable and spoil quickly. Therefore, enteral tube feeding formulas are made with fat in triglyceride form, which does not spoil as quickly but also is not absorbable by the body. RELiZORB breaks down the fats into absorbable forms (fatty acids and monoglycerides) during enteral tube feeding.

HOW DOES RELiZORB WORK?

Inside the RELiZORB cartridge, there are small white beads. You can see these beads through the clear cartridge (Figure 1). The lipase enzyme, which helps break down fats, is attached to the small white beads. The lipase and bead combination is called iLipase. As the enteral tube feeding 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 tube feeding 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.

**WHY ARE OMEGA-3 AND OMEGA-6 FATS IMPORTANT, AND HOW DOES RELIZORB BREAK DOWN OMEGA-3 AND OMEGA-6 FATS?**

Omega-3 and omega-6 fats are special fats that provide energy and are important for normal development and growth. The lipase in RELiZORB helps break down the fat in enteral tube feeding formula (which is in triglyceride form) into its absorbable (usable) forms (fatty acids and monoglycerides), which may help the body use omega-3 and omega-6 fats. People who have problems digesting and absorbing fats usually have reduced levels of omega-3 and omega-6 in their body.

**WHAT ENTERAL TUBE FEEDING FORMULAS CAN I USE WITH RELIZORB?**

For a listing of formulas that can be used with RELiZORB, visit [www.relizorb.com/formulas](http://www.relizorb.com/formulas). RELiZORB was tested in a laboratory with different enteral tube feeding formulas. During laboratory testing, RELiZORB was able to break down more than 90% of the fats into their absorbable forms for most of the formulas tested. These tests were done with 500 mL of formula with an enteral tube feeding pump set at a high flow rate of 120 mL/hour. The same or better fat breakdown was shown when RELiZORB was used with volumes lower than 500 mL and flow rates as low as 24 mL/hour.
WHAT PUMPS AND FEEDING SETS CAN I USE WITH RELIZORB?

RELiZORB must be used with enteral tube feeding pumps that have low flow/no flow alarms. RELiZORB has not been tested for use with gravity feed systems (systems that have no pumps).

Examples of the pumps tested with RELiZORB are listed in Table 1.

<table>
<thead>
<tr>
<th>Pump Name</th>
<th>Pump Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>EnteraLite® Infinity</td>
<td>Moog (Zevex Therapeutics)</td>
</tr>
<tr>
<td>Kangaroo™ ePump</td>
<td>Covidien</td>
</tr>
<tr>
<td>Kangaroo™ Joey</td>
<td>Covidien</td>
</tr>
</tbody>
</table>

For a detailed listing of pumps, enteral feeding pump tubing sets and patient extension sets tested with RELiZORB, visit www.relizorb.com/pumps.

EnterLite® Infinity is a registered trademark of Moog (Zevex Therapeutics). Kangaroo™ ePump and Kangaroo™ Joey are trademarks of Covidien.

WHEN TAKING RELIZORB, CAN I ALSO USE PERT (PANCREATIC ENZYME)?

RELiZORB is to be used with enteral feeding only; patients should follow physician’s guidance for PERT (pancreatic enzymes) use for meals and snacks. In clinical studies, the use of RELiZORB was shown to hydrolyze fat as intended when used during enteral feeding.
**RELIZORB SETUP PROCEDURE AND USE**

1. Set up the enteral tube feeding tubing set and feed set according to the pump manufacturer’s instructions. Prime the enteral feeding pump tubing set according to the manufacturer’s instructions.

2. Remove a RELiZORB pouch from its carton. Examine the RELiZORB pouch. Do not use the RELiZORB cartridge if:
   - the pouch seal is broken
   - the current date is past the expiration date shown on the pouch

3. Tear open the RELiZORB pouch from either end and remove the RELiZORB from its pouch. Do not use the RELiZORB cartridge if:
   - the RELiZORB is damaged
   - the RELiZORB has been previously used

4. Connect the RELiZORB cartridge to the end of the enteral feeding pump tubing set. Insert the outlet fitting from the enteral feeding pump tubing set into the inlet of the RELiZORB cartridge. Use a twisting motion until the connection is tight.

**FIGURE 4** Securing the enteral feeding pump tubing set to the RELiZORB cartridge inlet
5 Follow the pump manufacturer’s instructions to prime the feeding formula through to the outlet of the RELiZORB cartridge.

6 Connect the RELiZORB cartridge outlet to the inlet of the patient extension set or enteral feeding tube that connects to the patient.

7 If a patient extension set is being used, follow the pump manufacturer’s instructions to prime the feeding 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 24 and 120 mL/hr and proceed with feeding.
18 **RELIZORB DISASSEMBLY AND DISPOSAL**

When feeding is complete, disconnect the RELiZORB from the patient extension set or enteral feeding tube and enteral feeding pump tubing set.

Throw away the RELiZORB after use in your trash.

19 **TROUBLESHOOTING**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause(s)</th>
<th>Correction(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow Error Alarm</td>
<td>See pump instructions for the cause of the alarm.</td>
<td>If none of the actions in the pump instructions fix the Flow Error Alarm, remove the RELiZORB and replace it with a new RELiZORB.</td>
</tr>
<tr>
<td>Leakage from Connections</td>
<td>Improper connection of inlet or outlet fitting.</td>
<td>Disconnect and re-connect RELiZORB with a twisting motion until the connection is tight.</td>
</tr>
</tbody>
</table>
ADDITIONAL INFORMATION

If you would like more information, talk to your doctor or healthcare professional.

For more information, or to report a problem with RELiZORB, visit www.relizorb.com or call toll-free at 1-844-632-9271.
Quick Guide to RELiZORB Setup

1. Connect the RELiZORB cartridge to the end of the enteral feeding pump tubing set.

   ![Image of RELiZORB cartridge connected to tubing]

   NOTE: Do not overtighten the enteral feeding pump tubing set when connecting to RELiZORB. A small gap between the flange on the enteral feeding pump tubing set and the RELiZORB is normal. Prime the feeding formula through to the outlet of the RELiZORB cartridge.

2. Connect RELiZORB outlet to the patient extension set or enteral feeding tube.

3. If using a patient extension set, prime the feeding formula to the end of the patient extension set, and connect to the feeding port (button). If using a feeding tube, connect RELiZORB directly to the enteral feeding tube.

4. Set the pump to the prescribed flow rate between 24 and 120 mL/hr. Proceed with feeding.

To learn more about RELiZORB, please visit or call: www.relizorb.com 1-844-632-9271