

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

**DOJOLVI™**  
Triheptanoin oral liquid

Read this carefully before you start taking **DOJOLVI** 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 **DOJOLVI**.

**What is DOJOLVI used for?**

Dojolvi is used as a source of calories and fatty acids to treat adults and children with long-chain fatty acid oxidation disorders (LC-FAOD).

**How does DOJOLVI work?**

The body usually uses glucose (sugar) for energy; however, when all the glucose is used up, the body also gets energy from fat. People with LC-FAOD cannot use long-chain fat for energy. DOJOLVI is a source of medium chain fatty acids. It can provide energy to the body in two ways:

1. by working around the process to break down long chain fatty acids into energy; and
2. by providing another source of energy.

**What are the ingredients in DOJOLVI?**

Medicinal ingredients: Triheptanoin

Non-medicinal ingredients: None

**DOJOLVI comes in the following dosage forms:**

Liquid: 100% w/w of triheptanoin

**Do not use DOJOLVI if:**

- you are allergic to triheptanoin or to any other ingredients in this medicine including components of the container.

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

- you have feeding tube problems. Feeding tubes can breakdown over time. It is possible that using DOJOLVI with a feeding tube might also contribute to its breakdown. Check the feeding tube regularly to ensure it is not damaged and is working properly;
- you have pancreatic insufficiency. This is a condition where the pancreas does not make enough enzymes to help digest food properly;
- you or your partner are pregnant or planning to get pregnant;
- you are breastfeeding or plan to breastfeed.

**Other warnings you should know about:**

**Visits with your healthcare professional:** You should have regular visits with this healthcare professional so they can:

- determine how DOJOLVI is working for you,
- make adjustments to your dose, and
- talk to you about your diet.

**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 DOJOLVI:**

- Medicines called pancreatic lipase inhibitors, which act on enzymes in the gastrointestinal tract. An example is the medicine orlistat.
- A medicine used to treat seizures, bipolar disorder or migraines called valproic acid.

**How to take DOJOLVI:**

- Take DOJOLVI:
  - exactly as directed by your healthcare professional.
  - by mouth or give through a feeding tube. Follow the step-by-step instructions listed below. If you are not sure, contact your healthcare professional.
  - 4 or more times throughout the day with a meal or snack. You will take DOJOLVI about every 3 to 4 hours.
  - Mix it with liquid or soft food. Taking DOJOLVI on its own may cause side effects.
- Tracking your doses, especially as you start taking DOJOLVI, can help you get used to and continue with your treatment plan. It can also help your healthcare professional decide if changes to your dose are needed.
- If you are taking another medium-chain triglyceride (MCT) product, you must stop before your first dose of DOJOLVI.
- Your healthcare professional will tell you:
  - how much DOJOLVI to take;
  - how much liquid or soft food to use.
  - They may also recommend that you increase the amount of fats that you eat in your diet.
- Do not mix or give DOJOLVI with plastic items made of polystyrene or polyvinyl chloride (PVC).
- Only use DOJOLVI with supplies (including feeding tubes) made of:
  - stainless steel,
  - glass,
  - high or low density polyethylene,
  - polypropylene,
  - polyurethane, and
  - silicone.
  - Check all your supplies (including the feeding tube, if applicable) regularly. This is to ensure they are not broken or damaged in any way and that the feeding tube is working properly.

**Preparing and taking DOJOLVI by mouth:**

1. Gather the required supplies and information, including:

- the amount of liquid or soft food needed, as directed by your healthcare professional.
  - DOJOLVI bottle
  - an oral syringe or measuring cup
  - a clean bowl, cup or container made of one of the materials listed above.
2. Measure out:
    - the required amount of DOJOLVI using the oral syringe or measuring cup; and
    - the required amount of liquid or soft food and place in the bowl, cup, or container
  3. Add DOJOLVI to the liquid or soft food. Mix well.
  4. Swallow the DOJOLVI mixture.
  5. The DOJOLVI mixture may be stored for up to 24 hours in the refrigerator.

### **Preparing and giving a dose of DOJOLVI through a feeding tube:**

1. Gather the required supplies and information, including:
  - the amount of prepared tube feeding formula needed, as directed by your healthcare professional.
  - DOJOLVI bottle
  - an oral syringe
  - a clean bowl, cup or container made of one of the materials listed above.
  - a slip tip syringe
2. Measure out:
  - the required amount of DOJOLVI using the oral syringe or measuring cup; and
  - the required amount of prepared tube feeding formula and place in the bowl, cup or container.
3. Add DOJOLVI to the required amount of prepared tube feeding formula. Mix well.
4. Using a slip tip syringe, draw up all of the DOJOLVI-formula mixture.
5. Remove all air from the syringe.
6. Connect the syringe into the feeding tube port.
7. Push the mixture into the feeding tube port until the syringe is empty.
8. Flush out the feeding tube port using about 5 mL to 30 mL of water in the slip tip syringe. You may need more or less water to do this. Your healthcare professional will tell you how much water to use.
9. Throw away any leftover DOJOLVI-formula mixture. **Do not** save this for later.

**Usual dose:** The usual dose of DOJOLVI is different for everyone and will depend on how many calories you usually get from your food.

Your healthcare professional will tell you how much DOJOLVI to take. They may start you on a lower dose of DOJOLVI and increase the dose slowly over a few days or weeks. Babies may need a higher dose of DOJOLVI, since they may need more fats in their diet.

If you experience certain side effects, your healthcare professional may lower the dose of DOJOLVI.

### **Overdose:**

If you think you have taken too much DOJOLVI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose (one of the portions taken throughout the day), take the next dose as soon as possible. If it is not possible to take all the doses for the day, skip the missed dose.

**What are possible side effects from using DOJOLVI?**

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

- Abdominal pain
- Vomiting
- Diarrhea
- Nausea

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN FREQUENCY</b>			
<b>Feeding tube problems:</b> mechanical issues, softening, breaking, failure, or other malfunction of the feeding tube. Feeding tubes may not work as well or stop working over time when taking DOJOLVI.		x	
<b>Intestinal absorption problems in patients with pancreatic insufficiency:</b> diarrhea, stools that appear greasy or oily, abdominal bloating, gas, weight loss.		x	

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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 the DOJOLVI bottle upright between 15 - 30°C. **Do not** freeze.
- Once the bottle of DOJOLVI has been opened, use it within 9 months or by the expiration date on the bottle, whichever is earlier. There is a place on the DOJOLVI labels to write the date the bottle is opened.
- **Do not** use or store DOJOLVI in containers made of polystyrene or PVC.

Keep out of reach and sight of children.

## If you want more information about DOJOLVI:

- 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.html>); the manufacturer's website (<https://www.ultragenyx.com>) or by calling 1-833-388-5872.

This leaflet was prepared by Ultragenyx Pharmaceutical Inc.

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