Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Rufinamide-Trima 40 mg/ml Oral suspension

Active ingredient
rufinamide 40 mg/ml

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Rufinamide-Trima 40 mg/ml is used as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in adults, adolescents and children 1 year of age and older.

Therapeutic group: Antiepileptic medicines, carboxamide derivatives.
Lennox-Gastaut syndrome is the name given to a group of severe epilepsies in which you may experience repeated seizures of various types. Rufinamide-Trima 40 mg/ml has been given to you by your doctor to reduce the number of your seizures or fits.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient (rufinamide) or triazole derivatives or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine
Before and during treatment with Rufinamide-Trima 40 mg/ml, tell your doctor if:
- You have Congenital Short QT Syndrome or a family history of such a syndrome (electrical disturbance of the heart), as taking rufinamide could make it worse.
- You suffer from liver problems. There is limited information on the use of rufinamide in this group, so the dose of your medicine may need to be increased more slowly. If your liver disease is severe, the doctor may decide that Rufinamide-Trima 40 mg/ml is not recommended for you.
- You experience a skin rash or fever. These could be signs of an allergic reaction. See the doctor immediately, as very occasionally this may become serious.
- You suffer an increase in the number, severity or duration of your seizures, you should contact the doctor immediately if this happens.
- You experience difficulty walking, abnormal movement, dizziness or sleepiness, inform the doctor, if any of these happen.
- If you take this medicine and have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away** (see section 4).

Consult your doctor, even if these events occurred at any time in the past.

Children and adolescents
There is no information on the efficacy and safety of Rufinamide-Trima 40 mg/ml in children younger than 1 year of age. Do not use Rufinamide-Trima 40 mg/ml in children younger than 1 year of age.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
phenobarbital, fosphenytoin, phenytoin or primidone, you may need to be carefully monitored for two weeks at the start of, or after the end of treatment with rufinamide, or after any marked change in the dose. A change in the dose of the other medicines may be needed as they may become slightly less effective when given with rufinamide.

Antiepileptic medicines and Rufinamide-Trima 40 mg/ml
If the doctor prescribes or recommends an additional treatment for epilepsy (e.g., valproate) you must tell the doctor that you are taking Rufinamide-Trima 40 mg/ml, as the dose may need adjusting.
In adults and children, taking valproate at the same time as rufinamide will result in high levels of rufinamide in the blood. Tell your doctor if you are taking valproate, as the dose of Rufinamide-Trima 40 mg/ml may need to be reduced by your doctor.

Tell the doctor if you are taking hormonal/oral contraceptives, e.g., contraceptive pills. Rufinamide-Trima 40 mg/ml may make the pill not effective in preventing pregnancy. Therefore, it is recommended that you use an additional safe and effective contraceptive method (such as a barrier method, e.g., condoms) when taking Rufinamide-Trima 40 mg/ml.

Tell the doctor if you are taking the blood thinner warfarin. The doctor may need to adjust the dose.

Tell the doctor if you are taking digoxin (a medicine used to treat heart conditions). The doctor may need to adjust the dose.

Using this medicine and food
Rufinamide-Trima 40 mg/ml should be taken with food.

Pregnancy and breastfeeding
Rufinamide-Trima 40 mg/ml should not be taken during pregnancy or by women of childbearing age not using contraceptive measures, unless the doctor orders treatment with this medicine when it is determined to be necessary. You are advised not to breastfeed while taking Rufinamide-Trima 40 mg/ml, as it is not known if rufinamide is excreted in breast milk.

If you are a woman of childbearing age, you must use contraceptive measures while taking Rufinamide-Trima 40 mg/ml.

Consult your doctor or pharmacist before taking any medicine at the same time as Rufinamide-Trima 40 mg/ml.
If you are taking hormonal/oral contraceptives, e.g., contraceptive pills – see section 2 under 'Interactions with other medicines'.

Driving and using machines
Rufinamide-Trima 40 mg/ml may have a small up to a large effect on the ability to drive and operate machines.
Rufinamide-Trima 40 mg/ml may make you feel dizzy, drowsy and affect your vision, particularly at the beginning of treatment or after a dose increase. If this happens to you, do not drive or operate machines.
Children should be warned about riding bicycles or playing near the highway, etc.

Important information about some of this medicine's ingredients

Rufinamide-Trima 40 mg/ml contains sorbitol
Rufinamide-Trima 40 mg/ml contains 250 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Taking Rufinamide-Trima 40 mg/ml with other antiepileptic medicine which contains sorbitol may affect how much they work. Tell your doctor or pharmacist if you are taking any other antiepileptic medicine(s) with sorbitol.

Rufinamide-Trima 40 mg/ml contains methyl parahydroxybenzoate and propyl parahydroxybenzoate
These ingredients may cause allergic reactions (possibly delayed).

Rufinamide-Trima 40 mg/ml contains 200 mg propylene glycol in each 1 ml of suspension
Children aged 1-5 years: Consult the doctor before administering this medicine, especially if they are taking additional medicines containing propylene glycol or alcohol.
If you or your child suffer from a liver or kidney disease, do not use this medicine, unless recommended by the doctor. The doctor may perform additional tests during treatment with this medicine.
If you are pregnant or breastfeeding, do not use this medicine, unless recommended by the doctor. The doctor may perform additional tests during treatment with this medicine.
Adults, adolescents and children weighing 30 kg or over: propylene glycol in this medicine may have effects similar to those of drinking alcohol and increase the probability of side effects.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

It may take a while to find the best dose of Rufinamide-Trima 40 mg/ml for you. The dose will be calculated for you by the doctor and will depend on your age, weight and whether you are taking Rufinamide-Trima 40 mg/ml with another medicine called valproate.

Children aged between 1 and 4 years
The recommended starting dose is 10 mg (0.25 ml) for each kilogram of body weight, each day, taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 10 mg (0.25 ml) for each kilogram of body weight every third day.

The maximum daily dose will depend on whether or not you are also taking valproate. The maximum daily dose without valproate intake is 45 mg (1.125 ml) for each kilogram of body weight, each day. The maximum daily dose with valproate intake is 30 mg (0.75 ml) for each kilogram of body weight, each day.

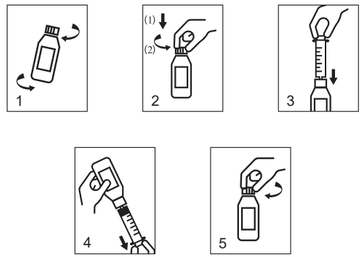
Children 4 years of age or older weighing less than 30 kg
The recommended starting dose is 200 mg (5 ml) a day, taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 200 mg (5 ml) every third day.

The maximum daily dose will depend on whether or not you are also taking valproate. The maximum daily dose without valproate intake is 1,000 mg (25 ml) each day. The maximum daily dose with valproate intake is 600 mg (15 ml) each day.

Adults, adolescents and children weighing 30 kg or over
The recommended starting dose is 400 mg (10 ml) a day, taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 400 mg (10 ml) every other day.

The maximum daily dose will depend on whether or not you are also taking valproate. The maximum daily dose without valproate intake is no more than 3,200 mg (80 ml), depending on body weight. The maximum daily dose with valproate intake is no more than 2,200 mg (55 ml), depending on body weight.
Some patients may respond to lower doses and your doctor may adjust the dose depending on how you respond to the treatment.
If you experience side effects, your doctor may increase the dose more slowly.
Rufinamide-Trima 40 mg/ml oral suspension must be taken twice every day, once in the morning and once in the evening.
Rufinamide-Trima 40 mg/ml should be taken with food.
Do not exceed the recommended dose.

Method of administration
Make sure to measure the dose using the syringe provided.
Instructions on how to use the syringe are provided below:



1. Shake well for 15 seconds before use.
2. Push down (1) and turn the cap (2) to open the bottle.
3. Insert the syringe into the opening of the adaptor in the bottle neck as far as possible.
4. To fill the syringe, turn the bottle upside down. With the syringe held in place, gently pull the plunger down to withdraw the medicine to the appropriate mark on the syringe, according to the dose prescribed by the doctor. Turn the bottle upright and gently remove the syringe from the bottle opening.
5. Replace the cap on the bottle.

- After dose administration, separate the syringe components and wash them thoroughly with cold tap water and soap.
- Shake off excess water and leave the syringe components to air dry. Do not wipe dry the dispensers.
- Do not place the syringe components in a home steriliser or dishwasher. Do not heat the syringe in a microwave (with or without the medicine).
- Do not clean and reuse the syringe after 40 uses, or if the markings on the syringe wash off.
- Keep the syringe out of the reach of children. Do not bite the syringe.
- Do not leave the medicine in the measuring syringe over a long time. The syringe is intended to come in contact with the medicine only while the medicine is measured and administered.

Do not reduce the dose or stop taking this medicine unless the doctor tells you to.

If you have accidentally taken a higher dose of Rufinamide-Trima 40 mg/ml
If you may have taken more Rufinamide-Trima 40 mg/ml than you should, tell the doctor or pharmacist immediately, or go to the nearest hospital emergency room and bring the medicine package with you.

If you forget to take Rufinamide-Trima 40 mg/ml
If you forget to take a dose, continue taking the medicine as normal. Do not take a double dose to make up for forgotten dose. If you miss taking more than one dose, seek advice from the doctor.

If you stop taking Rufinamide-Trima 40 mg/ml
If the doctor advises stopping treatment, follow their instructions concerning the gradual reduction of Rufinamide-Trima 40 mg/ml dose in order to lower the risk of an increase in seizures.
Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Rufinamide-Trima 40 mg/ml may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor immediately if you experience any of the following side effects, which can be very serious:
- Rash and/or fever. These could be signs of an allergic reaction. If they happen to you, tell your doctor or go to a hospital immediately.
- Change in the types of seizures you experience/more frequent seizures which last a long time (called status epilepticus). Tell your doctor immediately.
- A small number of people being treated with antiepileptics such as Rufinamide-Trima 40 mg/ml have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor immediately (see section 2).

Additional side effects
You may experience the following side effects during treatment with this medicine. Tell the doctor if you have any of the following:

Very common side effects (affect more than one in 10 users):
Dizziness, headache, nausea, vomiting, sleepiness, fatigue.

Common side effects (affect more than one in 100 users):
Problems associated with nerves including difficulty walking, abnormal movement, convulsions/seizures, unusual eye movements, blurred vision, trembling.

Problems associated with the gastrointestinal system including stomach pain, constipation, indigestion, loose stools (diarrhoea), loss or change in appetite, weight loss.

Infections: ear infection, flu, nasal congestion, chest infection.

In addition, patients have experienced anxiety, insomnia, nosebleeds, acne, rash, back pain, infrequent periods, bruising, head injury (as a result of accidental injury during a seizure).

Uncommon side effects (affect more than one in 1,000 users):
Allergic reactions and an increase in markers of liver function (hepatic enzyme increase).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il
In addition, you can report side effects to the following email: safety@trima.co.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
Do not use the medicine after the expiry date (exp. Date) which is stated on the package. The expiry date refers to the last day of that month.
Storage conditions:
No special storage conditions. Storage at room temperature is recommended.
After first opening, the medicine may be used for 3 months, but no later than the expiry date.
Do not use the medicine if you notice any change in the appearance or odour of the suspension. In case of change, return the medicine to the pharmacy.
Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to dispose of this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Sorbitol liquid (non-crystallising), propylene glycol, hydroxyethylcellulose, simethicone emulsion 30%, poloxamer 188, xanthan gum, methyl parahydroxybenzoate, propyl parahydroxybenzoate, blood orange (natural flavouring preparations, natural flavouring substances, estragol) citric acid anhydrous and purified water.

What the medicine looks like and contents of the pack:
A plastic bottle containing 460 ml of white – off-white suspension and a 25 ml measuring syringe graduated in 0.5 ml increments. Child-resistant packaging.

Manufacturer and Registration holder's name and address:
Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Approved in November 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry: 178-38-37248-99

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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