

Product Name	Enolio 10 micrograms/ml Oral Solution
MA Number	PL 60170/0001
Component	Patient Leaflet (oral solution)
Artwork Number	PL-LIO-OS-10-REV 05-BN

Package leaflet: Information for the user

ENOLIO® 10 micrograms/ml Oral Solution

Liothyronine sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of your medicine is Enolio 10 micrograms/ml Oral Solution but it will be referred to as Enolio throughout this leaflet.

What is in this leaflet

1. What Enolio is and what it is used for
2. What you need to know before you take Enolio
3. How to take Enolio
4. Possible side effects
5. How to store Enolio
6. Contents of the pack and other information

1. What Enolio is and what it is used for

The active substance of Enolio is liothyronine sodium which is called liothyronine in this leaflet.

Liothyronine is a form of thyroxine which is quick acting and long lasting. Thyroxine is a hormone produced by the thyroid gland in the neck which controls many body functions.

Liothyronine is used to:

- treat some of the more severe conditions in which the thyroid does not produce enough thyroxine.
- balance the effect of medicines used to treat an overactive thyroid.

2. What you need to know before you take Enolio

Do not take Enolio if you:

- are allergic to liothyronine or any of the other ingredients of this medicine (listed in section 6)
- have angina (chest pain when exercising) or conditions affecting your heart or circulation
- are suffering from thyrotoxicosis (condition due to over activity of the thyroid gland).

Talk to your doctor before you take this medicine if any of the above apply to you.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Enolio if you:

- are suffering from diabetes. Enolio may raise blood sugar levels
- are suffering from a condition called myxoedema (which can happen when you have a problem with your thyroid gland) which makes your skin look swollen and dry
- are elderly (65 years or over)
- have suffered from low levels of thyroid hormone in your body for a long time, as this may affect how your adrenal glands work. You may be given additional medication (corticosteroids) if this is the case
- are suffering from any heart problems
- have increased blood pressure
- suffer from increased heart rate, sleeplessness, loose watery stools (suggesting increased metabolism) on starting treatment. In this case a dose reduction may be needed
- are starting treatment, as an ECG test (a recording of the electrical activity of your heart) will be valuable
- are pregnant or breast feeding.

If you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel if you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect the results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory personnel, if you are taking such products (see section 'Other medicines and Enolio').

Other medicines and Enolio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Enolio may affect or be affected by the following medicines:

- Anticoagulants (e.g. warfarin) used to thin the blood and prevent blood clots
- Anticonvulsants (e.g. carbamazepine or phenytoin) used to prevent fits
- Insulin and other treatments for diabetes
- Medicines called cardiac glycosides (e.g. digoxin) used to treat heart conditions such as heart failure
- Tricyclic antidepressants (e.g. amitriptyline / imipramine) used to treat depression
- Colestyramine / colestipol which reduce the level of cholesterol (fats) in the blood
- Oral contraceptives ('the pill')
- Amiodarone, used to treat irregular heart beats
- Barbiturates, used to induce sleep and decrease anxiety
- Primidone, used for seizures or fits

If you are taking or have recently taken biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect the results of your laboratory tests (see section 'Warnings and Precautions').

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The decision on whether it is best to take Enolio during pregnancy or breast feeding will be made during discussions between you and your doctor.

Driving and using machines

Enolio should not interfere with your ability to drive or use machinery.

Enolio contains sodium methyl parahydroxybenzoate (E 219) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Enolio

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is as follows:

Adults:

The dose will depend upon your condition, ranging from 1 ml (10 micrograms) to 6 ml (60 micrograms) daily in divided doses.

Children and elderly:

The dose may be started at 0.5 ml (5 micrograms) a day. Your doctor will monitor your thyroid function regularly to make sure that you are given the right dose for your condition.

Method of Administration

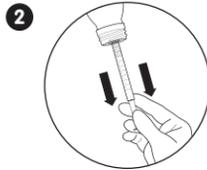
For oral administration. You should take the product with water.

A 5 ml graduated oral syringe with intermediate graduations of 0.25 ml is provided with your medicine.

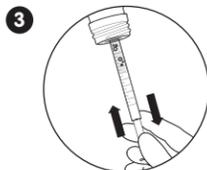
1. Open the bottle and insert the syringe into the adaptor.



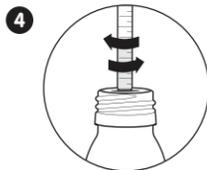
2. Turn the bottle upside down and while holding the syringe in place, gently pull the plunger down to draw out the medicine to the correct mark for your dose.



3. If any bubbles appear in the syringe, keep the bottle upside down, slowly push the plunger part way back into the bottle and then pull it out again. Repeat until there are no bubbles in the syringe.



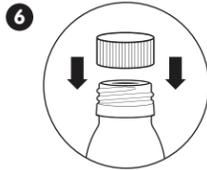
4. Turn the bottle upright and carefully remove the filled syringe from the adaptor using gentle twisting.



5. Insert the syringe tip into your mouth and press the plunger slowly to release the medicine. Repeat steps 2 to 5 as needed to achieve the required dose.



6. Replace the bottle cap after use, leaving the adaptor in place.



Wash the syringe with water after each use and allow it to dry completely before you next use it.

For infants and smaller children, drug administration can be performed by an adult using the above instructions. Be sure to press the plunger slowly to ensure that the child can swallow the solution easily and does not choke. You should give your child a drink of water to help wash the medicine down.

This medicine can be administered via a medium or large gastric, duodenal or nasal feeding tube if required. The tube should be rinsed twice with at least 10ml of water following administration.

If you take more Enolio than you should

This may cause agitation, confusion, headache, sweating and a rapid pulse. If you take more of this medicine than you should contact your doctor or nearest hospital casualty department as soon as possible. Take the bottle and this leaflet with you so the medical staff will know what you have taken.

If you forget to take Enolio

Take the next dose at the correct time and then go on as before. It is important, in order for your medicine to work, that doses are not forgotten. Do not take a double dose to make up for a forgotten dose.

If you stop taking Enolio

Do not stop taking Enolio unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek urgent medical advice if you experience the following side effects:

- An allergic reaction such as rash, itching or oedema (swelling / abnormal accumulation of body fluid)
- Angina pain (pain in the chest when exercising), irregular, thumping or fast heart beats. Seek urgent advice from your doctor if you experience these heart-related symptoms. This may be a sign that your dose of liothyronine needs to be reduced. You must not stop or reduce the amount of Enolio you are taking without consulting with your doctor first.

Other side effects you could experience (frequency cannot be estimated from the available data) are:

- Vomiting (being sick)
- Insomnia (sleeplessness)
- Fever
- Intolerance to heat
- Tremor (involuntary, rhythmic muscle movements)
- Muscle cramps or weakness
- Diarrhoea
- Restlessness or excitability
- Headache
- Flushing
- Sweating
- Loss of weight

Additional side effects in children

- Temporary loss of hair (frequency not known)

These effects normally mean the dose of Enolio needs changing. You should talk with your doctor if they occur. The effects usually go away when the dose has been changed.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enolio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not use your medicine if you notice that the bottle is damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Recycle the empty packaging where possible.

6. Contents of the pack and other information

What Enolio contains

- The active substance is liothyronine sodium. Each 1 ml of Enolio contains 10 micrograms of liothyronine sodium.
- The other ingredients are glycerol, citric acid monohydrate, sodium citrate, sodium methyl parahydroxybenzoate (E 219), sodium hydroxide and purified water.

What Enolio looks like and contents of the pack

Enolio is a clear, colourless solution supplied in amber glass bottles with a polypropylene child-resistant, tamper evident cap fitted with a polypropylene syringe adaptor. Each bottle contains 50 ml or 100 ml of Enolio. Not all pack sizes may be marketed. The carton also contains a 5 ml polypropylene oral syringe with graduations of 0.25 ml.

Marketing Authorisation Holder

Eclsix Ltd
329 Upper Fourth Street
Milton Keynes
MK9 1EH
United Kingdom

Manufacturer

Labomed Pharmaceutical
Company SA
84 Ioannou Metaxa str.
Koropi, Attica, 19441
Greece

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