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Package Leaflet: Information for the User

Levothyroxine Brillpharma 25 microgram/5 ml Oral Solution
Levothyroxine Brillpharma 50 microgram/5 ml Oral Solution
Levothyroxine Brillpharma 75 microgram/5 ml Oral Solution
Levothyroxine Brillpharma 100 microgram/5 ml Oral Solution
Levothyroxine 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Levothyroxine Brillpharma is and what it is used for

Levothyroxine Brillpharma contains the active ingredient levothyroxine sodium. It is used to treat hypothyroidism, a condition in which the thyroid gland is underactive and so does not make enough thyroxine for the body's needs. Levothyroxine Brillpharma is also used to treat thyroid cancer and diffuse non-toxic goitre or Hashimoto's thyroiditis, conditions in which the thyroid gland becomes enlarged causing a swelling in the front of the neck.

2. What you need to know before you take Levothyroxine Brillpharma

Do not take Levothyroxine Brillpharma:
- If you are allergic to levothyroxine or any of the ingredients of this medicine (listed in section 6)
- If you suffer from adrenal insufficiency and you do not have adequate corticosteroid cover
- If you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pancarditis)
- If you are pregnant do not take this medicine in combination with medicines to treat hyperthyroidism (see the section on Pregnancy and breast-feeding)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Levothyroxine Brillpharma

- If you have heart disease, problems with your circulation or high blood pressure
- If you are suffering from an overactive thyroid gland (hyperthyroidism), an underactive adrenal gland, diabetes or have had an underactive thyroid gland for some time.
- If you are of child bearing potential
- If you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect 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 (Please note the information in section Other medicines and Levothyroxine Brillpharma).
- If you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine.

Blood pressure will be regularly monitored when Levothyroxine Brillpharma treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (known as circulatory collapse) may occur.

Other medicines and Levothyroxine Brillpharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Levothyroxine can interfere with the action of some other drugs and some drugs can have an effect on Levothyroxine. In particular tell your doctor or pharmacist if you take the following drugs:

- Medication to stop your blood clotting (for example Warfarin)
- Medication for depression (for example Sertraline, Imipramine, Amitriptyline)
- Medication for epilepsy (for example Phenytoin, Phenobarbital, Carbamazepine).
- Medication for diabetes
- Rifampicin (for infections, particularly tuberculosis)
- Digoxin or Amiodarone (for your heart)
- Propranolol (for high blood pressure), Lovastatin (for high cholesterol levels) or Phenylbutazone or Aspirin (anti-inflammatory drugs)
- Oestrogen, oestrogen containing products and oral contraceptives, androgens or corticosteroids
- Sucralfate, Cimetidine or aluminium hydroxide for a stomach ulcer, Colestyramine to lower your cholesterol levels or calcium carbonate or iron supplements
- Chloroquine or proguanil for the prevention of malaria
- Protease inhibitors (for example ritonavir, indinavir and lopinavir) used to treat HIV
- Sevelamer (used to treat high levels of phosphate in the blood in patients with renal failure)
- Tyrosine kinase inhibitors (for example imatinib and sunitinib) used to treat cancer
- Propylthiouracil (used to treat hyperthyroidism)
- Beta-sympatholytics (drugs used to treat hypertension or anxiety)
- Beta-Sympathomimetics (used to treat cardiac arrest and low blood pressure)
- Glucocorticoids (steroid hormones used to treat adrenal insufficiency and other diseases)
- Soy-containing products (these can decrease absorption of levothyroxine)
- Orlistat (used to treat obesity)
- Ritonavir (used to control HIV and chronic hepatitis C virus)
- 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 results of your laboratory tests (see warnings and precautions).
- Products containing St. John's Wort (an herbal medicinal product).
- Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lanzoprazole) are used to reduce the amount of acid produced by the stomach, which may reduce the absorption of levothyroxine from the intestine and thereby make it less effective. If you are taking levothyroxine while receiving treatment with proton pump inhibitors, your doctor should monitor your thyroid function and may have to adjust the dose of your thyroid medicine.

Let your doctor or pharmacist know Levothyroxine Brillpharma can be taken with these medicines but not at the same time. If you go into hospital to have an operation, tell the anaesthetist or the medical staff that you are taking Levothyroxine Brillpharma. It may react with an anaesthetic (Ketamine) which you may be given before an operation. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
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. If you are pregnant while taking this medicine your doctor will monitor you closely.

Driving and using machines
Your medicine is unlikely to affect your ability to drive or to operate machinery.

Levothyroxine Brillpharma contains sodium methyl parahydroxy benzoate (E219) and sodium
Levothyroxine Brillpharma contains sodium methyl parahydroxy benzoate (E219) which may cause allergic reactions (possibly delayed).

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per maximum dose of 300 microgram, that is to say essentially 'sodium-free'.

3. How to take Levothyroxine Brillpharma

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Levothyroxine Brillpharma should be swallowed. Your doctor will have decided what dose you should take each day depending on your condition. Your doctor will take blood samples at regular intervals to monitor your response to treatment. If you are switching from the oral solution to the tablet version of levothyroxine or from the tablet version to the oral solution of levothyroxine your doctor will monitor you more closely.

Administration
You should take your Levothyroxine Brillpharma on an empty stomach, usually before breakfast.

The recommended dose is

For hypothyroidism:
Adults and children over 12 years:
The recommended starting dose is 50 to 100 microgram a day, increasing by 25 to 50 microgram every 3-4 weeks, until you are taking the right amount for your condition. The usual maintenance dose is 100 to 200 microgram daily. For diffuse non-toxic goitre or Hashimoto's thyroiditis the recommended dose is 50-200 microgram per day. For the treatment of thyroid cancer the recommended dose is 150-300 microgram per day

Older patients (over 50 years of age):
The recommended starting dose is 12.5 microgram a day, increasing by 12.5 microgram every 2 weeks until the correct dose is obtained. The usual final dose is between 50 and 200 microgram daily. This dose also applies to patients with severe hypothyroidism and to those with heart disease.

Children under 12 years:
The dose for children depends on their age or weight. They will be monitored to make sure they get the right dose. The following is a guide:

Age	Microgram per kg bodyweight
Up to 1 month	5-10 microgram
Over 1 month	5 microgram

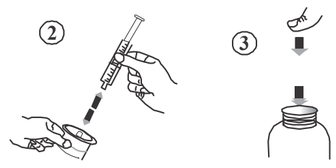
The duration of treatment is usually for life if you are being treated for hypothyroidism, non toxic diffuse goitre or Hashimoto's thyroiditis. Please use the oral syringe provided to deliver your specific dose (see instructions below). The syringe can be used to measure your dose by drawing the liquid to the correct mark on the syringe. For example if your dose is 50 microgram daily then the corresponding volume would be:

For the 25 microgram/5ml strength – 2 x 5ml (10ml in total)
For the 50 microgram/5ml strength – 5ml
For the 100 microgram/5ml strength – 2.5 ml

Method of Administration
You should use the enclosed 5 ml oral syringe (graduated at every 0.1 ml) together with the enclosed adaptor to attach the syringe to the bottle. This helps you to take a dose from the bottle.

Instructions for use
Open the bottle: press the cap and turn it anticlockwise (figure 1)

- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



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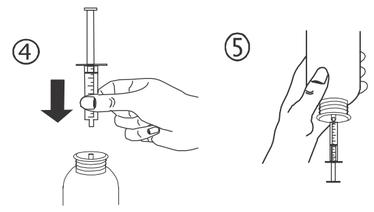
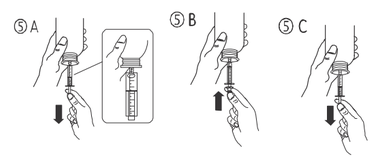
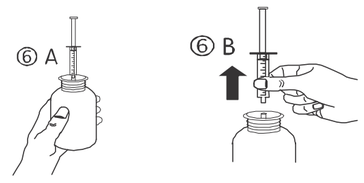
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



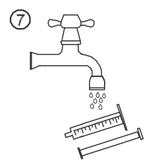
- Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth. Please ensure that you are sitting upright and the plunger must be pushed slowly to allow you to swallow the dose.
- After dosing, wash the syringe with water (figure 7).



If you take more Levothyroxine Brillpharma than you should
If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Symptoms of overdose include fever, irregular heart beat, muscle cramps, headache, restlessness, flushing, sweating, diarrhoea shaking (tremor), difficulty sleeping (insomnia) and very high temperature (hyperpyrexia). Always take any remaining medicine, the container and the label with you, so that the medicine can be identified.

If you forget to take Levothyroxine Brillpharma
If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. If you have forgotten several doses tell your doctor when you have your next checkup or blood test. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Levothyroxine Brillpharma
It can be dangerous to stop taking your medicine without your doctor's advice.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These usually only happens if the dose you are taking is too high.

If any of the following happen, stop taking Levothyroxine Brillpharma and tell your doctor immediately or go to the casualty department at your nearest hospital

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- Hives
- Fainting

Some patients may experience a severe reaction to high levels of thyroid hormone. This is called a "thyroid crisis" and you should contact your doctor immediately if you have any of the following symptoms:
- very high temperature; fast heart rate; irregular heartbeat; low blood pressure; heart failure; yellowing of the skin and eyes also called jaundice; confusion; fits, coma.

These are all very serious side effects. If you have them, you may have a serious allergic reaction to Levothyroxine Brillpharma. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare.

Tell your doctor if you notice any of the following side effects:
Not known (frequency cannot be estimated from the available data)
- fast or irregular heartbeats
- palpitations
- chest pain
- pain in joint
- muscle cramps or weakness
- headache
- restlessness
- excitability
- flushing
- sweating
- diarrhoea
- vomiting
- fever
- feeling unwell
- menstruation problems
- tremor
- sleeplessness
- excessive weight loss
- rash
- itching
- puffiness
- hair loss

Additional side effects in children and adolescents
- heat intolerance
- high blood pressure in the cranium
- hair loss at beginning of the treatment (temporary)
- deformity of the skull in infants caused by the early closure of joins in the skull bone (craniostenosis)
- growth in children may slow or stop due to changes in bone growth.

If you feel unwell in any other way, tell your doctor as soon as you can. Do not be alarmed by this list of possible events. You may not have any of them

Reporting of side effects:
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 by searching for MHRA yellowcard 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 Levothyroxine Brillpharma

- 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 label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package to protect from light.
- Discard after 60 days of first opening. Store in the original packaging after first opening.
- Levothyroxine Brillpharma is colourless and odourless.
- Do not use this medicine if you notice that the solution has an odour or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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.

6. Contents of the pack and other information

What Levothyroxine Brillpharma Oral Solution contains
The active substance is levothyroxine sodium. Each 5 ml of oral solution contains levothyroxine sodium equivalent to 25 microgram, 50 microgram, 75 microgram or 100 microgram. The other ingredients are glycerol (E422), citric acid monohydrate (E330) (for pH adjustment), Sodium Hydroxide (for pH ajustment), sodium methyl parahydroxy benzoate (E219) and purified water.

What Levothyroxine Brillpharma looks like and contents of the pack
Levothyroxine Brillpharma is a clear, colourless liquid.

This medicine is supplied in 100 ml amber coloured glass bottle with a child resistant closure and a 5 ml oral syringe (graduated at every 0.1 ml) with adaptor and packed in a carton.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Name and address:
Brillpharma Limited,
6 Sovereign Park, Luton, LU4 8EL,
United Kingdom
Tel no: 0044 (0)1582 545500
Email: info@brillpharma.co.uk

Manufacturer:
LM Manufacturing Limited
Sandretto Building,
Cavalry Hill Industrial Park, Weedon,
Northampton, NN7 4PP, United Kingdom

Levothyroxine Brillpharma 25 microgram/5 ml Oral Solution; PL 40496/0016
Levothyroxine Brillpharma 50 microgram/5 ml Oral Solution; PL 40496/0017
Levothyroxine Brillpharma 75 microgram/5 ml Oral Solution; PL 40496/0018
Levothyroxine Brillpharma 100 microgram/5 ml Oral Solution; PL 40496/0019

This leaflet was last revised in March 2025

To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or email) above.

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