

PACKAGE LEAFLET: INFORMATION FOR THE USER

TYRAQ

100micrograms tablets

LEVOTHYROXINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What TYRAQ is and what it is used for
2. Before you take TYRAQ
3. How to take TYRAQ
4. Possible side effects
5. How to store TYRAQ

1. WHAT TYRAQ IS AND WHAT IS IT USED FOR

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland. Levothyroxine is a synthetic version of this hormone. Thyroxine controls how much energy your body uses. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body's functions slow down. Some of the most common symptoms of hypothyroidism are:

- tiredness
- weight gain
- feeling depressed

Levothyroxine tablets are used to replace the thyroxine that your thyroid gland cannot produce and prevent the symptoms of hypothyroidism. Before starting your treatment your doctor will carry out a blood test to work out how much levothyroxine you need.

2. BEFORE YOU TAKE TYRAQ

Do not take this medicine if you:

- are **allergic** to levothyroxine or to any of the other ingredients
- suffer from an overactive thyroid gland that produces too much thyroid hormone (**thyrotoxicosis**)

- have any condition that affects your **adrenal glands** (your doctor will be able to advise you if you are not sure)
- If any of these apply to you, do not take this medicine and go back to your doctor to discuss your treatment.

Check with your doctor or pharmacist before taking Levothyroxine tablets if you:

- have suffered with an **under active thyroid** gland for a long time
- suffer from **heart** problems including angina, coronary artery disease or high blood pressure.
- are being treated for **diabetes**. The dose of your anti-diabetic medicine may need to be changed as levothyroxine can raise blood sugar levels.
- are **over 50 years** of age.
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Blood tests

Before you start taking levothyroxine your doctor will do a blood test to see how much thyroxine your thyroid gland is making and what dose of the medicine you will need. Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

Taking other medicines

Many medicines affect the way levothyroxine works. The effects of other drugs may also be affected by levothyroxine.

You must **tell your doctor** if you are taking or start taking any other medicines, including over the counter medicines, herbal remedies and vitamin supplements.

The following may affect the way that levothyroxine works:

- medicines for epilepsy such as **carbamazepine, phenytoin, primidone** and **barbiturates**
- **sertraline** - used to treat depression and anxiety disorders
- **antacids** – used to treat indigestion
- medicines containing **calcium salts**
- **cimetidine** – used to reduce excess stomach acid
- **proton pump inhibitors such as omeprazole, lansoprazole and pantoprazole** – used to reduce the amount of acid produced by the stomach
- **sucralfate** – used to treat and prevent stomach and duodenal ulcers
- **colestyramine** and **colestipol** – used to treat high level of fat in the blood
- **polystyrene sulphone resin** – used to reduce high levels of potassium in the blood
- medicines containing **iron** that are taken by mouth
- **rifampicin** – used to treat infections
- **imatinib** – used to treat certain types of cancer
- **beta blockers** such as **atenolol** and **sotalol** – used to treat high blood pressure and heart problems
- **oestrogen containing medicines** for hormone replacement therapy (HRT) and contraception (the 'pill')
- **androgen containing medicines** for male hormone replacement therapy
- **corticosteroids** such as **hydrocortisone** and **prednisolone** – used to treat inflammation
- **amiodarone** – used to treat an irregular heart beat

The following may be affected by levothyroxine:

- **anticoagulant medicines** to prevent blood clots such as **warfarin**
- medicines to treat diabetes such as **insulin** and **metformin**
- **tricyclic antidepressants** such as **amitriptyline, imipramine** and **dosulepin**
- medicines that stimulate the sympathetic nervous system such as **adrenaline** (epinephrine - used to treat severe allergic reactions) or **phenylephrine** (a decongestant found in many cold and flu treatments)
- **digoxin** – used to treat heart problems
- anti-inflammatory medicines such as **phenylbutazone** or **aspirin**

- **propranolol** – used to treat high blood pressure and heart problems
- **ketamine** – used as an anaesthetic. If you need to have an operation, please tell your doctor or anaesthetist that you are taking levothyroxine.

Pregnancy and breast-feeding

If you are pregnant particularly in the first three months of your pregnancy, planning to become pregnant or are breast-feeding, tell your doctor or pharmacist before taking this medicine. Your doctor will decide if you should continue treatment with levothyroxine whilst you are pregnant.

Important information about some of the ingredients

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3. HOW TO TAKE TYRAQ

You may be taking this medicine for the rest of your life. Always take Levothyroxine tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Your dose will be decided by your doctor and will depend on the results of your blood tests. The dose you should take will be on the label attached by your pharmacist. Swallow the tablets with plenty of water. You should usually take your tablets before breakfast or your first meal of the day.

Adults:

The usual starting dose is 50-100 micrograms every day. Your doctor may increase the dose you take every 3-4 weeks by 50 micrograms until your thyroxine levels are correct. Your final daily dose may be up to 100-200 micrograms daily.

Patients over 50 years of age:

The usual starting dose will be no more than 50 micrograms every day. The dose may then be increased by 50 micrograms every 3-4 weeks until your thyroxine levels are correct. Your final daily dose will be between 50-200 micrograms daily.

Patients over 50 years with heart problems:

The starting dose will be 25 micrograms every day or 50 micrograms every other day. The dose may be increased by 25 micrograms every 4 weeks until your thyroxine levels are correct. Your final daily dose will usually be between 50-200 micrograms daily.

Giving these tablets to children:

The dose for children depends on their age, weight and the condition being treated. Your child will be monitored to make sure he/she gets the right dose. You should give them their medicine at least half an hour before breakfast or their first meal of the day. If necessary, the tablets can be dissolved in 10-15ml of water and given with some more liquid (5-10ml). The dissolved tablets should be taken straight away. **Do not** keep the solution to give to your child later.

Congenital hypothyroidism in infants:

This is a condition where your baby has been born with a thyroid gland that does not produce enough thyroxine. The starting dose is 10 -15 micrograms/kg bodyweight per day for the first three months. The dose will then be adjusted depending on how your baby responds to the treatment.

Acquired hypothyroidism in children:

This is a condition where your child's thyroid gland stops working properly because it has been attacked by their immune system, e.g. in children with an autoimmune disease or following a viral infection. The starting dose is 12.5 to 50 micrograms a day. The dose should be increased gradually every 2 to 4 weeks depending on how your child responds to the medicine.

Juvenile myxoedema:

This is a condition where children and adolescents develop severe hypothyroidism (produce very low levels of thyroid hormones). The starting dose is 25 micrograms every day. The dose will then be increased by 25 micrograms every 2-4 weeks until your child shows mild symptoms of hyperthyroidism (a condition where the thyroid gland produces too much thyroxine). The dose will then be reduced slightly.

In children over 1 year, initially 2.5-5 micrograms per kg of bodyweight a day should be taken.

If you take more Levothyroxine than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose may include: fever, chest pain (angina), racing or irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating and diarrhoea. These signs can take up to 5 days to appear.

If you forget to take Levothyroxine

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose. If you forget to give your child their dose, contact your doctor or pharmacist for further advice.

Stopping the tablets:

These tablets are for long term use. You may need to take them for the rest of your life. Do not stop taking the tablets unless your doctor has told you to do so.

4. POSSIBLE SIDE EFFECTS

Some people may have side-effects when taking this medicine.

Stop taking the tablets and go to hospital at once if you have:

- a rare **allergic reaction** such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell. You may need urgent medical attention.

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; jaundice; confusion; fits and coma

Tell your doctor or pharmacist if any of the following side effects continue, get worse or if you notice any other side effects not listed.

Most of the side effects are similar to the symptoms of hyperthyroidism (where the thyroid gland makes too much thyroxine) and are due to your dose of the medicine being too high. They will usually disappear after reducing the dose or stopping the tablets. **However, you must not change the dose or stop the tablets without talking to your doctor first.**

- headache
- flushing
- high temperature, sweating
- weight loss
- tremor, restlessness, excitability, difficulty sleeping (insomnia)
- increased pressure around the brain in children that is not caused by a tumour or other diseases (benign intracranial hypertension)
- chest pain (angina), pounding, irregular or fast heartbeat
- diarrhoea, vomiting
- muscle cramps, muscle weakness,
- deformity of the skull in infants caused by the early closure of joints in the skull bone (craniostenosis)
- growth in children may slow or stop due to changes in bone growth
- irregular periods
- intolerance to heat

- temporary hair loss in children

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TYRAQ

- Keep out of the reach and sight of children.
- Do not store above 25°C. Store in the original package. Keep container in the outer carton.
- Do not use Levothyroxine tablets after the expiry date stated on the label/ carton/bottle. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.