

PACKAGE LEAFLET
PACKAGE LEAFLET: INFORMATION FOR THE USER

Levothyroxine IBSA 13 micrograms soft capsules
Levothyroxine IBSA 25 micrograms soft capsules
Levothyroxine IBSA 50 micrograms soft capsules
Levothyroxine IBSA 75 micrograms soft capsules
Levothyroxine IBSA 100 micrograms soft capsules
Levothyroxine IBSA 125 micrograms soft capsules
Levothyroxine IBSA 150 micrograms soft capsules
Levothyroxine IBSA 175 micrograms soft capsules
Levothyroxine IBSA 200 micrograms soft capsules

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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.

What is in this leaflet:

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

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

Levothyroxine IBSA contains the active ingredient levothyroxine sodium which 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 IBSA 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 IBSA

Do not take Levothyroxine IBSA

- If you are allergic to levothyroxine or any of the other 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 recently suffered from 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 IBSA:

- 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 have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine.

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 IBSA).

Other medicines and Levothyroxine IBSA

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 medicines and some medicines can have an effect on levothyroxine. In particular tell your doctor or pharmacist if you take the following medicines:

- 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 (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)
- products containing St. John's Wort (an herbal medicinal product)
- proton pump inhibitors: proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lansoprazole) 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 Levothyroxine IBSA.

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 results of your laboratory tests (see Warnings and precautions).

Levothyroxine IBSA 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 IBSA. It may react with an anaesthetic (Ketamine) which you may be given before an operation.

Pregnancy and breast-feeding

Pregnancy

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 IBSA contains sodium

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

3. How to take Levothyroxine IBSA

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

Levothyroxine IBSA should be swallowed whole.

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 or the tablet version to soft capsule of levothyroxine or from the soft capsule to tablet version or the oral solution of levothyroxine your doctor will monitor you more closely.

Dose:

For individual treatment, Levothyroxine IBSA soft capsules are available with a graduated content of 13–200 micrograms of levothyroxine sodium, so you generally only have to take one capsule a day.

Adults, children over 12 years:

For hypothyroidism the recommended dose is 50-100 micrograms a day, increasing by 25-50 micrograms every 3-4 weeks, until you are taking the right amount for your condition. The usual maintenance dose is up to 100 to 200 micrograms daily.

For diffuse non toxic goitre or Hashimoto's thyroiditis the recommended dose is 50-200 micrograms per day.

For the treatment of thyroid cancer the recommended dose is 150-300 micrograms (micrograms) per day.

Older patients (over 50 years of age):

The recommended starting dose is 13 micrograms a day, increasing by 13 micrograms every 2 weeks

until the correct dose is obtained. The usual final dose is between 50 and 200 micrograms 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, weight and the condition being treated. The child will be monitored to make sure he/she gets the right dose.

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 13 – 50 micrograms per day. The dose will then be increased every 2 - 4 weeks depending on how your child responds to the medicine .

Juvenile myxoedema in children:

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.

For young children under 5 years of age, your doctor is likely to prescribe levothyroxine as an oral solution instead of a soft capsule.

Route and/or method of administration:

- Swallow the capsule whole with adequate liquid (e.g. half a glass of water)
- Levothyroxine IBSA is best taken as a single dose on an empty stomach, usually before breakfast or the first meal of the day.

If you take more Levothyroxine IBSA 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 a fast heart beat, feeling anxious or nervous, feeling hyperactive, having uncontrollable muscle movements. 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 IBSA

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 check-up or blood test. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Levothyroxine IBSA

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 IBSA 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 IBSA. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare.

Tell your doctor or pharmacist 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
- weight loss
- rash
- itching
- puffiness.

Additional side effects in children and adolescents

- heat intolerance
- high blood pressure in the skull
- hair loss at beginning of the treatment (temporary)
- deformity of the skull in infants caused by the early closure of joints in the skull bone (craniosynostosis)
- growth in children may slow or stop due to changes in bone growth

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 at: 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 Levothyroxine IBSA

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 outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicine 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 IBSA contains

The active substance is levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 13 micrograms contains 13 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 25 micrograms contains 25 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 50 micrograms contains 50 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 75 micrograms contains 75 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 100 micrograms contains 100 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 125 micrograms contains 125 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 150 micrograms contains 150 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 175 micrograms contains 175 micrograms of levothyroxine sodium.

1 soft capsule of Levothyroxine IBSA 200 micrograms contains 200 micrograms of levothyroxine sodium.

The other ingredients are: gelatin (pork and beef origin), glycerol, purified water

What Levothyroxine IBSA looks like and contents of the pack

Levothyroxine IBSA are amber-coloured, round, oval soft capsules.

Each capsule is marked by a letter identifying the strength.

The soft capsules of Levothyroxine IBSA 13 micrograms are marked by the letter "A".

The soft capsules of Levothyroxine IBSA 25 micrograms are marked by the letter "E".

The soft capsules of Levothyroxine IBSA 50 micrograms are marked by the letter "G".

The soft capsules of Levothyroxine IBSA 75 micrograms are marked by the letter "H".

The soft capsules of Levothyroxine IBSA 100 micrograms are marked by the letter "K".

The soft capsules of Levothyroxine IBSA 125 micrograms are marked by the letter "N".

The soft capsules of Levothyroxine IBSA 150 micrograms are marked by the letter "S".

The soft capsules of Levothyroxine IBSA 175 micrograms are marked by the letter "U".

The soft capsules of Levothyroxine IBSA 200 micrograms are marked by the letter “Y”.

Levothyroxine IBSA is packaged in PVC-polychlorotrifluoroethylene (PCTFE)/aluminium blister packs of

30, 50 or 100 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

IBSA Farmaceutici Italia S.r.l.

Via Martiri di Cefalonia 2, 26900 - Lodi (Italy)

Manufacturer

IBSA Pharma Limited

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Colonial Way

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