

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

LEVOTHYROXINE SERB 200 micrograms/ml solution for injection/infusion Levothyroxine sodium

Read all of this leaflet carefully before you start using 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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levothyroxine SERB 200 micrograms/ml solution for injection/infusion is and what it is used for
2. What you need to know before you use Levothyroxine SERB 200 micrograms/ml solution for injection/infusion
3. How to use Levothyroxine SERB 200 micrograms/ml solution for injection/infusion
4. Possible side effects
5. How to store Levothyroxine SERB 200 micrograms/ml solution for injection/infusion
6. Contents of the pack and other information

1. What Levothyroxine SERB 200 micrograms/ml solution for injection/infusion is and what it is used for

Levothyroxine SERB 200 micrograms/ml solution for injection/infusion contains levothyroxine sodium which is a thyroid hormone

This medicine is used to treat severe under activity of the thyroid gland (myxoedema coma).

This medicine is also used for the treatment of hypothyroidism (insufficient activity of the thyroid gland) in replacement to oral therapy for patients who cannot swallow or have trouble taking oral medicine.

2. What you need to know before you use Levothyroxine SERB 200 micrograms/ml solution for injection/infusion

Do not use Levothyroxine SERB 200 micrograms/ml solution for injection/infusion

- If you are allergic to levothyroxine sodium or any of the other ingredients of this medicine (listed in section 6).
- If you have an active or unstable heart disease.
- If you suffer from underactive adrenal glands (adrenal insufficiency) and are not on adequate replacement treatment.
- If you have an overactive thyroid gland (hyperthyroidism) and are not on an adequate treatment.
- If your pituitary gland is not working very well.
- If you are pregnant do not take levothyroxine in combination with an anti-thyroid medicine.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Levothyroxine SERB 200 micrograms/ml solution for injection/infusion.

Thyroid hormones are not suitable for weight reduction. Taking thyroid hormones will not reduce your weight, if your thyroid hormone level is in a normal range. Serious or even life threatening side effects may occur if you increase the dose without special advice from your doctor, especially when taken together with other medicines for weight reduction.

Thyroid imbalance may occur if you need to change your medication to another levothyroxine-containing product. Talk to your doctor if you have any questions about changing your medication. Your doctor will do blood tests and closely monitor you. You should tell your doctor if you get any side effects as this may indicate that your dose needs to be adjusted up or down.

Tell your doctor if you:

- suffer from heart problems
- suffer from disorder of the adrenal glands (adrenal insufficiency)
- suffer from diabetes and are taking anti-diabetic or insulin treatment. The dose of your diabetic medicine may need to be altered
- have a history of epilepsy
- you are a postmenopausal woman who is at risk of brittle bones (osteoporosis)
- you are pregnant

If you experience an allergic reaction (see section possible side effects). Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away.

In all these situations, the prescription for the thyroid hormones treatment will be determined on a case-by-case basis and patients will be closely monitored

Premature babies

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

Other medicines and Levothyroxine SERB 200 micrograms/ml solution for injection/infusion

Some medicines may affect the effectiveness of Levothyroxine SERB 200 micrograms/ml solution for injection/infusion.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor if you are taking any of the following medicines:

- Medicines for diabetes (such as metformin, glimepiride, glibenclamide and insulin),
- medicines that affect blood coagulation (anticoagulant such as warfarin, apixaban),
- medicines for various heart conditions, including betablockers (such as propranolol), and diuretics (furosemide),
- medicines for controlling the high cholesterol (clofibrate),
- medicines for various conditions (glucocorticosteroids),
- medicines fo treat heart rhythm disorders (amiodarone),
- medicines for epilepsy (such as phenytoin, carbamazepine, phenobarbital),
- medicines for malaria (such as chloroquine, proguanil),
- medicines for depression and anxiety disorders (such as sertraline),
- medicines containing oestrogens (such as contraceptives-containing oestrogens, and drugs used for postmenopausal women),
- medicines containing androgens (such as testosterone),
- medicines to treat HIV infection called protease inhibitors (such as ritonavir, lopinavir),
- medicines to treat cancers (such as imatinib, sunitinib, sorafenib).
- medicines to treat the pain (such as salicylate)
- medicines to treat hyperthyroidism (such as propylthiouracil)

- medicines to treat tuberculosis (rifabutin, rifampicin).

Pregnancy, breast-feeding and fertility

If you are pregnant or planning to become pregnant or are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

The decision on whether it is in your best interests to have Levothyroxine SERB 200 micrograms/ml solution for injection/infusion during pregnancy or breast feeding will be made by your doctor.

Driving and using machines

Levothyroxine SERB 200 micrograms/ml solution for injection/infusion has no effect or a negligible effect on the ability to drive and use machines.

Levothyroxine SERB 200 micrograms/ml solution for injection/infusion contains sodium :

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

3. How to use Levothyroxine SERB 200 micrograms/ml solution for injection

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

Dosage

The dose you receive vary depending on the level of your thyroid hormones, your age and how well you can tolerate the drug.

In order to give you the right dose, your doctor will check your thyroid hormones levels.

You will continue to receive a daily dose of levothyroxine for injection/infusion until you are able to tolerate an oral dose and you are clinically stable.

Adults

Myxoedema coma:

The first day: initial dose of 200 to 500 micrograms given by infusion in the vein with a maximal dose at 500 micrograms.

As a maintenance dose you will receive between 75 to 90 microgramms daily.

Hypothyroidism where oral therapy is not feasible

You will normally start with caution with 25 micrograms per day and the dosage will be increased weekly by 25 micrograms until the appropriate dosage for your condition is established. The average dose is 75 to 110 micrograms given in one injection in the muscle or in the vein.

Elderly

If you are elderly and have heart problems, your treatment will start with a lower dose and will be built up slowly.

Use in children

Myxoedema coma:

Initial dose: 10 micrograms per kilogram of bodyweight.

Maintenance dose: lower doses.

Hypothyroidism where oral therapy is not feasible

- 5 to 12 micrograms per kilogram of bodyweight per day injected into the vein or the muscle. The dose is dependant on the patient response and on the thyroid hormones levels.

Method of administration

Injection (in the muscle or the vein)

For Myxoedema coma, the initial dose is preferably administered by the intravenous route.

If you use more Levothyroxine SERB 200 micrograms/ml solution for injection than you should

This can cause excess thyroid hormone action and you may suffer from symptoms such as nervousness, irritability, fatigue, a fast heartbeat or insomnia. In the event of these symptoms, it is essential that you consult your doctor.

If you stop using Levothyroxine SERB 200 micrograms/ml solution for injection/infusion

Stopping your treatment may stop the effect of the medicine. Do not stop treatment with Levothyroxine SERB 200 micrograms/ml solution for injection/infusion unless you have discussed this with your doctor.

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.

Contact your doctor immediately for any of the following:

- If you have signs and symptoms of an allergic reaction (difficulty in breathing, shortness of breath, swelling of the eyelids, face, lips, mouth or throat or tongue (angioedema), rash, wheezing, urticaria or itching (especially affecting your whole body).
- If you have signs of hyperthyroidism (rapid heart rate, insomnia, excitability, headache, increased temperature, sweating, rapid weight loss, diarrhoea) (frequency common).

Other side-effects

Very common (may affect more than 1 in 10 people)

- difficulty sleeping
- headache
- irregular heartbeats (palpitations)

Common (may affect up to 1 in 10 people)

- nervousness
- rapid heartbeat

Rare (may affect up to 1 in 1,000 people)

- increased brain pressure in children

Frequency not known

- restlessness
- tremor (shaking)
- chest pain, heart rhythm disturbances (for example, rapid heart rate),
- flushing, circulatory collapse in very low birth weight preterm neonates (rapid fall in blood pressure)
- loose stools (diarrhoea), being sick (vomiting) or feeling sick (nausea),
- sweating
- muscle weakness, muscle cramps
- brittle bones (osteoporosis) at high doses of levothyroxine for prolonged periods, especially in postmenopausal women
- in women – changes to your periods (menstrual irregularities)
- intolerance to heat
- fever
- loss of weight

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Levothyroxine SERB 200 micrograms/ml solution for injection/infusion

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

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 packaging and the ampoule after "EXP". The expiry date refers to the last day of that month.

After opening and/or dilution: the product must be used immediately.

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 SERB 200 micrograms/ml solution for injection/infusion contains

- The active substance is:
Levothyroxine sodium..... 200 micrograms
For one ampoule of 1 ml
- The other ingredients are:
Sodium hydroxide
Water for injections.

What Levothyroxine SERB 200 micrograms/ml solution for injection/infusion looks like and contents of the pack

This medicine is supplied in the form of a clear colourless solution for injection in a 1 ml ampoule. Box of 6 ampoules.

Manufacturer

SERB

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Marketing Authorisation Holder

SERB

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