

## **ANNEX IIIB**

### **PACKAGE LEAFLET: Information for the user**

#### **Product name**

**L-THYROXINE SERB, solution for injection**  
**Levothyroxine sodium**

#### **Frame**

**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 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.

#### **What is in this leaflet**

1. What L-THYROXINE SERB, solution for injection is and what it is used for
2. What you need to know before you use L-THYROXINE SERB, solution for injection
3. How to use L-THYROXINE SERB, solution for injection
4. Possible side effects
5. How to store L-THYROXINE SERB, solution for injection
6. Contents of the pack and other information

### **1. WHAT L-THYROXINE SERB, solution for injection IS AND WHAT IT IS USED FOR**

This medicine is a thyroid hormone— (ATC code: H03AA01)

This medicine is recommended for hypothyroidism (insufficient activity of the thyroid gland), whatever the cause.

The injectable form is used in patients who cannot swallow.

This medicine was personally prescribed for you by your doctor because it is specifically suited for your current health condition. You should not reuse it either for yourself or for another person without medical guidance.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE L-THYROXINE SERB, solution for injection**

#### **Do not use L-THYROXINE SERB, solution for injection:**

- If you are allergic to levothyroxine or any of the other ingredients of this medicine, listed in section 6.
- If you have an active or unstable heart disease.
- If you are pregnant do not take levothyroxine in combination with a synthetic anti-thyroid medicine.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using L-THYROXINE SERB, solution for injection.

Obesity without hypothyroidism is not an indication for thyroid hormones used either alone or in combination. Low doses do not have any effect and higher doses are dangerous, especially in combination with anorectics (appetite suppressants).

As a rule, the treatment must be clinically and biologically monitored by your doctor

Tell your doctor about any ancient disease or occurring during treatment, in particular:

- In case of cardiovascular diseases, especially coronary-artery disease (myocardial infarction, angina pectoris, heart rhythm disorders, worsening of heart failure) or hypertension,
- In case of adrenal insufficiency (reduced production of certain hormones). If you are predisposed to adrenal cortex glands failure, you will be asked to start treatment with a corticosteroid prior treatment with L-THYROXINE SERB, solution for injection is initiated.
- If you are diabetic and are taking insulin treatment, the administration of L-THYROXINE SERB, solution for injection may increase your insulin requirements. Medical monitoring is recommended, particularly when levothyroxine treatment is started, modified or discontinued.
- If you are diabetic and are taking insulin treatment, the administration of L-THYROXINE SERB, solution for injection may increase your insulin requirements. Medical monitoring is recommended, particularly when levothyroxine treatment is started, modified or discontinued.
- If you have a history of epilepsy, monitoring is recommended due to the risks of convulsions.

If you are pregnant or planning a pregnancy, inform your doctor as soon as possible so that he/she can closely monitor your pregnancy and adjust the doses if necessary (see section "Pregnancy, breast-feeding and fertility").

Due to an increased risk of serious cardiovascular accident or death, the initial dose must not exceed 500 µg.

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

### **Children**

Not applicable.

### **Other medicines and L-THYROXINE SERB, solution for injection**

Some medicines may affect the effectiveness of L-THYROXINE SERB, solution for injection.

Clinical and biological monitoring, as well as adjustment of your treatment dosage if required, may be necessary during treatment with certain medicines:

- medicines for epilepsy,
- medicines for malaria (chloroquine, proguanil),
- medicines containing oestrogens, used for non-contraceptive purposes,
- medicines to treat HIV infection,
- medicines to treat tuberculosis (rifabutin, rifampicin),
- medicines used especially to treat some types of cancer (imatinib, sunitinib),
- medicine used to treat obesity (orlistat).

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

### **L-THYROXINE SERB, solution for injection with food, drink and alcohol**

Not applicable.

### **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.

### **Pregnancy**

To ensure a healthy pregnancy, your condition needs to be properly balanced throughout the pregnancy. Consequently, levothyroxine treatment must be continued throughout your pregnancy and your doctor may need to change the dosage at the start of or during the pregnancy. Therefore appropriate medical monitoring will be put in place as soon as possible, particularly during the first half of your pregnancy. After your baby is born, a thyroid assessment of your baby is recommended.

Combination of L-THYROXINE SERB, solution for injection with anti-thyroid agents in the treatment of hyperthyroidism is not indicated during pregnancy. That is because very little L-THYROXINE SERB, solution for injection crosses the placenta whereas anti-thyroid drugs cross this barrier easily, resulting in a risk of hypothyroidism in the unborn child.

### **Breast-feeding**

Replacement therapy using levothyroxine is possible while breast-feeding.

### **Fertility**

No studies have been conducted on fertility. Hypothyroidism or hyperthyroidism are liable to affect fertility.

### **Driving and using machines**

L-THYROXINE SERB, solution for injection has no effect or a negligible effect on the ability to drive and use machines.

### **L-THYROXINE SERB, solution for injection contains**

Sodium hydroxide, water for injections.

## **3. HOW TO USE L-THYROXINE SERB, 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**

In all cases, strictly comply with the prescription from your doctor.

The administered doses vary depending on the degree of hypothyroidism, the subject's age and individual tolerance.

In order to adapt the dosage, it is recommended to perform an assay of thyroid hormones prior to treatment.

Daily administration of levothyroxine injection should be continued until the patient is able to tolerate an oral dose and is clinically stable.

### **Adults**

#### *Myxedema coma:*

Treatment consists of the administration of an initial dose of 500 µg on the first day as a slow intravenous infusion, followed by daily administration of 100 µg on average.

#### *Other indications:*

- The average dosage is 100 to 150 µg per day in a single administration. This dosage will be progressively established and with caution: start with 25 µg per day, then increase the daily dose by 25 µg at intervals of approximately one week.

Once the dosage has been established for a sufficiently long time, a new hormone assay will be performed to ensure that there is no overdose.

### **Use in children**

- The maintenance dose is generally 100 to 150 micrograms per m<sup>2</sup> of body surface area.
- For neonates and infants with congenital hypothyroidism, the initial recommended dosage is 10 to 15 micrograms per kilogram bodyweight per day for the first 3 months. Thereafter, the dose should be adjusted individually based on clinical and biological findings.
- For children with acquired hypothyroidism, the recommended initial dosage is 12.5 to 50 micrograms per day. The dose should be increased gradually every 2 to 4 weeks based on clinical and biological findings, until the full dose is reached.

### **Method of administration**

Injectable route (intramuscular or intravenous).

In the case of myxedema coma, the initial dose is preferably administered by the intravenous route.

**Note:** opening the self-breakable ampoule: "take the ampoule, with the coloured dot directed to the top. The ampoule opens easily when the thumb is placed on the coloured dot and gentle pressure is applied to bend the top, as indicated in the drawing."

Illustration:



### **Duration of treatment**

Hypothyroidism is frequently a lifelong disease; treatment should therefore be continued indefinitely.

### **If you use more L-THYROXINE SERB, solution for injection than you should**

In the event of acute intoxication, it is essential that you consult your doctor.

### **If you forget to use L-THYROXINE SERB, solution for injection**

If a dose was missed, resume the treatment without increasing the doses. If several doses have been missed, contact your doctor.

### **If you stop using L-THYROXINE SERB, solution for injection**

Not applicable.

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.

- Signs of hyperthyroidism (rapid heart rate or tachycardia, insomnia, excitability, headache, increased temperature, sweating, rapid weight loss, diarrhoea): if any of these happen, tell your doctor.
- Possibility of worsening of any type of heart disease: myocardial infarction, chest pain, heart rhythm disturbances (for example, rapid heart rate),
- Pain and reaction at the injection site.

### **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 national reporting system: French National Agency for the Safety of Medicinal and Health Products (ANSM) and Regional Pharmacovigilance Centres network - Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

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

## **5. HOW TO STORE L-THYROXINE SERB, SOLUTION FOR INJECTION**

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 and/or reconstitution: 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 L-THYROXINE SERB, solution for injection contains

- The active substance is :  
Levothyroxine sodium ..... 0,200 mg  
For one ampoule
- The other ingredients are: Sodium hydroxide, water for injections.

### What L-THYROXINE SERB, solution for injection looks like and contents of the pack

This medicine is supplied in the form of a solution for injection in a 1-mL ampoule. Box of 6 ampoules.

### Marketing Authorisation Holder

**SERB**  
40 AVENUE GEORGE V  
75008 PARIS  
FRANCE

### Exploitant

**SERB**  
40 AVENUE GEORGE V  
75008 PARIS  
FRANCE

### Manufacturer

**SERB**  
40 AVENUE GEORGE V  
75008 PARIS  
FRANCE

or

**SERB SA**  
AVENUE LOUISE 580  
1050 BRUXELLES  
BELGIUM

### Product name in EU/EEA countries.

Not applicable.

### This leaflet was last revised in April 2018

### Other

Not applicable.