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Helvetica Neue LT

CENEXI
A member of the Roche Group

Cenexi
Article 28028706
L-THYROXINE 0,2 mg 1 ml
Notice (page 3/4)
250 mm x 210 mm
Ligne de conditionnement : FC 320
Version 6 - 22.06.2007
Création
Modifications selon E-mail (M. HAÏM) du 16.05.2007
Ajout du texte anglais
Date de révision de la notice : Juin et June 2007
1 phrase en gras dans le texte en français
Suppression site web dans le logo

Customer approval:

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Information for the

L-THYROXINE SERB 0,2 mg / 1 mL

Levothyroxine

Solution for injection



What it is composition?

An ampoule of 1 mL contains

Levothyroxine sodium 0,2 mg
Excipients: Sodium hydroxide (q.s. pH 10.5), water for injections.

What is the existing packaging?

Solution for injection, 6 ampoules of 1 mL.

To which pharmaco-therapeutical class belongs L-THYROXINE SERB?

This drug is a THYROID HORMONE.

(H: Systemic hormones, non-sexual hormones).

Marketing Authorisation Holder:

SERB S.A.S.
Laboratoires Pharmaceutiques
53 Rue Villiers de l'Isle Adam
75020 Paris - FRANCE

What is L-THYROXINE SERB used for?

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

The injectable form is used among patients in the incapacity to swallow

This drug was prescribed for you by your physician because it is specifically suitable for your present health condition. You should not re-use it without any new medical guidance, either for yourself or for another person.

In what cases should L-THYROXINE SERB not be used?

This drug **should not be used** in the following cases:

- hyperthyroidism (exaggerated activity of the thyroid gland),
- rampant or unstabilized heart diseases.
- allergy to one of the components of L-THYROXINE SERB.

In case of doubt, it is absolutely necessary to ask your physician or pharmacist for advice.

What precautions should you follow upon taking L-THYROXINE SERB?

Special warnings:

Obesity without hypothyroidism is not an indication for thyroid hormones either used alone or in association. Small doses are without any action and larger doses are dangerous, especially associated with anorexigens ("hunger-cutting" drugs).

Activity and possible signs of intolerance only appear after a latency time of the order of 15 days to 1 month.

Precautions of use:

Call your physician in the case of:

- cardiovascular diseases or coronary heart diseases (disease of blood vessels irrigating the heart),
- adrenocortical gland insufficiency.

As a rule, the treatment should be subject to clinical and biological monitoring.

In case of doubt, do not hesitate to ask your physician or pharmacist for advice.

Drug interactions and other interactions

In order to prevent possible interactions between several drugs, any other current treatments should be reported to your physician or pharmacist systematically.

Pregnancy – Lactation:

A treatment based on thyroid hormones should be continued during pregnancy, under supervision of your physician.

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Lactation is possible during the treatment.

Generally, during pregnancy or lactation, you should always ask your physician or pharmacist for advice before using any drug.

How should L-THYROXINE SERB be used?

In every case, strictly observe the prescription of your physician.

Method and route of administration:

Injectable route (intravenous or intramuscular)

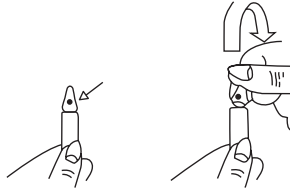
Warnings

Opening of the self-breakable ampoule.

“To take the ampoule, the coloured point directed on the top.

The ampoule opens easily while placing the inch on the coloured point and by exerting a light inflection top to the bottom, as indicated on the drawing”

Pictogram



Duration of the treatment:

Hypothyroidism is frequently a definitive disease and treatment should then be continued indefinitely. In all cases, strictly observe the prescription of your physician.

What should be done in the case of overdosage:

If this is acute intoxication, it is imperative to consult your physician.

What to do if administration of one or several doses was omitted:

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

What are the possible undesirable effects of L-THYROXINE SERB?

As with any active product, this drug may cause more or less disturbing effects in some persons:

- signs of hyperthyroidism (tachycardia, insomnia, sensitivity, headaches, rise in temperature, sweating, rapid weight loss, diarrhea). Call your physician,
- possibility of aggravating any heart disease (angina pectoris, myocardial infraction, arrhythmias);
- in children, possibility of hypercalciurea (excessive calcium concentration in urine),
- because of the presence of polyoxyethylated castor oil, possibility of nausea, vomiting, colics.

Report to your physician or pharmacist any undesired and discomfortable effect which is not be mentioned in this leaflet.

How should L-THYROXINE SERB be stored?

Do not use the medications after the expiry date indicated on the outer packaging.

Revision date:

June 2007

Never leave medication within the reach of children

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