PACKAGE LEAFLET: INFORMATION FOR THE USER

Berlthyrox® 100

100 micrograms, tablets

Active substance: levothyroxine sodium x H_2O

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Berlthyrox® 100 IS AND WHAT IT IS USED FOR

Berlthyrox® 100 is a thyroid-hormone preparation (chemically defined).

Berlthyrox® 100 is used:

- As a replacement for missing thyroid hormone in every form of an underactive thyroid
- For preventing renewed goitre formation after goitre surgery when thyroid function is normal
- For the therapy of benign goitre when thyroid function is normal
- As accompanying therapy to thyrostatic treatment of an overactive thyroid after achieving normal metabolic status
- In malignant tumour of the thyroid, mainly after surgery to suppress renewed tumour growth and to supplement missing thyroid hormone
- For thyroid suppression tests

2. BEFORE YOU TAKE Berlthyrox® 100

Do not take Berlthyrox® 100

- if you are allergic (hypersensitive) to levothyroxine sodium or any of the other ingredients of Berlthyrox® 100
- In any form of an untreated overactive thyroid
- In recent heart attack, acute inflammation of the heart muscle, in untreated adrenocortical insufficiency or untreated insufficiency of the pituitary
- If you are pregnant and you are taking medicines for an overactive thyroid (thyrostatics) at the same time (see also "Pregnancy and breast-feeding")

Take special care with Berlthyrox® 100

- The following diseases should be ruled out or treated before the beginning of a therapy with Berlthyrox® 100: Diseases of the coronary arteries (e.g. angina pectoris), high blood pressure, insufficiency of the pituitary gland or of the adrenal cortex and the presence of areas in the thyroid that produce thyroid hormone uncontrolled.
- If you suffer from insufficiency of the coronary arteries, a weak heart or heart-rhythm disturbances of the fast type, even a mildly overactive thyroid due to levothyroxine is to be avoided under all circumstances.
- If an underactive thyroid is caused by a disease of the pituitary gland, it is to be clarified whether there is adrenocortical insufficiency at the same time. Where appropriate, this would have to be treated before initiation of the thyroid-hormone therapy.
- If, as a post-menopausal woman, you suffer from an underactive thyroid and show an increased risk of osteoporosis, the thyroid function should be checked more frequently in order to avoid increased blood levels of levothyroxine.
- If, as a dialysis patient for example, you are being treated with the medicinal substance sevelamer because of too high blood phosphate levels, your doctor will possibly consider monitoring of certain blood values for the effectiveness of levothyroxine (see also "Taking other medicines" section).

A cautious dosage and frequent checks by a doctor are necessary in elderly patients.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Strengthening of the effect of Berlthyrox® 100 up to an increased side-effect risk:

- Salicylates (medicines for fever and pain), dicoumarol (blood clotting-inhibiting medicine), high doses of furosemide (urine output-increasing medicine) (250 mg), clofibrate (medicine for lowering increased blood-fat values) and other substances may increase the blood levels of levothyroxine.
- Fast intravenous administration (into the vein) of phenytoin may lead increased blood levels of thyroid hormone and assist the development of heart- rhythm disturbances.

Weakening of the effect of Berlthyrox® 100:

- Colestyramine, colestipol and colesevelam (agents for lowering blood fats) inhibit the uptake of levothyroxine from the intestines and should therefore be taken 4 - 5 hours after Berlthyrox® 100.

- The uptake of levothyroxine from the intestines may be lessened by taking aluminium-containing, gastric acid-binding antacids, calcium carbonate, as well as iron-containing medicines, at the same time. Berlthyrox® 100 should therefore be taken at least two hours before these.
- Propylthiouracil (medicine for an overactive thyroid), glucocorticoids (adrenocortical hormones), β-blockers (blood pressure-lowering medicines) and contrast media containing iodine may lessen the conversion of levothyroxine to the more effective form (T3) of the thyroid hormone.
- Sertraline (medicine for depression) and chloroquine/proguanil (medicines for malaria and rheumatic diseases) lessen the effectiveness of levothyroxine.
- Barbiturates (certain sleeping agents) and certain other medicines may accelerate the breakdown of levothyroxine by the liver.
- The levothyroxine requirement may rise while hormone preparations for contraception ("the pill") are being taken or during a hormone-replacement therapy after the menopause.
- Sevelamer and lanthanum carbonate (medicine for lowering increased phosphate levels in the blood of dialysis patients) may possibly lessen the uptake and effectiveness of levothyroxine. Therefore, Berlthyrox® 100 should be taken at least one hour before or three hours after taking sevelamer or lanthanum carbonate. Your doctor will check your thyroid function more frequently (see also "Take special care with Berlthyrox® 100") section.

Other possible interactions:
- Amiodarone (medicine for treating heart-rhythm disturbances) may – due to its high iodine content – trigger both an overactive and an underactive thyroid. Particular caution is required in nodular goitre with possibly unidentified areas forming hormones uncontrolled (autonomies).
- Levothyroxine may increase the effect of certain blood clotting-inhibiting agents (coumarin derivatives) and lessen the effect of blood sugar-lowering agents. If treatment with these medicines and levothyroxine is taking place at the same time, your doctor will check the blood-coagulation values or blood-sugar levels, particularly at the beginning, and adjust the dosage of the blood clotting-inhibiting or blood sugar-lowering medicines where appropriate.

Taking Berlthyrox® 100 with food and drink
Soya-containing products may impair the uptake of levothyroxine from the intestines. At the beginning and after the end of a soya-containing diet in particular, an adjustment of the dose of Berlthyrox® 100 may become necessary.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
A consistent hormone-replacement treatment with thyroid hormones is particularly important during pregnancy and breast-feeding and is therefore to be continued. Despite extensive use during pregnancy, a risk for the unborn child has not yet become known. The quantity of thyroid hormone passing into the breast milk during breast-feeding is very low, even in high-dose levothyroxine therapy, and is therefore harmless.
Due to the increased blood levels of oestrogen (female sex hormone), the levothyroxine requirement may rise during pregnancy in patients with an underactive thyroid. The thyroid function should therefore be checked both during and after a pregnancy and the thyroid-hormone dose adjusted where appropriate.
However, Berlthyrox® 100 must not be taken at the same time with medicines for an overactive thyroid (thyrostatics) during pregnancy, as this makes a higher dosage of the thyrostatics necessary. Thyrostatics may (unlike levothyroxine) reach the circulation of the child through the placenta and are capable of bringing about an underactive thyroid in the unborn child. An overactive thyroid during pregnancy should therefore be treated exclusively with low-dose thyrostatic medicines.
A thyroid suppression test should not be carried out during a pregnancy.
In pregnancy and breast-feeding, the dose that the doctor has prescribed should be kept to exactly and not exceeded.
Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

3. HOW TO TAKE Berlthyrox® 100
Always take Berlthyrox® 100 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The individual daily does should be determined by laboratory-diagnostic and clinical examinations. A treatment with thyroid hormones is to be begun particularly cautiously in elderly patients, in patients with a disease of the coronary arteries and in patients with a severely or long-standingly underactive thyroid. This means that a lower starting dose is to be chosen that is then increased slowly and at longer intervals with frequent thyroid-hormone checks. Experience has shown that a lower dose is also adequate in low body weight and in large nodular goitre.
Dosage
The usual dose is:

Use		*Dose [micrograms/day]*
Underactive thyroid:		
Adults	Initially	25 - 50
(Increase at 2- to 4-week intervals by 25 - 50 micrograms)	Afterwards	100 - 200
Prevention of renewed goitre formation after goitre surgery		75 - 200

Benign goitre when thyroid function is normal		75 - 200
Accompanying therapy to thyrostatic treatment of an overactive thyroid		50 - 100
After thyroid surgery because of a malignant tumour		150 - 300
Thyroid suppression scintigram:		200 micrograms/day (14 days long until the scintigram is carried out)

Children with an underactive thyroid (inborn and acquired hypothyroidism)
- The maintenance dose for long-term treatment of an underactive thyroid (inborn and acquired hypothyroidism) is generally 100 - 150 micrograms levothyroxine per m^2 body surface area per day.
- For newborns and infants with and inborn underactive thyroid gland, rapid hormone substitution is especially important to achieve normal mental and physical development. The initial recommended dose is 10 - 15 micrograms levothyroxine per kg body weight per day for the first 3 months. After that, the doctor will adjust the daily dose individually according to clinical measurements (especially thyroid-hormone blood levels).
- For children with an acquired underactive thyroid gland, the initial recommended dose is 12.5 - 50 micrograms levothyroxine per day. The doctor will increase the daily dose gradually every 2 - 4 weeks until the full replacement dose is reached. For this, the doctor will consider the thyroid-hormone blood levels especially.

Where appropriate, the use of a dosage form with a lower active-substance content is recommended for the initiation of a therapy and for dose increase in adults, as well as for the treatment of children.
For long-term treatment, it is recommended to change to a dosage form with a higher active-substance content where appropriate.

Note on easier divisibility:
Place the tablet on a hard, even surface with the breaking notch facing upwards. If you now press down with your finger on the tablet, you will obtain two tablet halves.
Please speak to your doctor if you have the impression that the effect of Berlthyrox® 100 is too strong or too weak.

Method of use
The entire daily dose is swallowed whole with a little liquid on an empty stomach in the morning at least half an hour before breakfast.
Infants receive the entire daily dose at least half an hour before the first meal of the day. Allow the tablet to disintegrate in some water (10 – 15 ml) and administer the resultant suspension (which must be freshly prepared for each dose!) with some more liquid (5 – 10 ml).

Length of use
- In an underactive thyroid: usually lifelong
- In prevention of renewed goitre growth: a few months or years up to lifelong
- In benign goitre: a few months or years up to lifelong

A treatment period of 6 months up to two years is necessary for the treatment of benign goitre. If treatment with Berlthyrox® 100 has not brought the desired success within this time, other therapeutic options should be considered.
- In accompanying therapy to the treatment of an overactive thyroid: depending on the length of thyrostatic medication
- In thyroid surgery because of a malignant tumour of the thyroid: usually lifelong

The doctor determines the length of treatment.

If you take more Berlthyrox® 100 than you should
If there has been an overdose, the typical signs of an overactive thyroid may occur:
Pounding heart, heart-rhythm disturbances, a feeling of tightness around the heart (angina pectoris), muscle weakness and muscle cramps, feeling hot, excessive sweating, fever, trembling fingers, inner unrest, sleeplessness, weight loss, vomiting, diarrhoea, menstrual disturbances, headache, increased pressure in the brain.
Please visit your doctor if such complaints occur.

If you forget to take Berlthyrox® 100
Do not take double the dose if you have forgotten the previous intake, but remain in the determined rhythm.

If you stop taking Berlthyrox® 100
Taking Berlthyrox® 100 regularly in the prescribed dosage is necessary for the treatment to be successful. If the treatment is interrupted or ended prematurely, there may therefore be recurrence of complaints whose nature depends on the respective underlying disease.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Berlthyrox® 100 can cause side effects, although not everybody gets them.
The following frequencies are taken as a basis when evaluating side effects:

Very common:	may affect more than 1 user in 10
Common:	may affect 1 to 10 users in 100
Uncommon:	may affect 1 to 10 users in 1,000
Rare:	may affect 1 to 10 users in 10,000
Very rare:	may affect fewer than 1 user in 10,000,
Not known:	frequency cannot be estimated from the available data

If it is used properly, side effects are not expected during treatment with Berlthyrox® 100.
If the dose strength is not tolerated in isolated cases, or there has been an overdose, then, particularly in the case of too rapid dose increase at the beginning of treatment, the typical signs of an overactive thyroid may occur (pounding heart, heart-rhythm disturbances, a felling of tightness around the heart [angina pectoris], muscle weakness and muscle cramps, feeling hot, excessive sweating, fever, trembling fingers, inner unrest, sleeplessness, weight loss, vomiting, diarrhoea, menstrual disturbances, headache, increased pressure in the brain). (See also "If you take more Berlthyrox® 100 than you should").
After consultation with the doctor treating you, the daily dose should be reduced or tablet-taking interrupted for several days. As soon as the side effect has disappeared, the treatment can be recommenced with cautious dosage.
In hypersensitivity to levothyroxine or any of the other ingredients, there may be allergic reactions like nettle rash, cramps of the bronchial musculature with breathlessness (bronchospasm) and swelling of the larynx. The occurrence of severe allergic shock has been described in isolated cases. Please go to a doctor at once if hypersensitivity reactions occur.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Berlthyrox® 100

Keep out of the reach and sight of children.
Do not use Berlthyrox® 100 after the expiry date which is stated on the blister and folding box after "EXP". The expiry date refers to the last day of that month.

Storage conditions
[PVDC/PVC-Alu blister] Do not store above 25 °C.
[Alu-Alu blister] Do not store above 25 °C.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose this medicine if no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Berlthyrox® 100 contains

- The active substance is: levothyroxine sodium x H_2O (106.4 - 113.6 micrograms of levothyroxine sodium x H_2O, equivalent to 100 micrograms of levothyroxine sodium)
- The other ingredients are: Calcium hydrogen phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate (type A) (Ph. Eur.), dextrin (from maize starch), long-chain partial glycerides

What Berlthyrox® 100 looks like and contents of the pack
Berlthyrox® 100 are almost white to slightly beige, round, slightly domed tablets with a break-mark on one side and "100" engraved on the other side.
Berlthyrox® 100 is available in original packages with 25, 50 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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