

Information and direction for use

Thybon® 20 Henning

20 micrograms, tablets

Active ingredient: liothyronine hydrochloride

Please read the entire information leaflet carefully before taking the medication, as it contains important information.

- Keep the information leaflet. You may wish to read it again at a later stage.
- If you have further questions, ask your doctor or pharmacist.
- This medication was prescribed for you personally. Do not give it to others. It can harm other people, even if they have the same complaints as yourself.
- Should you notice side effects, ask your doctor or pharmacist. This also applies to side effects not mentioned on this information leaflet. See section 4.

What is contained in this information leaflet

1. What is Thybon® 20 Henning and what is it used for?
2. What should you consider before taking Thybon® 20 Henning?
3. How should you take Thybon® 20 Henning?
4. What side effects may occur?
5. How should Thybon® 20 Henning be stored?
6. Content of package and other information.

1. What is Thybon® 20 Henning and what is it used for?

Thybon® 20 Henning is a drug which contains the thyroid hormone liothyronine as its active ingredient. It has the same effects as the naturally formed hormone. You have been given Thybon® 20 Henning to replace missing thyroid hormone and/or to relieve your thyroid.

Thybon® 20 Henning is used:

- to bridge periods of thyroid hormone deficiency during the diagnosis of thyroid carcinoma and the preparation for radiotherapy
- for the replacement (substitution) of the missing hormone in cases of hypothyroidism with simultaneous proven or suspected T_4/T_3 reduced transformation capacity (generally in combination with levothyroxine)
- for the examination of thyroid function (thyroid suppression test).

2. What should you consider before taking Thybon® 20 Henning?

Thybon® 20 Henning must not be taken:

- If you are allergic to liothyronine hydrochloride or one of the other ingredients of Thybon® 20 Henning which are listed in section 6,
- If you suffer from any of the following diseases or conditions:
 - Untreated hyperthyroidism,
 - Untreated weakness of the adrenal cortex,
 - Untreated weakness of the pituitary gland (hypopituitarism) if it results in a weakness of the adrenal cortex requiring treatment,
 - A recent heart attack,
 - Acute myocarditis,
 - An acute inflammation of all outer layers of the heart (pancarditis).

Patients, who have already suffered a heart attack, or who simultaneously suffer from pain in the heart region with constriction sensation (angina pectoris), cardiac insufficiency or fast-type arrhythmia, must not take Thybon® 20 Henning.

If you are pregnant, you must not take Thybon® 20 Henning at the same time as medication inhibiting hyperthyroidism (so-called thyreostatics) (see also section on 'pregnancy and breastfeeding').

Before starting a therapy with Thybon® 20 Henning, the following diseases or conditions have to be excluded or treated:

- Disease of the coronary blood vessels,
- High blood pressure (hypertension),
- Weakness of the pituitary gland and/or the adrenal cortex,
- The presence of areas in the thyroid producing thyroid hormone uncontrollably (thyroid autonomy).

Before a so-called thyroid suppression test to examine thyroid function is carried out, these diseases or conditions must also be excluded or treated. However, thyroid autonomy must not be excluded, as one of the purposes of the test is to detect it.

Warnings and precautions

Special care when using Thybon® 20 Henning must be taken:

- If you are suffering from coronary blood vessel disease, non-acute heart muscle inflammation, or if you have been suffering from hypothyroidism for a long time. In such cases, excessive hormone levels in the blood must be avoided. For that reason, your thyroid levels should be measured regularly. Speak to your doctor if taking Thybon® 20 Henning causes mild signs of hyperthyroidism (see section 4. 'What side effects may occur?').
- If you are suffering from hypothyroidism caused by a disease of the pituitary gland. A possible coexisting weakness of the adrenal cortex must be treated by your doctor first (hydrocortisone therapy). Inadequate therapy may lead to acute adrenal cortex failure (Addison crisis).
- If there is suspicion that areas of your thyroid produce thyroid hormone uncontrollably. Before treatment, this should be examined through further tests of thyroid function.
- With post-menopausal women, where there is an increased risk of osteoporosis. Thyroid function should be examined regularly by the attending physician to avoid increased thyroid hormone levels in the blood and to ensure the lowest required dosage is applied.

- If you suffer from diabetes. Please pay attention to the notes in section 'Taking Thybon® 20 Henning in conjunction with other medication'.
- If you are treated with anticoagulant medication (e.g. Dicumarol) or medication affecting the thyroid (e.g. Amiodarone, Tyrosine-kinase inhibitors [medication for the treatment of cancer], Salicylate, and high doses of Furosemide). Please pay attention to the notes in section 'Taking Thybon® 20 Henning in conjunction with other medication'.
- With premature infants with a very low weight at birth. Because of their not yet fully developed adrenal function, utmost care must be taken at the beginning of the Liothyronine therapy, as it may result in a circulatory collapse (see also under 4. 'What side effects may occur?').

Inappropriate use

You must not take Thybon® 20 Henning to lose weight. If the thyroid hormone level in your blood is in the normal region, taking additional thyroid hormones does not lead to weight loss. Additional thyroid hormone can have serious or even life-threatening side effects, especially in conjunction with certain weight loss remedies.

Change of therapy

If you are already treated with Thybon® 20 Henning, changing to another medication containing thyroid hormone should only take place under the supervision of your doctor, carrying out blood tests.

Elderly people

With elderly people, dosage levels should be established more carefully (especially if there are heart problems), and there should be more regular check-ups by the physician.

Taking Thybon® 20 Henning in conjunction with other medication

Inform your doctor or pharmacist if you are taking/using other medication, have taken/used other medication recently, or intend to take/use other medication.

Thybon® 20 Henning influences the effects of the following groups of medicines and preparations:

- Antidiabetics (medication lowering blood sugar levels) (e.g.: Metformin, Glimperide, Glibenclamide and Insulin): If you are diabetic, you should have your blood sugar level checked regularly, especially at the beginning and at the end of a thyroid hormone therapy. If necessary, your doctor may have to adjust the dosage of the medication lowering the blood sugar level, as Levothyroxine may reduce the blood sugar lowering effects.
- Coumarin derivatives (anticoagulant medication):
If Thybon® 20 Henning is used at the same time as Coumarin derivatives (e.g. Dicumarol), blood coagulation should be checked regularly. If necessary, the physician has to reduce the dosage of the anti-coagulant, as thyroid hormones can increase the effect of anti-coagulant substances.

The effect of Thybon® 20 Henning is influenced by other medication as follows:

- Ion-exchange resins:
Take medicine to lower blood fat level (for example Cholestyramine, Colestipol) 4 to 5 hours after taking Thybon® 20 Henning. Otherwise these drugs inhibit the absorption of thyroid hormone from the intestine and reduce its effectiveness. Substances for the removal of increased potassium or phosphate concentrations in the blood (calcium and sodium salts of polystyrene sulfonic acid, Sevelamer) may also reduce the absorption of Liothyronine from the intestine. These substances should therefore be taken 4 or 5 hours after taking Thybon® 20 Henning.
- Bile acid complexing agents:
Colestevam (medication to reduce raised cholesterol concentration levels in the blood) may reduce the absorption of Liothyronine from the intestine. Therefore, Thybon® 20 Henning should be taken at least 4 hours before Colesevalam.
- Medication binding gastric acid containing aluminium, medication containing iron, calcium carbonate:
Take Thybon® 20 Henning 25 at least 2 hours before medication binding gastric acid containing aluminium (antacids, sucralfates), medication containing iron or calcium carbonate. These drugs may otherwise reduce the absorption of thyroid hormones from the intestine and consequently their effects.
- Amiodarone, contrast agent containing iodine:
Amiodarone (medication for the treatment of arrhythmia) and contrast agents containing iodine (certain agents used in clinical roentgenology) can – due to their high iodine content – cause hyperthyroidism as well as hypothyroidism. Particular care must be taken in the case of adenomatous goitre (nodose struma), in case there may be unidentified areas in the thyroid producing thyroid hormone uncontrollably (autonomous areas). If necessary, your doctor will adjust the dosage of Thybon® 20 Henning.
- Tyrosine-kinase inhibitors (medication for the treatment of cancer):
If you are using Liothyronine and tyrosine-kinase inhibitors simultaneously (e.g. Imatinib, Sunitinib, Sorafenib, Motesanib), your physician should carefully monitor your disease symptoms and check your thyroid function. The effectiveness of thyroid hormones may be reduced, and, if necessary, your doctor will adjust the dosage of Liothyronine.
- The following medication can influence the effects of Thybon® 20 Henning:
 - Salicylates, especially in dosages higher than 2.0g/day (fever-reducing and pain relief medication),
 - Dicoumarol (anti-coagulant medication),
 - High doses (250 mg) of Furosemide (diuretic medication)
 - Clofibrate (medication to lower raised blood fat levels)
- Contraceptive or hormone therapy medication:
If you are taking contraceptive hormone preparations containing oestrogen ('the pill') or receive post-menopausal hormone replacement therapy, your thyroid hormone requirement may increase.
- Sertraline, Chloroquine/Proguanil:
Sertraline (anti-depressant medication) and Chloroquine/Proguanil (medication for the treatment of malaria and rheumatic diseases) reduce the effectiveness of thyroid hormones.

- Barbiturates, Rifampicin, Carbamazepine, Phenytoin:
 - Barbiturates (medication for the treatment of convulsions, narcotics, certain sleep-inducing drugs), Rifampicin (antibiotic), Carbamazepine (medication for the treatment of convulsions) and Phenytoin (medication for the treatment of convulsions, arrhythmia remedy) can reduce the effectiveness of thyroid hormones.
 - Protease inhibitors (medication for the treatment of HIV infections):
- If you use thyroid hormones and protease inhibitors simultaneously (Lopinavir, Ritonavir), your physician should carefully monitor your disease symptoms and check your thyroid function. It can come to a loss of the effectiveness of thyroid hormones, if these are taken at the same time as Lopinavir/Ritonavir.

Taking Thybon® 20 Henning with food and drink

If your diet contains soya, your physician will regularly check the thyroid hormone level in your blood. If necessary, your physician will have to adjust the dosage of Thybon® 20 Henning during and after a soya-based diet. This is because soya products can reduce the absorption of Liothyronine from the intestine and thus its effectiveness.

Pregnancy and breast feeding

If you are pregnant or breast feeding, have a feeling that you may be pregnant, or wish to become pregnant, consult your doctor or pharmacist before taking this medication. A correct treatment with thyroid hormones is especially important for mother and child during pregnancy and breast feeding. Treatment must therefore be carried out consistently and under supervision of the attending physician. Although thyroid hormones have been used extensively during pregnancy, there has been no indication so far of undesired effects on the pregnancy or the health of the unborn or newborn child. Have your thyroid function checked both during and after pregnancy. If necessary, your doctor will have to adjust your dosage, as during pregnancy more thyroid hormone may be required due to increased oestrogen levels in the blood (female sex hormone). During pregnancy, you may not take Thybon® 20 Henning at the same time as medication that inhibits hyperthyroidism (so-called antithyroid agents), as this necessitates a higher dosage of the antithyroid agents. Anti-thyroid agents (as opposed to thyroid hormones) can get into the blood circulation of the child via the placenta, and can cause hypothyroidism in the unborn child. If you suffer from hyperthyroidism, your doctor should treat this exclusively with low dosages of thyreostatic drugs. The amount of thyroid hormone that passes into breast milk even during a high dosage thyroid hormone therapy is very small and therefore harmless. During pregnancy and breastfeeding, your doctor will not carry out a suppression test.

Fitness to drive and operate machinery

There have been no studies examining whether taking Thybon® 20 Henning affects your fitness to drive and operate machinery.

3. How should you take Thybon® 20 Henning?

Always take Thybon® 20 Henning exactly according to your doctor's instructions. Ask your doctor or pharmacist if you are unsure.

Dosage

Every patient has an optimal thyroid hormone level. The average regular adult dosage of 50 micrograms of liothyronine hydrochloride per day (2.5 tablets of Thybon® 20 Henning) and the initial dosage of 20 micrograms of liothyronine hydrochloride per day (1 tablet of Thybon® 20 Henning) are only reference points. Your attending physician will use these to determine your required dosage. For an examination of thyroid function by means of a thyroid suppression test, 60-100 micrograms of liothyronine hydrochloride are used per day (corresponding to between 3 and 5 tablets of Thybon® 20 Henning), for a duration of 8 to 10 days. For this, tablets containing 100 micrograms of liothyronine hydrochloride are also available.

Older patients, patients with coronary blood vessel disease, patients with hypothyroidism

For older patients, patients with coronary blood vessel disease and patients with severe or long-standing hypothyroidism, the treatment with thyroid hormones is started particularly carefully (low initial dosage, which is increased gradually and after longer time intervals, following frequent thyroid hormone tests).

Patients with a low body weight and patients with a large goitre

Experience shows that for patients with a low body weight and patients with a large goitre, a smaller dosage is sufficient.

How to take your medication

To achieve a better tolerance of the medication, take several smaller doses throughout the day, unchewed and with plenty of fluid, preferably a glass of water.

Duration of treatment

The duration of treatment is determined by your doctor.

If you have taken larger quantities of Thybon® 20 Henning than you should have

The signs of an overdose are described in section 4. "What side effects may occur?". Please consult your doctor if such symptoms occur.

If you have forgotten to take Thybon® 20 Henning

Should you have taken too little or should you have forgotten to take your medication on one occasion, do not take the missed dose later. Stick to your prescribed rhythm.

If you stop taking Thybon® 20 Henning

For a successful treatment, it is necessary to take Thybon® 20 Henning regularly in the dosage prescribed by your physician. Under no circumstances should you independently change, interrupt or stop the treatment with Thybon® 20 Henning early, as otherwise your symptoms may reappear. Should you have further questions about how to use this medication, ask your doctor or pharmacist.

4. What side effects may occur?

Like all drugs, this medication may have side effects, which may not materialise in every case.

Intolerance of dosage, overdose

Should particular patients experience an intolerance of the prescribed dosage, or in cases of an overdose, especially if the dose is increased too quickly at the beginning of the treatment, the typical symptoms of hyperthyroidism may appear.

Very frequent (can occur in more than one in ten patients)

- Palpitations
- Sleeplessness
- Headaches

Frequent (can occur in up to one in ten patients)

- Palpitations (tachycardia)
- Nervousness

Rare (can occur in up to one in 1000 patients)

- Increased intracranial pressure (especially in children)

Not known (frequency cannot be estimated on the basis of available data)

- Hypersensitivity
- Arrhythmia
- Pain characterised by a tightness of the chest (angina pectoris symptoms)
- Allergic skin reaction (e.g. rash, nettle rash)
- Inner unrest
- Muscle weakness, muscle cramps
- Sensation of heat, intolerance of heat
- Irregular periods
- Diarrhoea
- Vomiting
- Weight loss
- Shaking (shivering)
- Excessive sweating
- Fever
- The following side effect was observed when another thyroid hormone (levothyroxine) was used, and cannot be ruled out for liothyronine: bone atrophy (osteoporosis) when taking large doses of levothyroxine, especially in post-menopausal women, and when treatment continues over a long period of time.

Hypersensitivity to the active ingredient or other ingredients of Thybon® 20 Henning

In the case of hypersensitivity to liothyronine or one of the other ingredients of Thybon® 20 Henning, there may be allergic reactions of the skin (e.g. rash, nettle rash) or the respiratory system. Inform your doctor of any side effects. They will decide whether the daily dosage should be reduced or the treatment be interrupted for several days. As soon as the side effects have disappeared, the treatment can be continued with a carefully calculated dosage.

Reporting side effects

Should you notice any side effects, ask your doctor or pharmacist. This also applies to side effects not listed on this information leaflet. By reporting side effects, you can help us to provide more information about the safety of this medication.

5. How should Thybon® Henning 20 be stored?

Store this medication out of the sight and reach of children. You must not use the product after the 'Use By' date printed on the carton and the blister pack. The 'Use By' date refers to the last day of the month indicated. Do not store in temperatures over 25°C. Store the blister pack in the carton, to protect the contents from light.

6. Content of package and other information

What Thybon® 20 Henning contains

The active ingredient is liothyronine hydrochloride.

1 tablet contains 20 micrograms of liothyronine hydrochloride.

Other ingredients are: preagglutinated corn starch (maize), maize starch, microcrystalline cellulose, sodium carbonate, sodium thiosulfate 5H₂O (Ph. Eur.), fine-particle silicon dioxide, hydrated castor oil.

What Thybon® 20 Henning looks like and contents of the pack

Thybon® 20 Henning are white, round tablets with a bevel edge, embossed on both sides. They have a score line on one side, and on both sides the mark '1B'. The tablets can be split into equal doses. Thybon® 20 Henning is available in packets of 50 and 100 tablets. It is possible that not all pack sizes will be available.

Pharmaceutical Company

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