Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Levothyroxine Teva 100 micrograms Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Levothyroxine Teva 25 micrograms contains 25 micrograms of levothyroxine sodium

Excipient(s) with known effect:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White to off-white, round, 8mm in diameter, plain tablets with a cross break-line on one side and debossing L4 on the other side

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Hypothyroidism,
- Prophylaxis against goitre recurrence following resection of euthyroid goitre,
- Benign, euthyroid goitre.
- Co-therapy in the antithyroid treatment of hyperthyroidism, once euthyroid status has been achieved.
- Suppression and replacement therapy in thyroid malignancy, especially post thyroidectomy.
- Thyroid suppression test.

4.2 Posology and method of administration

Thyroid hormone therapy/replacement

Posology
The dosing information serves as a guideline. The individual daily dose should be determined by laboratory diagnostic tests and clinical examinations.

If any residual thyroid function remains, a lower replacement dose may be sufficient.

In elderly patients, patients with coronary heart disease and patients with severe or chronic hypothyroidism, thyroid hormone treatment must be initiated with particular caution, i.e. by selecting a low initial dose and increasing it slowly and at longer intervals, with frequent thyroid hormone monitoring.
Experience has shown that a lower dose is also sufficient in patients with a low body weight and in patients with large goitres.
As the tablets can be divided into equal doses, starting dose of 12.5 micrograms can be used.

As T_4 or fT_4 levels may be increased in some patients, determination of the serum TSH concentration is better suited for monitoring the treatment regimen.

Indication		**Dose (Micrograms of levothyroxine sodium/day)**
Hypothyroidism:		
Adults initially		25-50

followed by (increased at 2 to 4 week intervals in increments of 25-50 micrograms)		100-200
Prophylaxis against goitre recurrence:		75-200
Benign euthyroid goitre:		75-200
Co-therapy in the antithyroid treatment of hyperthyroidism:		50-100
Post thyroidectomy due to thyroid malignancy:		150-300
Thyroid suppression scintigraphy:	Levothyroxine Teva 100 micrograms tablets	200 micrograms (equivalent to 2 tablets)/day (for 14 days until the scintigram is performed)

Paediatric population
In congenital and acquired hypothyroidism, the maintenance dose is generally 100-150 micrograms per m^2 body surface area per day.

For neonates and infants with congenital hypothyroidism, where rapid replacement is important, the initial recommended dosage is 10-15 micrograms per kg BW per day for the first 3 months.
Thereafter, the dose should be adjusted individually according to the clinical findings and thyroid hormone and TSH values.

For children with acquired hypothyroidism, the initial recommended dosage is 12.5-50 micrograms per day. The dose should be increased gradually every 2 to 4 weeks according to the clinical findings and thyroid hormone and TSH values until the full replacement dose is reached.

Method of administration
The total daily dose is taken in the morning on an empty stomach at least half an hour before breakfast. The tablets are swallowed whole, without chewing with liquid.

Paediatric population
Infants are given the total daily dose at least half an hour before their first meal of the day. For this, the tablet is allowed to dissolve in some water (10-15 ml) and the resulting fine dispersion (to be freshly prepared for each dose!) is administered with some more liquid (5-10 ml).

Duration of treatment

In most cases, treatment is life long when used in hypothyroidism and thyroidectomy due to thyroid malignancy, several months or years and even life long when used for euthyroid goitre and prophylaxis against goitre recurrence, or is dependent on the duration of the antithyroid medicinal product when used as co therapy in the treatment of hyperthyroidism.
For the treatment of euthyroid goitre, a treatment period of 6 months up to 2 years is necessary. If treatment with Levothyroxine Teva has failed to achieve the desired success within this time, other therapeutic options should be considered.

Thyroid suppression test
For performing thyroid suppression tests, 150-200 micrograms of levothyroxine sodium are taken daily for 14 days.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1,
- untreated hyperthyroidism,
- untreated adrenal insufficiency,
- untreated pituitary insufficiency (when leading to adrenal insufficiency requiring treatment),
- treatment with levothyroxine must not be initiated in acute myocardial infarction, acute myocarditis and acute pancarditis.

Combination therapy of hyperthyroidism with levothyroxine and anti-thyroid agents is not indicated in pregnancy.

For use during pregnancy and lactation, see section 4.6.

4.4 Special warnings and precautions for use

Before starting thyroid hormone therapy, the following diseases or conditions must be excluded or treated:

– coronary heart disease,

- angina pectoris,
- hypertension,
- pituitary and/or adrenocortical insufficiency,
- thyroid autonomy.

Prior to performing thyroid suppression tests, these diseases or conditions must likewise be excluded or treated, with the exception of thyroid autonomy, which may be the reason for performing the suppression test.

Even relatively mild, medicinal product induced hyperthyroid function must be strictly avoided in cases of coronary heart disease, heart failure, tachyarrhythmias, myocarditis of non-acute course, chronic hypothyroidism or in patients with a history of myocardial infarction. In thyroid hormone therapy, more frequent monitoring of thyroid hormone parameters must be performed in these patients (see section 4.2).

In secondary hypothyroidism, it must be established whether adrenocortical insufficiency is also present. If this is the case, replacement must firstly be performed (hydrocortisone). Without an adequate supply of corticosteroids, thyroid hormone therapy might precipitate an Addisonian crisis in patients with adrenocortical insufficiency or pituitary insufficiency (see section 4.3).

If thyroid autonomy is suspected, it is recommended that a TRH test or suppression scintigram be performed.

When initiating levothyroxine therapy in patients at risk of psychotic disorders, it is recommended to start at a low levothyroxine dose and to slowly increase the dosage at the beginning of the therapy. Monitoring of the patient is advised. If signs of psychotic disorders occur, adjustment of the dose of levothyroxine should be considered.

When administering levothyroxine therapy to postmenopausal women, who are at increased risk of osteoporosis, dosage of levothyroxine sodium should be titrated to the lowest possible effective level and thyroid function should be monitored more frequently to avoid supraphysiological blood levels of levothyroxine (see section 4.8).

Care is required when levothyroxine is administered to patients with known history of epilepsy. Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Thyroid hormones should not be given for weight reduction. In euthyroid patients, treatment with levothyroxine does not cause weight reduction. Substantial doses may cause serious or even life-threatening undesirable effects, particularly in combination with certain substances for weight reduction, and especially with sympathomimetic amines.

Hypothyroidism and/or reduced control of hypothyroidism may occur when orlistat and levothyroxine are co-administered (see section 4.5). Patients taking levothyroxine should be advised to consult a doctor before starting or stopping or changing treatment with orlistat, as orlistat and levothyroxine may need to be taken at different times and the dose of levothyroxine may need to be adjusted. Further, it is recommended to monitor the patient by checking the hormone levels in the serum.

Hypersensitivity reactions (including angioedema), sometimes serious, have been reported with levothyroxine use. If signs and symptoms of allergic reactions occur, treatment with Levothyroxine Teva must be discontinued and appropriate symptomatic treatment initiated (see section 4.3 and 4.8).

If a switch to another levothyroxine-containing product is required, there is a need to undertake a close monitoring including a clinical and biological monitoring during the transition period due to a potential risk of thyroid imbalance. In some patients, a dose adjustment could be necessary.

Monitoring is required in patients receiving concomitant administration of levothyroxine and medicinal products (such as amiodarone, tyrosine kinase inhibitors, salicylates and furosemide at high doses) which may affect the thyroid function. See also section 4.5.

Thyroid replacement therapy may cause an increase in dosage requirements of insulin or other anti-diabetic therapy. Care is needed for patients with diabetes mellitus and diabetes insipidus.

For diabetics and patients on anticoagulant therapy, see section 4.5.

Interferences with laboratory test

Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results. The risk of interference increases with higher doses of biotin.

When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed.

For patients taking biotin-containing products, laboratory personnel should be informed when a thyroid function test is requested. Alternative tests not susceptible to biotin interference should be used, if available (see section 4.5).

Paediatric population

Haemodynamic parameters should be monitored when levothyroxine therapy is initiated in very low birth weight preterm neonates as circulatory collapse may occur due to the immature adrenal function.

Parents of children receiving thyroid agent should be advised that partial loss of hair may occur during the first few months of therapy, but this effect is usually transient and subsequent regrowth usually occurs.

Excipient(s)

Sodium

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

4.5 Interaction with other medicinal products and other forms of interaction

Antidiabetic agents
Levothyroxine may reduce the antihyperglycaemic effect of antidiabetics (such as metformin, glimepiride, glibenclamide as well as insulin). Blood glucose levels must therefore be regularly monitored in patients with diabetes, particularly at the start and at the end of thyroid hormone therapy. The antihyperglycaemic dosage should be adjusted as necessary.

Coumarin derivatives
Levothyroxine may potentiate the effect of coumarin derivatives due to plasma protein binding displacement. With concomitant treatment, regular monitoring of blood coagulation is therefore required and the anticoagulant dosage must be adjusted as necessary (dose reduction).

Ion exchange resins, bile acid sequestrants
Ion exchange resins, such as colestyramine, colestipol, sevelamer, calcium salts and sodium salts of polystyrene sulphonic acid, inhibit the absorption of levothyroxine by binding thyroid hormones in the gastro-intestinal tract and should therefore not be administered within 4 to 5 hours of taking Levothyroxine Teva.
Colesevelam binds to levothyroxine and reduces levothyroxine absorption from the gastro-intestinal tract. No interaction was observed when levothyroxine was taken at least 4 hours before colesevelam. Therefore levothyroxine should be administered at least 4 hours prior to colesevelam.

Gastric acid binding agents containing aluminium, medications containing iron or calcium
Absorption of levothyroxine can be reduced by concomitant intake of gastric acid binding agents containing aluminium (antacids, sucralfate) and medications containing iron or calcium. Levothyroxine Teva should therefore be taken at least two hours before these medications.

Proton pump inhibitors (PPIs)
Co-administration with PPIs may cause a decrease in the absorption of the thyroid hormones, due to the increase of the intragastric pH caused by PPIs.
Regular monitoring of thyroid function and clinical monitoring is recommended during concomitant treatment. It may be necessary to increase the dose of thyroid hormones.
Care should also be taken when treatment with PPI ends.

Propylthiouracil, glucocorticoids and beta receptor blockers
These substances inhibit conversion of T_4 to T_3 and may lead to a reduced serum concentration of T3.

Amiodarone and iodinated contrast media
Due to their high iodine content the media can initiate both hyperthyroidism and hypothyroidism. Particular caution should be exercised in patients with nodular goitres with possibly undetected autonomy. Amiodarone inhibits the peripheral conversion of T4 (levothyroxine) to T3 resulting in a reduced serum concentration of T3 and an increased serum TSH level. Due to this effect of amiodarone on thyroid function, a dose adjustment of Levothyroxine Teva may be required.

Salicylates, dicumarol, furosemide, clofibrate
Levothyroxine may be displaced from plasma protein binding by salicylates (specifically at doses greater than 2.0 g/day), dicumarol, high doses (250 mg) of furosemide, clofibrate and other substances. This may lead to an initial transient increase in free thyroxine hormones, overall followed by a decrease of total thyroid hormones levels.

Oestrogen based contraceptives, medications used in postmenopausal hormone replacement
Levothyroxine requirements may increase during intake of oestrogen based contraceptives or during postmenopausal hormone replacement therapy. Increased binding of levothyroxine may occur, leading to diagnostic and therapeutic errors.

Sertraline, chloroquine/proguanil
These substances reduce the efficacy of levothyroxine and increase the serum TSH level.

Tricyclic antidepressants

Levothyroxine increases receptor sensitivity to catecholamines thus accelerating the response to tricyclic antidepressants (e.g. amitriptyline, imipramine).

Tyrosine kinase inhibitors
Tyrosine kinase inhibitors (e.g. imatinib, sunitinib, sorafenib, motesanib) may decrease the efficacy of levothyroxine. Therefore, it is recommended that patients are monitored for changes in thyroid function at the start or end of concomitant treatment. If necessary, the levothyroxine dose has to be adjusted.

Digitalis preparations
If levothyroxine therapy is initiated in digitalised patients, the dose of digitalis may require adjustment. Hyperthyroid patients may need their digoxin dosage gradually increased as treatment proceeds because initially patients are relatively sensitive to digoxin.

Sympathomimetic agents
The effects of sympathomimetic agents (e.g. adrenaline) are enhanced.

Effect of drugs inducing cytochrome P-450
Enzyme inducing drugs such as rifampicin, carbamazepine, phenytoin, barbiturates and products containing St John's Wort (*Hypericum perforatum L.*) may increase hepatic clearance of levothyroxine, resulting in reduced serum concentrations of thyroid hormone.
Therefore, patients on thyroid replacement therapy may require an increase in their dose of thyroid hormone if these products are given concurrently.

Protease inhibitors
Post-marketing cases have been reported indicating a potential interaction between ritonavir containing products and levothyroxine. Levothyroxine has been reported to lose its therapeutic effect when co administered with lopinavir/ritonavir. Clinical symptoms and thyroid function should therefore be carefully monitored in patients concomitantly using levothyroxine and protease inhibitors. Thyroid-stimulating hormone (TSH) should be monitored in patients treated with levothyroxine at least the first month after starting and/or ending ritonavir treatment.

Orlistat
Hypothyroidism and/or reduced control of hypothyroidism may occur when levothyroxine and orlistat are taken at the same time. This could be due to a decreased absorption of levothyroxine. See also section 4.4.

Soya products
Can reduce the intestinal absorption of levothyroxine. In children, there have been reports of a rise in the serum TSH level when they were given a diet containing soya and treatment with levothyroxine for congenital hypothyroidism. Unusually high doses of levothyroxine may be required to achieve normal serum levels of T4 und TSH. During and upon termination of a diet containing soya, close monitoring of serum T4 and TSH levels is necessary; a dose adjustment of levothyroxine may be required.

Coffee
Concomitant intake of levothyroxine with coffee should be avoided as this may reduce the absorption of levothyroxine from the gastrointestinal tract.
Therefore, it is recommended to leave a period of half an hour to one hour between taking levothyroxine and consuming coffee to reduce the risk of interactions. Patients who are already being treated with levothyroxine are advised not to change their coffee drinking habit without levothyroxine levels being checked and monitored by their treating physician.

Semaglutide
Co-administration of semaglutide may affect levothyroxine exposure. Total exposure (AUC) of thyroxine (adjusted for endogenous levels) was increased by 33% following administration of a single oral dose of semaglutide and maximum exposure (C_{max}) was unchanged. Monitoring of thyroid parameters and dose adjustments should be considered when treating patients with levothyroxine at the same time as semaglutide.

Interferences with laboratory test
Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results (see section 4.4).

4.6 Fertility, pregnancy and lactation

Particularly during pregnancy and lactation, treatment with thyroid hormones must be consistently administered.

Suppression tests must not be performed during pregnancy and lactation.

Pregnancy
Maintenance of thyroid hormone levels within the normal range is vital for pregnant women to ensure optimal maternal and foetal health. Despite extensive use during pregnancy, no undesirable effects on pregnancy or foetal/neonatal health have been reported to date for levothyroxine.

Levothyroxine requirements may increase during pregnancy due to oestrogen. Thyroid function should therefore be monitored both during and after pregnancy and the thyroid hormone dose adjusted as appropriate. Since elevations in serum TSH may occur as early as 4 weeks of gestation, pregnant women taking levothyroxine should have their TSH measured during each trimester, in order to confirm that the maternal serum TSH values lie within the trimester-specific pregnancy reference range. An elevated serum TSH level should be corrected by an increase in the dose of levothyroxine. Since postpartum TSH levels are similar to preconception values, the levothyroxine dosage should return to the pre-pregnancy dose immediately after delivery. A serum TSH level should be obtained 6-8 weeks postpartum.

During pregnancy levothyroxine sodium is contraindicated as an adjunct to treatment of hyperthyroidism with antithyroid drugs. Additional intake of levothyroxine may increase the required dosage of antithyroid drugs.
Antithyroid drugs, unlike levothyroxine, cross the placental barrier in effective doses and therefore hypothyroidism in the fetus may result. Therefore, hyperthyroidism during pregnancy should be always treated with low-dose single-substance therapy using an antithyroid drug.

Breast-feeding
Levothyroxine is secreted into breast milk during lactation but the concentrations achieved at the recommended therapeutic dose level are not sufficient to cause development of hyperthyroidism or suppression of TSH secretion in the infant.

Fertility
Hypothyroidism or hyperthyroidism are likely to have an effect on fertility. Treatment of hypothyroidism with levothyroxine must be adjusted based on monitoring of laboratory parameters because an insufficient dose is not likely to improve the hypothyroidism and an overdose can lead to hyperthyroidism.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. As levothyroxine is identical to the naturally occurring thyroid hormone, Levothyroxine Teva is not expected to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

If the dosage strength is not tolerated in individual cases or in the event of an overdose, the typical symptoms that occur with hyperthyroidism may appear, particularly if the dose is increased too rapidly at the start of treatment. In these cases, the daily dosage should be reduced, or the medication should be stopped for several days. Treatment may be restarted with cautious dose adjustment once the side effects have disappeared.

In the case of hypersensitivity to levothyroxine or any of the excipients of Levothyroxine Teva, allergic reactions of the skin (e.g. angioedema, rash, urticaria) and respiratory tract region may occur.

The frequencies of adverse events are ranked according to the following: very common (³ 1/10), common (³ 1/100 to < 1/10), uncommon (³ 1/1,000 to < 1/100), rare (³ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

Immune system disorders:
Not known: hypersensitivity reactions.

Endocrine disorders:
Common: hyperthyroidism.

Metabolism and nutrition disorders:
Not known: increased appetite.

Psychiatric disorders:
Very common: insomnia.
Common: nervousness.
Not known: inner restlessness, excitability.

Nervous system disorders:
Very common: headache.
Rare: benign intracranial hypertension (pseudotumor cerebri), particularly in children.
Not known: tremor.

Cardiac disorders:
Very common: palpitations.
Common: tachycardia.
Not known: anginal discomfort, cardiac arrythmias, heart failure, myocardial infarction.

Vascular disorders:
Not known: flushing, hypertension, circulatory collapse in very low birth weight preterm neonates (see section 4.4).

Respiratory, thoracic and mediastinal disorders:
Not known: dyspnoea.

Gastrointestinal disorders:
Not known: abdominal pain, nausea, diarrhoea, vomiting.

Skin and subcutaneous tissue disorders:
Not known: angioedema, rash, urticaria, pruritus, hyperhidrosis, transient hair loss in children.

Musculoskeletal and connective tissue disorders:
Not known: muscle cramps, muscle weakness, osteoporosis at suppressive doses of levothyroxine, especially in postmenopausal women, mainly when treated for a long period, craniostenosis in infants and premature closure of epiphysis in children.

Reproductive system and breast disorders:
Not known: menstrual irregularities.

General disorders and administration site conditions:
Not known: heat intolerance, fever.

Investigations:
Not known: weight loss.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Symptoms
An increased T3 level is a more reliable sign of an overdose than elevated T4 or fT4 levels.

Symptoms of a moderate to severe metabolic increase occur in the event of overdose and intoxication (see section 4.8). Discontinuation of treatment and a follow up examination are recommended, depending on the extent of the overdose.

In cases of intoxication incidence (suicide attempts) in humans, doses of up to 10 mg levothyroxine have been tolerated without complications. Serious complications, such as a threat to vital functions (respiration and circulation), are not anticipated unless coronary heart disease is present. Nevertheless, cases of thyrotoxic crisis, seizures, heart failure and coma have been reported. Individual cases of sudden cardiac death have been reported in patients with many years of levothyroxine abuse.

Treatment
In the event of an acute overdose, gastrointestinal absorption can be reduced by administering medicinal charcoal. Treatment is mostly symptomatic and supportive. For severe beta sympathomimetic effects such as tachycardia, state of anxiety, agitation and hyperkinesia, symptoms can be alleviated with beta receptor blockers. Antithyroid agents are not indicated, as the thyroid is already fully quiescent.

At extremely high doses (suicide attempt), plasmapheresis may be of assistance.

An overdose with levothyroxine demands a prolonged period of monitoring. Onset of symptoms may be delayed by up to 6 days, due to the gradual conversion of levothyroxine to liothyronine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Thyroid Hormones, ATC code: H03AA01

Mechanism of action
The action of synthetic levothyroxine contained in Levothyroxine Teva is identical to that of the naturally occurring thyroid hormone, which is mainly produced by the thyroid gland. The body cannot differentiate between endogenously produced and exogenous levothyroxine.

Following partial conversion to liothyronine (T_3) particularly in the liver and kidney and after passage into bodily cells, the characteristic thyroid hormone effects on development, growth and metabolism are observed, mediated by activation of T_3 receptors.

Thyroid hormone replacement leads to normalisation of metabolic processes. Thus, for example, a rise in cholesterol due to hypothyroidism is significantly reduced by the administration of levothyroxine.

5.2 Pharmacokinetic properties

Absorption
Depending to a large extent on the type of galenic formulation, up to ≤ 80% of orally administered levothyroxine is absorbed when taken in the fasting state, mainly from the upper small intestine. Absorption is significantly reduced if the product is administered with food. Peak plasma levels are reached about 2 to 3 hours after ingestion.

At the start of oral therapy, onset of action occurs after 3 to 5 days.

Distribution
The volume of distribution is calculated to be about 10 to 12 l. Levothyroxine is approximately 99.97% bound to specific transport proteins. As this protein hormone binding is not covalent, there is a constant and very rapid exchange between free and bound hormone.

Levothyroxine crosses the placenta only in small amounts. During normal dose therapy, only small amounts of levothyroxine are secreted into breast milk.

Biotransformation and Elimination
Metabolic clearance for levothyroxine is around 1.2 l plasma/day. It is mainly degraded in the liver, kidney, brain and muscle. The metabolites are excreted with the urine and faeces.

The half life of levothyroxine is about 7 days, although it is shorter in hyperthyroidism (3 to 4 days) and longer in hypothyroidism (about 9 to 10 days).

Due to its high protein binding, levothyroxine is not amenable to haemodialysis or haemoperfusion.

5.3 Preclinical safety data

Acute toxicity
Acute toxicity of levothyroxine is very low.

Chronic toxicity
Chronic toxicity studies were performed in different animal species (rats, dogs). At high doses, signs of hepatopathy, increased occurrence of spontaneous nephrosis and organ weight changes were seen in rats. No significant adverse reactions were observed in dogs.

Mutagenicity
There are no data available with regard to the mutagenic potential of levothyroxine. To date, there has been no suspicion or evidence of offspring damage due to genome changes caused by thyroid hormones.

Carcinogenicity
Long term animal studies have not been performed to investigate the tumorigenic potential of levothyroxine.

Reproductive toxicity
Thyroid hormones cross the placenta in very small amounts.

There are no available data regarding impairment of male or female fertility. There is no suspicion or evidence that this might occur.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Maize starch, pregelatinised
Microcrystalline cellulose
Silica, colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

100 micrograms: PVC/PVDC white– Aluminium blisters

Pack sizes: 20, 28, 30, 50, 56, 60, 84, 90, 100, 112 and 250 tablets.

PA/Al/PVC/Al – Aluminium perforated unit dose blisters
Pack size: 50
PVC/PVDC white – Aluminium perforated unit dose blisters
Pack size: 50

PA/Al/PVC/Al – Aluminium blister calendar packs
Pack size: 98

PVC/PVDC white – Aluminium blister calendar packs
Pack size: 98

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Teva Pharma B.V.
Swansweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA0749/143/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 23rd November 2012
Date of last renewal 28th October 2017.

10 DATE OF REVISION OF THE TEXT

October 2025