SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TODAVİT powder for solution for I.M./I.V. injection/ infusion
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

In each vial;	
Vitamin A (as Retinol palmitate)	3500 IU (2,06 mg)
Vitamin D3 (Cholecalciferol) (made from sheep wool.)	220 IU (0,22 mg)
Vitamin E (11,2 mg Vitamin E as acetate)	11,2 IU
Vitamin C (Ascorbic acid)	125 mg
Vitamin B1 (Thiamine; 3,935 mg asThiamine HCl)	3,51 mg
Vitamin B2 (Riboflavin; 5,26 mg Riboflavin sodium phosphate)	4,14 mg
Vitamin B6 (Piridoxin; 5,5 mg as Piridoxin hydrochloride)	4,53 mg
Vitamin B12 (Cyanocobalamin)	0,006 mg
Folik acid	0,414 mg
Pantothenic acid (16,15 mg asDexpanthenol)	17,25 mg
D-Biotin	0,069 mg
Nicotinamide	46 mg

Excipients:

Sodium hydroxide: q.s.

Soy lecithin: 112.5 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Yellow-orange colored lyophilized cake.

Sterile.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

In accordance with the daily needs of adults and children over 11 years of age,it is indicated when oral intake is contraindicated or inadequate (malnutrition, gastrointestinal malabsorption, parenteral nutrition, etc.) or when it is not possible, intravenously.

4.2. Posology and method of administration

Posology / Application frequency and duration:

In adults and children over 11 years old, the daily dose is 1 vial.

In special cases with increased nutritional requirements (severe burns, etc.), high doses such as 2-3 vials daily can be used.

Method of Application:

It is used intravenously or intramuscularly.

Intravenous use:

- 5 mL water of injection is applied into the vial with an injector. The vial is shaken gently to provide a homogeneous mixture.
- Then it can be applied as a slow intravenous injection (at least 10 minutes) or it can be applied by infusion in isotonic sodium chloride or dextrose solutions.

TODAVİT can also be added by adding to parenteral nutrition mixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements.

Intramuscular use:

- The preparation in the lyophilized vial is diluted with 2.5 mL of water for injection.
- It is recommended to make the application deep intramuscularly.

See also section 6.6 for application details.

Additional information on special populations

Renal /Hepatic impairment

There is no specific dosage recommendation for this group of patients, as there is no specific study for this population. Fat-soluble vitamin levels should be monitored in those with impaired kidney function and should not be used in those with jaundice since it contains glycocolic acid.

Dosage in patients with hepatic impairment: In patients with hepatic jaundice or pronounced cholestasis according to laboratory values, it is necessary to carefully monitor hepatic functions at repeated doses and long-term applications and adjust the dose accordingly (see section 4.4 Special warnings and precautions for use).

Pediatric Population

The dose and infusion rate to be applied are adjusted by the physician according to the patient's weight, clinical and biological status, and co-administration, as in adults. There are insufficient data on its use under the age of 11 in this population.

Geriatric population

The dose and infusion rate to be applied are adjusted by the physician according to the patient's weight, clinical and biological status, and co-administration, as in adults.

4.3. Contraindications

-Hypersensitivity to the substances in its composition

- Thiamine (vitamin B1) intolerance

- Children under 11 years old

- If you are allergic to peanuts or soya.

TODAVİT is contraindicated in the presence of hypervitaminosis.

4.4. Special warnings and precautions for use

- Since it contains vitamin A in its composition, when applied with other preparations containing vitamin A, the total dose administered should be calculated.

- TODAVİT does not contain vitamin K. Vitamin K should be applied separately when necessary.

- During intravenous bolus administration, a moderate and only increase in SGPT transaminases was observed in several patients with the development of inflammatory enterolith. The increase in the level of transaminases drops rapidly with discontinuation of the application. It is recommended to follow the levels of transaminases in these patients.

- Since TODAVİT contains glycocolic acid, it is necessary to carefully monitor hepatic functions at repeated doses and in long-term applications in patients with hepatic jaundice or marked cholestasis according to laboratory values.

- The preparation does not lose its effectiveness for 6 hours, protected from light, at room temperature after reconstitution, and should not be stored at room temperature for more than 6 hours after reconstitution.

-Folic acid in the composition of TODAVİT may camouflage an existing state of pernicious anemia.

- Vitamin D3, one of the active ingredients of TODAVİT, is a vitamin of animal origin derived from sheep's wool.

- In the production process of TODAVİT, hydrochloric acid or sodium hydroxide is added to make pH 5-7.

This medicinal product contains less than 1 mmol (23 mg) sodium per dose; in other words, it does not contain sodium.

4.5. Interaction with other medicinal products and other forms of interaction

- Since decarboxylation of L-Dopa takes place through an enzyme bound to vitamin B6, vitamin B6 (pyridoxine) can reduce the effectiveness of L-Dopa. To prevent this interaction, a dopa decarboxylate inhibitor such as carbidopa can be added to the treatment.

-Folic acid can increase metabolism of some antiepileptics such as phenobarbital, phenytoin

and primidone. Plasma concentrations of antiepileptics used with folic acid should be monitored and their doses adjusted if necessary.

Additional information on special populations
No interaction studies have been performed.

Pediatric population:
No interaction studies have been performed

4.6. Pregnancy and lactation
General recommendation
Pregnancy category: C

There is not enough data on the use of TODAVİT in pregnant women. Studies on animals are insufficient in terms of effects on pregnancy / and-or / embryonal / fetal development / or or / birth / and-or / postpartum development (see section 5.3). The potential risk for humans is unknown.

Women with childbearing potential / Contraception

It has no known negative effects.

Pregnancy

Vitamins can be taken according to daily requirement amounts. However, there is no controlled study conducted in animals or pregnant women with daily dose in the amounts contained in TODAVİT. Therefore, TODAVİT should be used if there is a clear and precise requirement during pregnancy (if the possible benefit to the mother is more than the possible harm to the fetus).

TODAVİT contains vitamin A. Vitamin A requirements are met during normal nutrition. There are some data showing that it increases the risk of teratogenicity when used in high doses (over 10,000 IU per day) during pregnancy. In the first trimester of pregnancy and women planning to become pregnant, doses higher than 10,000 IU daily should not be used. This situation is especially high in terms of vitamin A liver etc. It should be taken into consideration in those who consume food.

Lactation

It is not recommended to use TODAVİT in breastfeeding mothers, since it is known that vitamins are secreted with milk and the risk of overdose in the child.

Reproduction / Fertility
No adequate data is available on the effect on reproduction.

4.7. Effects on ability to drive and use machines
It has no effect on the ability to drive and use machines.

4.8. Undesirable effects

The frequency classification of adverse drug reactions is as follows:

Very common (≥ 1/10), Common (≥ 1/100; < 1/10), Uncommon (≥ 1/1000; < 1/100), Rare (≥ 1/10,000; < 1/1000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data)

Allergic reactions to vitamin B1 may occur.

Immune system diseases
Rare: allergic reactions
Very rare: Anaphylactic shock

In addition, in some cases an increase in SGPT transaminases may occur during intravenous bolus injection (see section 4.4 Special warnings and precautions for use). There is a risk of pain in the intramuscular injection site. In order not to cause pain in intramuscular injection, it is recommended that the application be performed intramuscularly or by intravenous injection (see section 4.2 Posology and method of administration).

4.9. Overdose and treatment

In long-term and high dose applications, symptoms of A hypervitaminosis and D hypervitaminosis (related to hypercalcemia) may develop.

Clinical symptoms of acute A hypervitaminosis include gastrointestinal disorders, headache, intracranial hypertension (understood as a tense fontanel in infants), papillary edema, psychiatric disorders, irritability, convulsions, delayed generalized desquamation

Clinical symptoms of chronic A hypervitaminosis (in cases without vitamin A deficiency, the risk of poisoning during long-term and high doses administration) include intracranial hypertension, cortical hyperosteosis of long bones and early epiphysis fusion. In chronic cases, the diagnosis is usually made with painful and sensitive subcutaneous swelling in the extremities. On the x-ray, periosteal thickening is observed in the diaphysis in the ulna, fibula, clavicle and ribs. In case of overdose, the application should be terminated immediately, the patient should be evaluated and appropriate laboratory tests should be performed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic Group: Intravenous solution supplements, vitamins
ATC Code: B05XC

TODAVİT is a lyophilized multivitamin preparation suitable for parenteral use after reconstitution with sterile water for injection. The acidity of the preparation was adjusted with sodium hydroxide and hydrochloric acid to pH 5-7 after reconstitution. Vitamins in the composition of TODAVİT are organic substances that are required in small amounts for many metabolic processes in the body. They are not synthesized at all in the body, or they are synthesized inadequate and very little. Vitamins can be classified as water-soluble and fat-soluble:

-Vitamins A, D, E, K are fat-soluble vitamins.

- Biotin, folic acid, niacin, pantothenic acid, vitamins B1, B2, B6 and B12, and vitamin C are classified as water-soluble vitamins.

Vitamin deficiencies can usually develop after dietary inadequate intake or increased need, such as pregnancy, or during illnesses (such as chronic alcoholism, hyperthyroidism, cachexia, severe illnesses or injuries), such as absorption, use or excretion.

Vitamin preparations can be used clinically in the prevention and treatment of specific vitamin deficiencies.

When there is a vitamin deficiency, it is often accompanied by other vitamin deficiencies (clinically or subclinically). Therefore, the use of multivitamin preparations may be beneficial in these patients.

The use of high amounts of vitamins is recommended in many diseases. However, there is insufficient information about the utility of this use. The excessive intake of water-soluble vitamins has little effect due to their excretion in the urine. Excessive intake of fat-soluble vitamins is dangerous due to their accumulation in the body.

Water-soluble vitamins tend to be gradient when diluted, especially in solutions that are exposed to light. The addition of vitamins to nutritional mixes should be done just before the infusion. After the mixture is prepared, they should generally be used within 24 hours and protected from light.

Vitamin A:

- It is found in the body in 3 ways: retinol, retinoic acid and retinal.

Physiological functions of vitamin A are mixed: it takes part in cell proliferation and differentiation, visual and reproductive functions, and steroid metabolism.

Vitamin D:

- Takes part in phosphorus and calcium homeostasis.

- Stimulates specific transport mechanisms in the intestine, bones and kidney, and increases serum calcium, phosphorus levels.

- The main effects of vitamin D are:

o Stimulation of active transport of calcium and phosphorus from the gut

o Stimulation of calcium and phosphorus resorption from bone

o Stimulation of renal reabsorption of calcium.

Vitamin E:

Its main function is to protect some basic molecules from oxidation and stabilize cell membranes in cellular metabolism as an antioxidant. It protects vitamin A and carotenes from oxidation.

- Takes part in the regulation of the synthesis of the "heme" part of the hemoglobulin molecule in erythrocytes.

Vitamin B1 (thiamine):

- It is present in a small amount in the body.

- It acts as a coenzyme in oxidative decarboxylation reactions.

- It is necessary for reactions in energy metabolism.

- Its active form, thiamine-pyrophosphate (TPP), is involved in carbohydrate metabolism and neural conduction.

Vitamin B2 (riboflavin):

-It undergoes phosphorylation, leading to the formation of two phosphorus esters, flavin monoucleotide (FMN), which is the prosthetic group of some enzymes, and flavin adenine dinuclotide (FAD). These flavoproteins have important roles in the degradation of different substrates.

- It is involved in enzymatic reactions producing cellular energy (Krebs cycle, respiratory chain, metabolism of fatty acids and purine).

Niacin (nicotinic acid):

- Active form; nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) are two coenzymes.

These two coenzymes act as hydrogen acceptors and donors. They are involved in the synthesis and degradation of carbohydrates, lipids and proteins.

Vitamin B5 (pantothenic acid):

- It is included in the composition of Coenzyme-A. It is involved in many metabolic reactions, especially the synthesis and degradation reactions of sugars, fatty acids and steroids.

Vitamin B6:

- It is involved in many metabolic reactions.

- As a coenzyme in the metabolism of amino acids, decarboxylation is required for transmination, deamination and transsulfilation reactions.

Biotin:

- It has an important role in the intermediate metabolism of carbohydrates, lipids and proteins.

- It has an important role in carboxylation reactions.

- It is involved in the metabolism of purine, pyrimidine and some amino acids (leucine, ornithine, citrulline, methionine, etc.).

Folic acid:

- It does not have biological activity alone. Its biologically active form is its reduced form.

-Tetrahydrofolic acid, a reduced form of folic acid, is a common substrate for all the folic coenzymes involved in the transfer of monocarbonate groups formed as a result of serine and histidine metabolism.

- Takes part in the synthesis of methionine, purine and nucleic acids.

Vitamin B12 is essential for the synthesis of pyrimidines and DNA.

C vitamin:

- Its biological functions are not yet fully understood.

- Contributes to the transfer of hydrogen ions and regulation of intracellular oxidation-reduction potential.

- Amino acid is necessary for collagen, microsomal metabolism of drugs, production and metabolism of adrenergic hormones, and folate metabolism.

- Also takes part in the defense mechanism and antibody synthesis against bacterial and viral infections.

5.2. Pharmacokinetic properties

The pharmacokinetic properties of TODAVİT are the same as those of 12 vitamins in its composition.

General properties

Absorbation:

It is not applicable as the product is given intravenously.

Distribution:

- Vitamin A:

Vitamin A circulates in plasma bound to a specific α1-globulin (retinol-binding protein).

Under normal conditions, vitamin A has been stored in the body in sufficient quantities up to about 2 years. Vitamin A is mainly stored as retinyl palmitate, while small amounts of retinol and retinal are stored in the liver. It is distributed as retinyl palmitate in kidney, lung, adrenal, retina and intraperitoneal adipose tissue in smaller amounts except liver. It cannot easily pass through the placenta; dispersed into milk.

- Vitamin D (cholecalciferol):

The metabolites of vitamins D, which are chemical substances with similar chemical structure and collectively called vitamin D, include alphacalcidiol (1-hydroxy cholecalciferol), calcitriol (1,25-dihydroxycholecalciferol), cholecalciferol (vitamin D3), dihydrotacysterol (DHT) and ergocalciferol (vitamin D2). takes place. TODAVİT contains cholecalciferol (vitamin D3), which is normally produced by ultraviolet ray in human skin. Cholecalciferol in the composition of TODAVİT is metabolized to 25-hydroxycholecalciferol in the liver, and then it is hydroxylated in the kidneys and turns into calcitriole (1.25-dihydroxycholecalciferol), which is considered the most active form of vitamin D. Vitamin D3 metabolites are transported in the plasma with specific plasma proteins and continue their therapeutic activity in plasma for about 3-5 days. It passes through the placenta; dispersed into milk.

- Vitamin E:

It is rapidly distributed to all tissues and stored in adipose tissue. Vitamin E passes through the placenta; dispersed into milk.

- Vitamin C (ascorbic acid):

It is dispersed into the watery compartments of the body. It is found in high concentrations in the adrenal cortex, leukocytes, platelets, and pituitary gland.

- Vitamin B1 (thiamine):
- Thiamine is widely distributed in all tissues, with the highest concentrations in the liver, brain, kidneys and heart tissue. When the intake is higher than the daily requirement, the level in the tissues is 2-3 times higher than normal.
- Vitamin B2 (riboflavin):

The rate of protein binding in plasma is 60%. It is bound to plasma proteins as riboflavin 5-phosphate (flavin mononucleotide [FMN]) and flavin adenine dinucleotide (FAD). Riboflavin is widely distributed as FMN and FAD in many tissues, including gastrointestinal mucosa cells, erythrocytes and liver tissue. Riboflavin is freely stored only in the retinal tissue; There is limited storage mainly in the form of FAD in the liver, spleen kidneys and heart. Riboflavin passes through the placenta; dispersed into milk.

- Vitamin B6 (pyridoxine):

Vitamin B6 is a water-soluble B-complex vitamin found in many foods such as pyridoxine, pyridoxal and pyridoxamine. These forms of vitamin B6 taken with foods are converted into pyridoxal phosphate and pyridoxamine phosphate, which are essential co-enzymes in the synthesis of carbohydrate and lipid metabolism, GABA, which is an inhibitory neurotransmitter with the molecule, of some amino acids such as tryptophan in the human body. Pyridoxine hydrochloride in the composition of TODAVIT is not bound to proteins in plasma. It is mainly stored in the liver and to a lesser extent in muscle and brain tissue.

- Vitamin B12 (cyanocobalamin):

Vitamin B12 is a vitamin B group that contains cobalt. Cyanocobalamin and hydroxycobalamin are synthetic forms of vitamin B12. Vitamin B12 is distributed to the liver, bone marrow and other tissues. Vitamin B12 passes through the placenta; dispersed into milk.

- Vitamin B9 (folic acid):

Normal levels of folate in serum about 5 to 15 ng / mL; Its normal levels in the cerebrospinal fluid are about 16 to 21 ng / mL.

- Vitamin B5 (pantothenic acid):

It is distributed to all tissues with a concentration of 2 to 45 mcg / g.

- Vitamin B8 (biotin):

Biotin is found in plasma freely or depending on proteins; it is mainly stored in the liver.

- Nicotinamide:

Nicotinamide, also known as niacin amide, is the amide of vitamin B3 (niacin). Nicotinamide is a water-soluble vitamin from the group of B vitamins. In the human body, niacin turns into nicotinamide, and therefore both work the same in terms of vitamin functions. However, nicotinamide does not have the same pharmacological and toxic effects as niacin, and although it may have toxic effects to the liver in adults at doses higher than 3 g daily, it does not lower cholesterol or cause flushing.

Biotransformation:

- Vitamin A:

Retinol esters taken orally are hydrolyzed in the gastrointestinal lumen by pancreatic enzymes. Retinol conjugates with glucuronic acid; ß-glucuronide enters the enterohepatic circulation, oxidizes and turns into retinal and retinoic acid. Retinoic acid undergoes decarboxylation and undergoes advanced conjugation with glucuronic acid. Retinol is mainly converted to retinyl palmitate as re-esterified.

- Vitamin D3 (cholecalciferol):

Cholecalciferol in the composition of TODAVİT is metabolized to 25-hydroxycholecalciferol in the liver, and then hydroxylated in the kidneys and turns into calcitriole (1.25-dihydroxycholecalciferol), which is considered the most active form of vitamin D. It has been determined that calcitriol has many metabolites with different degrees of vitamin D activity. These metabolites are: 1 25, 25-dihydroxy-24-oxo-cholecalciferol; 1 α23,25-trihydroxy-24-oxo-cholecalciferol;1α, 24R, 25-trihydroxycholecalciferol; 1 α, 25Rdihydroxycholecalciferol- 26,23S-lactone;1α,25S,26-trihydroxycholecalciferol; 1α 25-dihydroxy-23-oxo-cholecalciferol; la, 25R, 26-trihydroxy-23-oxo-cholecalciferol and l-hydroxy-23-carboxyl-24, 25, 26, 27-tetranocholecalciferol.

- Vitamin E (alpha-tocopherol):

It is extensively metabolised to the glucoronides of the tocopheronic acid and its γ–lactone, mainly in the liver.

- Vitamin C (ascorbic acid):

Vitamin C exchanges electrons by interacting with enzymes with mono-oxigenase or di-oxigenase activity, which play a role in the biosynthesis of noradrenaline and carnitine, the amitization of peptide hormones, and tyrosine metabolism. Therefore, no real metabolism can be mentioned. Dehydro-ascorbate, oxalic acid, 2-O-methyl ascorbate and 2-ketoascorbitol, whose metabolites can be counted, are excreted in the urine from the body.

- Vitamin B1 (thiamine):

Thiamine is rapidly metabolized to thiamine pyrophosphate (co-carboxylase) coenzyme by taking ATP in plasma.

- Vitamin B2 (riboflavin):

It is transformed into riboflavin 5-phosphate (flavin mononucleotide [FMN]) by undergoing phosphorylation in gastrointestinal mucosa cells, erythrocytes and liver; The FMN formed in the liver turns into flavin adenine dinucleotide (FAD) in the liver.

Vitamin B6 (pyridoxine):

Pyridoxine is converted to 4-pyridoxic acid metabolite metabolized in the liver.

- Vitamin B12 (cyanocobalamin):
- Vitamin B9 (folic acid):

Folic acid converts to 7,8-dihydrofolic acid in the liver and then to 5,6,7,8-tetrahydrofolic acid

- Vitamin B5 (pantothenic acid)
- Vitamin B8 (biotin)
- Nicotinamide:

In cells, niacin turns into nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) in very similar ways to nicotinamine. NAD^+ and $NADP^+$ play a role as a coenzyme in a series of oxidation-reduction enzyme reactions.

Elimination:

- Vitamin A:

Retinal, retinoic acid and other water-soluble metabolites are excreted in urine and faeces. Retinoic acid is mainly excreted in bile by elimination of bile. Unchanged retinol is generally not excreted in the urine.

- Vitamin D 3 (cholecalciferol):

The elimination half-life of calcitriol in serum is 9-10 hours. D vitamins are eliminated from kidneys and eliminated through urine and bile and excreted in faeces.

- Vitamin E (alpha-tocopherol):

Vitamin E is mainly eliminated through bile and excreted in faeces. It also has urinary excretion.

- Vitamin C (ascorbic acid):

It is believed that the average half-life of ascorbic acid is about 16 to 20 days. Since vitamin C is a water-soluble vitamin, it is excreted in the urine. Threshold plasma values of ascorbic acid for excretion from the kidneys are considered to be between 0.8 and 1.4 mg / dl. Vitamin C above these levels is excreted through the kidneys.

- Vitamin B1 (thiamine):

Excess thiamine is excreted in the urine.

- Vitamin B2 (riboflavin):

The half-life of vitamin B12 after oral or IM injection is about 66 to 84 minutes. Up to 9% of an

applied dose is unchanged; It is not known how the remainder was eliminated.

- Vitamin B6 (pyridoxine):

The plasma half-life is about 15 to 20 days. It is mainly excreted in the urine as a 4-pyridoxic acid metabolite.

- Vitamin B12 (cyanocobalamin):

50% to 98% of vitamin B12 is excreted in the urine.

- Vitamin B9 (folic acid):

Up to 90% of folic acid is eliminated in urine and in small amounts in faeces.

- Vitamin B5 (pantothenic acid):

About 70% is excreted in the urine.

- Vitamin B8 (biotin):

Biotin is mainly excreted unchanged in the urine.

- Nicotinamide

Linearity / nonlinear situation:

There is not enough data on this subject.

Characteristic features in patients

- Vitamin A:

In patients with pneumonia and chronic nephritis, unchanged retinol can also be excreted in the urine.

- Vitamin D3 (cholecalciferol):

Serum vitamin D levels decrease in patients with nephritic syndrome or hemodialysis, and the time to reach the highest levels of external vitamin D in plasma is prolonged.

- Vitamin B2 (riboflavin):

Its elimination by hemodialysis is slower than its normal excretion from the kidneys. Although urinary elimination is slower in newborn babies, the total amount discarded is the same as in infants.

Pharmacokinetic / pharmacodynamic relationship (s)

Plasma concentrations of vitamins A, D and E reach their normal levels in patients receiving TODAVİT during long-term parenteral nutrition and thus maintain within their normal limits**.**

5.3. Preclinical safety data
Pre-clinical safety studies have not been performed with TODAVİT.
In safety studies with each vitamin in the composition of TODAVİT, no evidence of a potential risk for use in humans was found.

6. PHARMACEUTICAL PROPERTIES

6.1. List of Excipients

Glycine

Glycocolic acid

Soya lecithin

Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)

Water for injection

6.2. Incompatibilities
The compatibility of drugs with the same application set should be evaluated in advance. In order to determine whether the drugs to be used together do not cause any incompatibility, attention should be paid to the mixture to be clear and the summary of product characteristics of the product to be applied together should be checked.

6.3. Shelf-life
24 months

Although TODAVİT does not lose its effectiveness for 6 hours after reconstitution, protected from light at room temperature and 24 hours in the refrigerator, it is recommended to be used as soon as possible.

6.4. Special precautions for storage
It should be stored protected from light at room temperature below 25 ° C.

6.5. Nature and contents of container

Amber colored Type 1 glass vial sealed with a bromobutyl stopper and a transparent flip off cap.

6.6. Special precautions for disposal of waste materials derived from the medicinal product and other handling

Unused products or waste materials should be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

Vials are for single use. Partially used vials should not be stored, local regulations should be discarded.

It is recommended to be used intravenously with slow infusion after reconstitution as described in the section "Section 4.2 Posology and method of administration".

If intramuscular application will be performed, it is recommended to apply deeply.

If it is to be applied by infusion in isotonic sodium chloride or dextrose solutions, the final mixture should be checked before use. Only clear and particle-free products should be used.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

2019/689

9. DATE OF FIRST LICENSE/RENEWAL OF THE LICENSE

Date of first license: 19.12.2019
Date of renewal of the license:

10. DATE OF REVISION OF THE TEXT