

PACKAGE LEAFLET

TYOSOD 0.5 g I.V. powder for solution for injection

It is administered intravenously.

Sterile

- **Active substance:** Each vial contains 0.5 g thiopental sodium (as thiopental sodium and sodium carbonate) as the active substance.
- **Excipient(s):** There are no excipients.

Please read this PACKAGE LEAFLET carefully before you start having this medicine, because it contains important information for you.

- *Keep this package leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are using this drug, if you go to a doctor or a hospital please tell your doctor that you are taking this medicine.*
- *Follow the instructions, written in this package leaflet, exactly. Do not use **higher** or **lower** doses other than the recommended dose to you.*

This leaflet includes the following topics:

- 1. What TYOSOD is and what it is used for?**
- 2. Before you use TYOSOD**
- 3. How to use TYOSOD?**
- 4. Possible side effects**
- 5. How to store TYOSOD?**

1. What TYOSOD is and what it is used for?

TYOSOD contains thiopental sodium (as thiopental sodium and sodium carbonate) as the active substance. It is an anesthetic agent, which may be given:

- as a general anesthetic or to make you sleepy before using another anesthetic agent,
- before using agents to prevent pain or to relax muscles,
- to control fits,
- to reduce intracranial pressure.

This injection is usually given to you by a doctor directly into a vein.

2. Before you use TYOSOD

DO NOT USE TYOSOD in the following cases

If you;

- are **allergic** to thiopental sodium or have had a reaction to thiopental or to other barbiturates (such as some anesthetics),
- have any **respiratory abnormality** (difficulty in breathing), such as obstruction in your lungs or tubes,
- have **acute asthma** (short term)
- are in **severe shock**
- have **myotonic dystrophy** - a muscular disease
- have **porphyria** - a metabolic disorder.

If any of these apply to you, inform your doctor or nurse, they will usually give you another medicine instead.

Take SPECIAL CARE with TYOSOD in the following cases

If you have/are any of the following, inform your doctor before using TYOSOD as dose adjustment may be required:

- **heart disease** or **circulatory problems**, as these can suddenly be made more severe by TYOSOD
- severe **anaemia**, blood pressure problems (high **blood pressure** or low **blood pressure**), increased **blood potassium**, increased **blood urea**, **bacterial infection** in the blood, **severe bleeding**
- **liver** or **kidney disease**
- increased **pressure in the brain**
- **muscle weakness** or **degeneration** (such as myasthenia gravis or muscular dystrophies)
- **thyroid gland** problems
- **diabetes**
- **dehydration, malnutrition** or **wasting**
- underproduction of steroid hormones by the **adrenal gland** (even when controlled by cortisone)
- **a metabolic disorder** caused by an underactive thyroid gland (dose may need to be reduced)
- **asthma**

- **burns**
- **in shock**
- **hypovolaemia** - low levels of fluids in the body
- **elderly** (dose may need to be reduced)
- **taking opioid analgesic** - strong pain relievers
- **on a sodium-controlled diet** as this medicine contains 53.5 mg sodium per vial.

Please consult your doctor if these warnings apply to you, even at any time in the past.

Use of TYOSOD with food and beverages

No data available.

Pregnancy

Before using the drug, consult your doctor or pharmacist.

If you are pregnant or planning to become pregnant, your doctor will consider the benefits and risks of giving TYOSOD to you.

If you notice that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Before using the drug, consult your doctor or pharmacist.

If you are breastfeeding, your doctor will consider the benefits and risks of giving TYOSOD to you.

Driving and using machines

You may experience dizziness (vertigo), disorientation or sedation; these will disappear very quickly. Do not drive or use machinery, especially during the first 24-36 hours after the injection.

Important information on some of the ingredients of TYOSOD

This medicinal product contains 53.5 mg sodium per vial. This should be considered for patients on a controlled sodium diet.

Taking with other medicines

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines including those without a prescription.

The following medicines can affect, or be affected by this injection and may need to be adjusted before or after receiving this injection:

- Antibiotics (medicines to treat bacterial infections such as vancomycin, isoniazid and sulfonamides)
- Sulfafurazole (an antibiotic) - smaller doses of TYOSOD given more frequently may be required
- Antihypertensives (used to treat high blood pressure or heart problems), such as ACE inhibitors, angiotensin-II receptor antagonists, alpha blockers, beta-blockers, calcium antagonists, diuretics, vasodilating antihypertensives, alpha adrenergic neuron blockers)
- Nitrates (used to treat angina)
- Antidepressants (used to treat depression); such as monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants
- Benzodiazepines, such as midazolam - to treat anxiety
- Lithium (used to treat mania, manic-depressive illness or depression)
- Analgesics (used to treat pain); such as aspirin
- Opioid analgesics (strong pain relievers); such as morphine, fentanyl and pethidine
- Phenothiazines (used to treat psychosis and nausea); such as promethazine
- Drugs that have an effect on the gastrointestinal tract (gut), such as metoclopramide or droperidol
- Drugs that have an effect on the central nervous system (CNS)
- Cyclizine (used to treat dizziness, nausea and vomiting)
- Drugs used in the treatment of high blood pressure; such as diazoxide, methyldopa, moxonidine, hydralazine, minoxidil and nitroprusside
- Probenecid (used to treat gout and high uric acid in the blood)
- Oral anticoagulants (to thin your blood)
- Estrogens (oral contraceptives or hormone replacement therapy)
- Herbal medicines; such as valerian or St. John's Wort.

Alcohol and TYOSOD

The effect of alcohol may be increased in the period after treatment with thiopental sodium (at least the first 24 hours).

If you are using or have recently used any prescribed or unprescribed medicine, please give information to your doctor or pharmacist.

3. How to use TYOSOD?

Instructions for the proper use and dose/administration frequency:

The sterile powder is made into solution and is **not mixed** with other acidic injections.

The dose will be adjusted according to **your age, sex, body weight** and response to the medication.

Administration route and method:

This injection is usually given directly into your vein by your doctor, but it can also be given as a drip into the vein.

If TYOSOD is accidentally administered into an artery instead of a vein, it can cause damage to your tissues. Your doctor will treat these effects (similar problem occurs if TYOSOD leaks from the vein into the surrounding tissues). If you experience severe pain near the injection site, inform your doctor or nurse immediately so that treatment can be started as soon as possible.

Different age groups:

Use in children:

Anesthesia:

Adults: 100-150 mg injected over 10-15 seconds.

Use in children:

Anesthesia: The calculated dose is usually 2-7 mg/kg.

Use in the elderly:

Anesthesia: As for adults, although sometimes lower doses may be required.

You will normally feel the effects within 30 seconds and be asleep within one minute. Further small doses will be given to you as necessary (you will normally be asleep during this process).

Convulsions (fits):

75mg to 125mg, given as soon as possible after the convulsion begins. Further doses may be required and your doctor will decide the best dose to give.

Neurological patients with raised intracranial pressure: Intermittent injections of 1.5 to 3mg/kg.

Reduced doses may be needed if you have:

- liver disease (including jaundice), shock, dehydration, severe anaemia, high blood level of potassium, infection in your blood
- myxoedema (a metabolic disorder caused by an underactive thyroid gland).
- received morphine or similar medicines before you are given TYOSOD
- received a medicine called sulfafurazole - your doctor may need to give you smaller and more frequent doses of TYOSOD

Increased doses may be needed if you:

- are a heavy and frequent drinker of alcohol
- regularly take non-prescribed drugs.

The dose of TYOSOD may need to be increased or given with another medicine to increase its effect.

Special cases:

Kidney/Liver insufficiency:

In patients with severe renal impairment, 75% of the overall dose is administered at the usual dosing frequency.

There is no information on its use in hepatic insufficiency.

If you have the impression that the effect of TYOSOD is too strong or weak, talk to your doctor or pharmacist.

If you have more TYOSOD than you should:

This product will be given to you under medical supervision, it is therefore unlikely that you will be given too much. However, if you feel unwell you should tell your doctor immediately. Symptoms could be: rapid shallow breathing or feeling faint or dizzy.

If you had more TYOSOD than you should have, you should talk to a doctor or pharmacist.

If you forget to take TYOSOD

Do not take a double dose to compensate for the forgotten individual dose.

Effects that may occur when the treatment with TYOSOD is terminated

No data available.

4. Possible side effects

Like all medicines, there may be side effects in people who are sensitive to the ingredients of TYOSOD.

If you experience any of the following allergic reactions, ask medical attention immediately:

Unknown

- Difficulty in breathing or swallowing, swelling of the face, lips, tongue and throat
- Other allergic reactions such as skin rashes and itching.

When injected, TYOSOD can cause:

Unknown

- Cough, sneeze or airway spasm; difficulty breathing
- Reduction in blood pressure - usually observed when thiopental is given for the first time
- Drowsiness, nausea with or without vomiting, anorexia (decreased appetite), malaise (feeling generally unwell), tiredness, dizziness, headache
- Delirium (sudden severe confusion)-may occur in older patients
- With excessive doses of thiopental, chills, low body temperature and severely reduced brain function may occur.
- Confusion, amnesia (memory loss or impairment)
- Decreased heart pump activity or irregular heartbeats
- Low blood pressure or other effects on circulation
- Thiopental injection has been reported to be associated with decreased blood potassium levels during the infusion and increased blood potassium levels after the infusion has been discontinued.
- Tissue damage if injection leaks into surrounding tissues. **If you have severe pain at the injection site, inform your doctor immediately.**

If you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, which are mentioned or not mentioned in Package Insert, talk to your

doctor, pharmacist or nurse. Moreover, report side effects that you have experienced to Turkey Pharmacovigilance Center (TUFAM) by clicking icon “Reporting Side Effects” on the website www.titck.gov.tr or by calling 0 800 314 00 08, which is the line of Reporting Side Effects”. By reporting side effects, you will contribute to learn more about the safety of the medicine you are using.

5. How to store TYOSOD?

Keep TYOSOD out of reach and sight of children and in its package.

It should be stored at room temperature below 25°C. Keep away from sunlight.

The preparation for intravenous injection should be used after reconstitution of the sterile powder with water for injection and discarded after seven hours.

Use in accordance with expiration date.

Do not use TYOSOD after the expiration date on the package.

Do not use TYOSOD if you notice any defects in the product and / or its packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanization and Climate Change.

Marketing Authorization Holder:

VEM İlaç San. ve Tic. A.Ş.

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42 Maslak A Blok Sit. No: 2/134

Sarıyer/İSTANBUL/TÜRKİYE

Manufacturing Site:

VEM İlaç San. ve Tic. A.Ş.

Çerkezköy Organize Sanayi Bölgesi

Karaağaç Mahallesi, Fatih Bulvarı, No: 38

Kapaklı/TEKİRDAĞ/TÜRKİYE

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