Package leaflet: Information for the user

Temelor 4 mg/ml oplossing voor injectie
lorazepam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, evenif their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Temelor is and what it is used for

Temelor belongs to a certain group of sedative-hypnotic medicines, called benzodiazepines. Temelor is used for adults and adolescents above 12 years as a sedative to initiate certain interventions (premedication), such as small or large surgical procedures or certain extensive physical examinations.
Temelor is used for adults and adolescents above 12 years who suffer from severe fears or tension and for any reason can not take any tablets.
Temelor is used for adults, adolescents, children and infants aged 1 month and older in the control of status epilepticus.

2. What you need to know before you use Temelor

Do not use Temelor:
- If you are allergic to the active substance, other benzodiazepines, benzodiazepine-like substances or any of the other ingredients of this medicine (listed in section 6);
- If you suffer from myasthenia gravis (a disease in which muscle weakness occurs due to the impairment of the transfer of nerve impulses to muscles);
- If you suffer from severe respiratory distress;
- If you suffer from sleep apnoea syndrome (severe respiratory disturbances may occur during sleep);
- If you have severe liver problems.

Temelor may not be injected into an artery.

Children
Children under 12 years old are not allowed to use Temelor, except for the control of status epilepticus.

Warnings and precautions

Talk to your doctor or nurse before using Temelor:
- If you suffer from chronic respiratory disturbances.
- If your liver or kidney function is reduced.
- If you are elderly or debilitated.
- If you suffer from epilepsy or "green star" (acute narrow angle glaucoma).

For 24 hours after Temelor administration, you should stay under observation. Early walking (within 8 hours after Temelor use) can make you fall and injure.
A reduction of allertness may also last for more than 24 hours, for example if you are older or use other medicines.
If you are an outpatient and Temelor is used for a short-term procedure, you must be accompanied by a responsible adult upon discharge from the hospital.

You may not drive vehicles or take activities requiring attention during 24-48 hours after administration. You may not remember what you have experienced, during a certain period of time after Temelor administration.

Patients with mental disorders
Temelor is not a first choice in the treatment of mental disorders. Temelor may not be used as a single agent in the treatment of depression or fears associated with hypersensitivity.
Benzodiazepines may have an disinhibitory effect in depressed patients and may cause suicidal tendencies.
You must gradually reduce Temelor treatment.

Use of Temelor may result in dependence
Use of benzodiazepines may result in physical or psychological dependence. To reduce the risk of dependence, the lowest effective dose of Temelor should be used and the duration of the therapy should be as short as possible.
If you stop the treatment suddenly you may experience withdrawal symptoms: headache, muscle ache, extreme fear, tension, restlessness, confusion, irritability, mood swings, depression and insomnia.
You may also temporarily return to the symptoms for which you temporarily received Temelor (see also "If you stop using Temelor" in section 3).

Elderly or debilitated patients and children
Your doctor will prescribe a lower dose. In addition, your doctor will monitor you regularly and adjust the dose according to your response (see “How to use Temelor”).
Elderly and children may experience reactions that are completely opposite to what you expect from Temelor treatment, such as: restlessness, excitement, aggressiveness, delusions, rage attacks, nightmares, certain mental disorders (psychoses) inappropriate and other opposing behavior. If these reactions occur, your doctor will stop the treatment.
Children may be particularly allergic to the excipients of this medicine (see section “Temelor contains benzyl alcohol and propylene glycol”).

Other medicines and Temelor
Tell your doctor if you are using, have recently used or might use any other medicines. You should not use Temelor concurrently with scopolamine (a medicine for travel disease).
Concomitant use of the following medicinal products may enhance Temelor calming /relieving effect:
- anti-psychiatric agents,
- agents used for sleeping,
- sedative and / or tranquilizers,
- anti-depressants,
- some highly active prescription analgesics (narcotic analgesics),
- anti-epileptic drugs,
- agents that cause general or local anesthesia (anesthetics),

- agents used in allergies or travel disease(antihistamines),
- agents used to treat gout and hyperuricemia (e.g. probenecid).

Concomitant use of lorazepam and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Temelor together with opioids the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Temelor with food and drink and alcohol
Temelor calming / relieving effect can be enhanced by the simultaneous use of alcoholic beverages. This may persist up to 48 hours after Temelor administration.
You should not use alcohol 48 hours after Temelor administration.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You should only use Temelor during pregnancy if this is strictly necessary, for a period as short as possible at the lowest possible dose.

Lorazepam passes in small amounts into breast milk. During use of Temelor, breastfeeding is not recommended.

There are no data on the possible effects of lorazepam administered by injection or infusion on female fertility.

In addition, this medicine contains benzyl alcohol, a preservative that can cross the placenta and pass into breast milk. This medicine also contains propylene glycol (see "Temelor contains benzyl alcohol and propylene glycol").

Driving and using machines
To control a vehicle or operate a machine, you must be able to respond well and quickly and decide. You must also be able to move quickly and accurately.
If you use Temelor, control of these skills can be reduced because Temelor can adversely affect the alertness, responsiveness, memory and accuracy of muscle movements.
Therefore, you can not drive a vehicle or take other activities requiring attention 24 to 48 hours after administration.

Temelor contains benzyl alcohol and propylene glycol
This medicine contains 21 mg benzyl alcohol in each 1 ml of solution for injection.
This medicine contains 840 mg propylene glycol in each 1 ml of solution for injection.

Benzyl alcohol may cause allergic reactions.
Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your new-born baby (up to 4 weeks old) and do not use for more than a week in young children (less than 3 years old), unless recommended by your doctor.
Ask your doctor for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this

medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
Do not use this medicine if you are taking disulfiram (a medicine used to treat chronic alcoholism) or metronidazole (an antibiotic), unless recommended by your doctor.
There have been reports of polyethylene glycol toxicity (eg acute tubular necrosis) during administration of lorazepam, including at doses higher than recommended.

3. How to use Temelor

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
This medicine will be given to you by a health care professional. It will be given in a vein (intravenous) or in a muscle (intramuscularly). The dose will be decided by the doctor and is based on your body weight. The medicine will be given to you 15 to 20 minutes before the procedure (intravenous) or at least 2 hours before the procedure (intramuscularly).

Use as premedication
The recommended dose into a vein (intravenous) is based on body weight (0.044 mg per kg body weight), up to a total of 2 mg, 15 to 20 minutes before the expected procedure. Sometimes larger doses up to 4 mg can be administered.
The recommended dose into a muscle (intramuscular) is 0.05 mg per kg body weight, with a maximum of 4 mg in total, at least 2 hours before the expected procedure.

Use in treatment of the symptoms of severe anxiety and tension in people who cannot take tablets
The recommended dose is 2 to 4 mg, i.e. 0.05 mg per kg body weight. If necessary, the dose may be repeated after 2 hours. The injection will be given into a vein (intravenously) or into a muscle (intramuscularly).

Use in status epilepticus
Adult dose: 4 mg intravenously.
Elderly (over 65 years of age): The elderly may respond to lower doses; thus, half the normal adult dose may be sufficient.
Dosage in adolescents, children and infants from 1 month of age: 0.1 mg/kg body weight intravenously with a maximum of 4 mg/dose.
If the seizure lasts longer than 10-15 minutes, the doctor may decide to administer another dose. A maximum of 2 doses may be administered.

Use in children
Temelor should not be used in children under 12 years of age, except for the control of status epilepticus (see also section 2).

Use in elderly and debilitated patients
Clinical studies have shown that patients over 50 years of age have a deeper and longer lasting reduction in consciousness when lorazepam is administered intravenously. Under normal circumstances, a starting dose of 2 mg should be sufficient unless a greater degree of sedation and/or amnesia is desired.

Use in patients with kidney or liver disorders
Temelor should not be used in patients with severe liver disorders. When Temelor is used in patients with mild to moderate liver or kidney disorders, a starting dose of 0.05 mg/kg (but not more than 2 mg) is recommended.

If you use more Temelor than you should
If you have are given more medicine than you should you may get symptoms such as sleepiness, mental confusion and lethargy, in mild overdose and low blood pressure, difficulty in controlling movements, respiratory depression and coma, in severe cases.
The treatment of an overdose will mainly consist of supportive measures, including maintaining breathing and monitoring your fluid balance (how much fluid you take in and pass out).

If you forget to use Temelor
Given that Temelor solution for injection is administered in hospital, this information is not applicable.

If you stop using Temelor
You should discontinue or stop the treatment following doctor's instructions only.

If you are being treated for the symptoms of severe anxiety and the treatment is discontinued suddenly, you should consider the possible occurrence of one or more of the following withdrawal symptoms: headache, muscle ache, extreme fear, anxiety, tension, excitement, restlessness, confusion, irritability, mood swings, sweating, depression, and insomnia.
In more serious cases, withdrawal symptoms may include: loss of feelings, loss of reality, where the (familiar) environment seems unreal, alienation of self and self-esteem (depersonalisation), numbness and tingling of the arms and legs, greatly increased sensitivity to light, noise and touch, increased hearing, ear pains, involuntary movements, vomiting, delusions (hallucinations) or attacks of falling disease (epileptic attacks).
Also, the symptoms for which you received Temelor may temporarily return to a great extent.

To minimize the risk of these symptoms occurring, it is recommended to gradually reduce the dose and discontinue the treatment.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Side effects usually occur at the start of treatment and gradually disappear during treatment or when the dose is reduced.

The following side effects were reported after using lorazepam:

Very common: may affect more than 1 in 10 people
- fatigue.

Common: may affect up to 1 in 10 people
- sleepiness during daytime,
- drowsiness,
- dizziness,
- coordination problems (ataxia),
- muscle weakness.

Uncommon: may affect up to 1 in 100 people
- confusion,
- depression,
- emotional flattening,
- sleep disturbances,

- headache,
- decreased alertness,
- visual disturbances,
- double vision (diplopia),
- nausea,
- gastrointestinal problems,
- skin reactions,
- change in sex drive.

Rare: may affect up to 1 in 1,000 people
- blood dysfunction (dyscrasia),
- temporary memory loss,
- contradictory reactions,
- decreased blood pressure (hypotension),
- elevated blood pressure (hypertension),
- liver disease related abnormalities.
- psychiatric disorders: excitation (agitation), nervousness, irritability, aggressiveness, suspicion, rage attacks, nightmares, observations of things that are not there (hallucinations), severe mental illness in which control over behavior and behavior is disturbed (psychosis), inappropriate behavior. These side effects occur mainly in children and older people.

Other side effects:
- pain, burning sensation, redness and inflammation at the site of injection have been reported.
- dependence may occur after repeated use for several weeks (see section 2).
- breathing difficulties in severe anesthesia may occur.
- withdrawal symptoms occurs after discontinuation of treatment (see section "If you stop using Temelor")
- acidification of the blood due to oxygen deficiency in the body tissues, disturbance of the water and salt balance, decreased blood pressure, death of certain cells in the kidneys (acute tubule necrosis), caused by the excipients of this medicinal product. These symptoms are more likely to occur in patients with renal failure and in children (see also "Warnings and precautions").

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Temelor

Keep this medicine out of the sight and reach of children.
Store and transport refrigerated (2-8ºC). Keep in the outer carton to protect from light.
Chemical and physical in-use stability has been demonstrated for 1 hour at 2-8º C. From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
Do not use this medicine after the expiry date which is stated on the label and on the carton after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Temelor contains
- The active substance is lorazepam; each 1 ml of solution contains 4 mg lorazepam.
- The other ingredients are macrogol 400, benzyl alcohol and propylene glycol.

What Temelor looks like and contents of the pack
A clear, colourless or almost colourless hypertonic solution, free from visible particles.
Temelor is packed in Type I (Ph.Eur), clear glass ampoule of 2 ml filling capacity. Each ampoule contains 1 ml of solution. The ampoules are placed in moulded polyvinyl chloride trays, which are then sealed by a protective PE transparent foil.
The polyvinyl chloride trays are inserted in a carton box together with a leaflet. Temelor is supplied in packs of 5 and 10 ampoules of 1 ml solution.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen
Medochemie Ltd
1-10 Constantinoupoleos Street
3011 Limassol, Cyprus

Fabrikant
Medochemie Ltd (Ampoule Injectable Facility)
48 Iapetou Street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol, Cyprus

In het register ingeschreven onder:
RVG 122954

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	TEMELOR 4 mg/ml oplossing voor injectie
Bulgarije	ТЕМЕЛОР 4 mg/ml инжекционен разтвор
Cyprus	TEMELOR 4 mg/ml solution for injection
Tsjechië	TEMELOR
Estland	TEMELOR 4 mg/ml süstelahus
Kroatië	TEMELOR 4 mg/ml otopina za injekciju
Litouwen	TEMELOR 4 mg/ml injekcinis tirpalas
Letland	TEMELOR 4 mg/ml šķīdums injekcijām
Malta	TEMELOR 4 mg/ml solution for injection
Roemenië	TEMELOR 4 mg/ml soluţie injectabilă

Deze bijsluiter is voor het laatst goedgekeurd in maart 2024.

The following information is intended for healthcare professionals only:

Instruction for use
Temelor is slightly viscous when cool.

Intramuscular administration:
In order to facilitate intramuscular administration, dilution with an equal volume of a compatible solution is recommended, such as sodium chloride 9 mg/ml (0.9%) solution for injection, 5% glucose or water for injection.
Temelor can be also administered undiluted, if given deeply in a large muscle mass.

Intravenous administration:
In case of intravenous administration, Temelor should always be diluted with an equal volume with sodium chloride 9 mg/ml (0.9%) solution for injection, 5% glucose or water for injection.
The injection rate should not exceed 2 mg / min. Parenteral medicines must be inspected visually for the presence of particles or discolourations prior to administration.

Instructions for dilution for intravenous use
Extract the desired amount of [Product name] into the syringe, then slowly suck the desired volume of diluent. Retract the piston slightly to provide an additional mixing space. Immediately mix the contents by repeatedly twisting the syringe until a homogeneous solution has formed. Do not shake vigorously as this will cause air bubbles.

Temelor should not be mixed with other drugs in the same syringe. Do not use if solution has developed a colour or a precipitate.
No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.