

TRANPAM TABLET

Lorazepam (0.5mg and 1mg)

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What Tranpam Tablet is used for

Lorazepam is the active ingredient of Tranpam Tablet 0.5mg or 1mg.

It is indicated for the treatment of anxiety and tension states, as a sedative premedicant (before surgery), in the control of muscle spasm as in tetanus and in the management of alcohol withdrawal symptoms.

How Tranpam Tablet works?

Lorazepam is a short acting benzodiazepine. It has a more specific antianxiety effect than other sedatives such as barbiturates. It also possesses anticonvulsant, sedative, muscle relaxant and amnesic properties.

It is a benzodiazepine which acts on chemicals in the brain.

Before you take Tranpam Tablet

- When you must not use it

- If you have known hypersensitivity to Lorazepam or any other ingredients of Tranpam Tablet.
- If you have known hypersensitivity to benzodiazepines
- If you have an eye problem called acute narrow-angled glaucoma.
- If you are pregnant or a nursing mother.
- If you have pre-existing central nervous system depression or coma
- If you have myasthenia gravis (a disease which causes severe muscle weakness), severe liver problem, severe lung problem or stop

breathing during sleep (sleep apnoea).

- Before you start to use it

You must tell your doctor if:

- you have allergies to any medicine which you have taken previously to treat your current condition.
- you are pregnant, trying to become pregnant or breast-feeding.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of these medicines:

Alcohol, antidepressants, antihistamines, general anesthetics, other hypnotics or sedatives and antipsychotic.

This is because the sedation, breathing and heart or blood vessel depression effect may be enhanced or they might interfere with Tranpam metabolism.

Taking Tranpam tablet with an opioid medicine (medicine to relieve pain) can depress your central nervous system. Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Please talk to your pharmacist or doctor if you are not sure about this.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Tranpam Tablet

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Adults:

Anxiety: 1-4 mg daily in 2 or 3 divided doses with the largest doses taken at night. Maximum 10mg daily.
Insomnia (difficulty falling and/or

staying asleep) associated with anxiety: 1-2mg at bedtime.

Premedication: 2-3 mg the night before operation. 2-4mg one to two hours before operation.

Elderly or debilitated patients: ½ the usual adult doses or less

Children:

5 to 13 years:

Premedication: 0.5mg – 2.5mg (50ug per kg-body weight) not less than one hour before operation.

Lorazepam is not recommended for the treatment of anxiety or insomnia in children.

- When to use it

Your doctor will decide when it is appropriate for you to use Tranpam Tablet according to the type of condition you have.

It is to be taken orally with a glass of water.

- How long to use it

Continue taking Tranpam Tablet for as long as doctor recommends.

- If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

- If you take too much (Overdose)

Overdosage produces central nervous system depression and coma. Impairment of consciousness is fairly rapid. More common is a sleep-like state from which patients can be temporarily raised by appropriate stimuli. There is usually little or no respiratory problem or severe low blood pressure. Consumer is advised to go to the nearest hospital if overdose happens.

While you are using Tranpam Tablet

- Things you must do

- Contact your doctor if your symptoms does not improve.

- If you do become pregnant whilst taking Tranpam Tablet, tell your doctor.
- Must be used with care in those with chronic lung problem.
- Care should be taken in elderly or debilitated patients who may be more prone to adverse effects.
- Caution is required in patients with impaired liver or kidney function and decreased mental function particularly due to arteriosclerosis (diseases characterized by thickening and loss of elasticity of the arterial walls result in impaired blood circulation).

- Things you must not do

- Do not give Tranpam Tablet to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Tranpam Tablet for you and your condition.
- Lorazepam is not to be used in the treatment of chronic psychiatric illness or phobia or obsessional states.
- Do not concurrent use this medication with alcohol and other medicines which may cause drowsiness or sleep.

- Things to be careful of

- Sedative effects of lorazepam are most marked during the first few days of administration. You should not drive or operate any machinery.
- Anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) can occur as early as the first time the product is taken.
- Complex sleep-related behaviors which may include sleep driving, making phone calls, preparing and eating food (while asleep) has been recorded.

Side Effects

Like all medicines, Tranpam Tablet can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Most common: drowsiness, sedation and ataxia (failure of muscular

coordination). It is mostly dose-dependent and elderly or debilitated patients are especially susceptible to these reactions.

- Others: vertigo (a form of dizziness), headache, confusion, mental depression, slurred speech (abnormal speech) or dysarthria (difficulty in articulating words), changes in libido, tremor, visual disturbances, urinary retention or incontinence (inability to control urinating), gastro-intestinal disturbances, changes in salivation, amnesia and paradoxical (different from what is expected) excitation and disinhibition (unrestrained behavior).
- Rare: Jaundice, blood disorders and hypersensitivity have been reported.
- Respiratory depression and hypotension (low blood pressure) occasionally occur with high dosage and parenteral administration.
- Rebound anxiety and insomnia may be a result of tolerance to the effects of lorazepam or part of a withdrawal syndrome.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Tranpam Tablet

- Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light, heat and moisture.

Keep out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via

wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

Tranpam Tablet 0.5mg:

- What it looks like

The tablet is greenish-blue, round, scored of diameter 7mm flat with 'MPI' marking.

- Ingredients

- ◆ Active ingredient: Tranpam 0.5mg tablet contains 0.5mg Lorazepam.
- ◆ Inactive ingredients: The other ingredients are microcrystalline cellulose pH101, potato starch, corn starch, lactose, magnesium stearate and brilliant blue FCF

Tranpam Tablet 1.0mg:

- What it looks like

The tablet is blue, round, scored of diameter 7mm flat with 'MPI' marking.

- Ingredients

- ◆ Active ingredient: Tranpam 1mg tablet contains 1.0mg Lorazepam.
- ◆ Inactive ingredients: The other ingredients are microcrystalline cellulose pH101, potato starch, corn starch, lactose, magnesium stearate and indigocarmine.

MAL Number:

Tranpam Tablet 0.5mg:

MAL19900509AZ

Tranpam Tablet 1mg

MAL19900510AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Pulau Pinang, Malaysia.

Date of Revision

08/12/2020

Serial Number:

NPRA(R2/1)190119/20