ANPRO-ZOLPIDEM TABLET

Zolpidem Tartrate (10mg)

What is in this leaflet

What Anpro-Zolpidem Tablet is used for

It is indicated in the treatment of sleep disorders in occasional insomnia (difficulty falling and/or staying sleep) and transient (impermanent) insomnia.

How Anpro-Zolpidem Tablet works

Zolpidem tartrate is the active ingredient of Anpro-Zolpidem Tablet. It has similar sedative properties to benzodiazepine medicines.

Zolpidem Tartrate belongs to a group of medicines called imidazopyridine hypnotics. It works by acting on your brain to help you sleep.

Before you use Anpro-Zolpidem Tablet

- *When you must not use it*
  - If you are allergic (hypersensitive) or to zolpidem tartrate or to any other ingredients in the formulation.
  - If you have acute and/ or severe breathing problems.
  - If you have severe, acute or chronic liver problem because of the risk of encephalopathy (disorder or disease of the brain).
  - If you have sleep apnea (stop breathing for short periods at night).
  - If you have severe muscle weakness problem (myasthenia gravis).

- *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.
  - You are dependent on alcohol or other medicines.
  - You have insomnia.
  - You are suffering from major depression.
  - You are elderly or suffering from kidney or liver impairment, which exposed to accumulation risk upon taking Zolpidem repeatedly.

- *Taking other medicines*

  Please tell your doctor or pharmacist if you are taking or have recently taken any of these medicines:
  - Alcohol – can increase the sedative effects and impairing alertness.
  - Other central nervous system depressants – morphine derivatives, neuroleptics, barbiturates, anxiolytic agents, other hypnotics, sedating antidepressants, sedating antihistamines, central antihypertensives, baclofen, thalidomide and pizotifen may increase central depression and impair vigilance.
  - Morphine derivatives and barbiturates also increase the risk of respiratory depression when ventilation is inadequate to perform needed gas exchange. This can be fatal in overdoses.
  - Buprenorphine – concurrent use increases the risk of fatal respiratory depression.
  - Ketoconazole - concurrent use produces slight increase in sedation
  - Rifampicin – increases liver metabolism and may reduce the efficacy of zolpidem.

  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 Anpro-Zolpidem 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. Take this medicine only by mouth.

- *How much to use*

  Adult

  One tablet daily

  Elderly or people with liver insufficiency

  Half a tablet daily.

  Maximum Dose

  One tablet daily. The tablets can be prescribed continuously or when required, depending on individual symptoms.

  Use in children

  Zolpidem should not be used in children under 18 years old.

- *When to use it*

  Use as directed by your doctor or pharmacist.

  The tablet should be taken immediately before bedtime. Take the tablet with a glass of water.

- *How long to use it*

  Zolpidem should be taken for the shortest duration possible, ranging from a few days to a maximum 4 weeks, including the tapering period:
  - Two to five days for occasional insomnia.
  - Two to three weeks for transient insomnia.
  - In cases where longer treatment periods are required (exceeding four weeks), careful and repeated reevaluation of the individual condition should be carried out.

  Discontinuation of treatment:
  Dose reduction can only be done by the doctor, and not by yourself. Please refer to your doctor for further advice.

- *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 use too much (overdose)*

  Central nervous system depression may happen ranging from drowsiness to coma, depending on the dose ingested.

  In mild cases, the person may be confused and lethargic. In more severe cases, the person may present with low muscle tone, low blood pressure, breathing difficulty and death in rare cases. Coma and fatal zolpidem overdoses are rare.

  Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*
  - Contact your doctor if your symptoms worsen or they do not improve.
  - If you do become pregnant whilst taking Anpro-Zolpidem Tablets, tell your doctor.
  - Contact your doctor immediately if anaphylaxis (severe allergic reactions) and angioedema (facial swelling) occurs.
  - Be aware of complex sleep-related behaviours which may include sleep driving, making phone calls, preparing and eating food while asleep.

- *Things you must not do*

  Do not give Anpro-Zolpidem Tablet to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Anpro-Zolpidem Tablet for you and your condition.

- *Things to be careful of*
  - It is recommended that Zolpidem is not used at any stage of pregnancy, especially in the first trimester. In the last trimester of pregnancy, the lowest effective dose should be used.
  - Breastfeeding is not recommended during Zolpidem treatment.
  - Stop taking Zolpidem if you experienced complex sleep-related behaviours.
  - Physical or psychological dependence (a need to keep taking the medicine) may develop with the use of Zolpidem.
  - Withdrawal symptoms such as agitation, anxiety, irritability and headache may occur when treatment is discontinued in those who have developed dependence.
  - A condition called rebound insomnia may occur when you stop this medicine. This is an inability to sleep which may be worse than the insomnia you had before as you may also experience mood changes, anxiety and agitation. However, this is temporary and can be minimized by gradual dose reduction.
  - You may experience anterograde amnesia (loss of memory) and impaired psychomotor (a slowing-down of thought and a reduction of physical movements) function several hours after taking the tablets. This can be avoided by taking the tablets immediately before bedtime.
  - You may experience unusual behavioural disorders or psychiatric reactions such as worsening of insomnia, nightmares, agitation, nervousness, suggestibility, euphoria (feeling of excitement and happiness) , irritability, anger outbursts, aggression, anterograde amnesia, delirium (serious disturbance in mental abilities that results in confused thinking and reduced awareness of your environment), oniric delirium (related to dreams), hallucinations (a false notion, belief and impression), psychotic symptoms, disinhibitions with impulsivesness.

  Potentially dangerous disorder like aggressiveness, unusual behavior or automatic behavior (involuntary movements or utterances) with post-event amnesia (loss memory) may occur.

Treatment should be discontinued and elderly are more susceptible to these reactions.

- Monitor closely those with breathing difficulty as Zolpidem can depress the respiratory function.
- Avoid driving or operating machinery as there is a risk of drowsiness. Avoid combining this medication with other sedating products.
- When Zolpidem is used for several weeks, the sedating or hypnotic effect may decrease. Tolerance may develop but the dosage should not be increased.

Side effects

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

- Neuro-psychiatric disorders – anterograde amnesia, behaviour disorders, impaired consciousness, irritability, aggressiveness, agitation, hallucinations, somnambulism (sleepwalking), physical and psychological drug dependence, withdrawal symptoms or rebound insomnia, feelings of ebriety (intoxication), ataxia (the loss of full control of bodily movements), headaches, confusion, reduced vigilance, drowsiness (especially in the elderly), insomnia, tension and changes in sex drive.
- Skin disorders – skin rash, pruritus (itching), superficial or deep (angioedema) urticaria (hives), hyperhidrosis (excessive sweating).
- Ocular disorders – diplopia (double vision).
- Gastrointestinal disorders – diarrhoea, nausea, vomiting, abdominal pain.
- Liver effects – elevated liver enzymes.
- Immune system disorders – angioedema (swelling under the skin).
- General – muscle hypotonia (poor muscle tone), asthenia (lack or loss of strength), unsteady gait or falls (especially in the elderly and when dosage recommendation is not followed).

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Anpro-Zolpidem 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

- *What it looks like*

  A yellow, oblong tablet of size 10 x 4mm.

  They are supplied in blisterpack 10x10's.

- Ingredients
  - Active ingredient
    Each tablet contains 10mg of the active substance, zolpidem tartrate.
  - Inactive ingredients
    The other ingredients are potato starch, microcrystalline cellulose pH101, sodium starch glycolate, sodium lauryl sulphate, magnesium stearate, talc, titanium dioxide and quinoline yellow.

- *MAL Number*
  MAL09072796AZ

Manufacturer and Product Registration Holder

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