

ANPRO-ZOLPIDEM TABLETS 10MG

Zolpidem Tartrate (10mg)

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What Anpro-Zolpidem Tablets 10mg 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 Tablets 10mg works?

Zolpidem Tartrate is the active ingredient of Anpro-Zolpidem Tablets 10mg. 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 take Anpro-Zolpidem Tablets 10mg

-When you must not take it

- If you are allergic (hypersensitive) to Zolpidem Tartrate or any other ingredients of Anpro-Zolpidem Tablets 10mg 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 take 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 conceive 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

Taking Anpro-Zolpidem Tablets 10mg 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 are the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

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, anxiolytics 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 - increase 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 take Anpro-Zolpidem Tablets 10mg

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 (1) tablet daily

Elderly or people with liver insufficiency

Half a tablet daily.

Maximum Dose

One (1) tablet daily. The tablet 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 four (4) weeks, including the tapering period:

- Two (2) to five (5) days for occasional insomnia.
- Two (2) to three (3) weeks for transient insomnia.
- In cases where longer treatment periods are required (exceeding four (4) 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 TAKE 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)

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 taking Anpro-Zolpidem Tablets 10mg

-Things you must do

- Contact your doctor if your symptoms worsen or they do not improve.
- If you do become pregnant while taking Anpro-Zolpidem Tablets 10mg, 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 Tablets 10mg to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Anpro-Zolpidem Tablets 10mg 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.
- Breast-feeding 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 impulsiveness.

- Potentially dangerous disorder like aggressiveness, unusual behaviour or automatic behaviour (involuntary movement 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 Tablets 10mg 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 and 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 visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of Anpro-Zolpidem Tablets 10mg

-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 10x4mm.

-Ingredients

- ◆ Anpro-Zolpidem Tablets 10mg contains 10mg Zolpidem Tartrate (active ingredient).
- ◆ 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

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Manufacturer and Product Registration Holder

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