

ALPRALINE TABLET 0.5MG “S.T.”

Alprazolam (0.5mg)

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What Alpraline Tablet is used for

Alpraline Tablet is used for the treatment of moderate or severe anxiety states and anxiety associated with depression

How Alpraline Tablet works

Alpraline Tablet contains the active ingredient Alprazolam. Alprazolam has a high affinity for the benzodiazepine binding site in the brain, and it is thought to work by its action on brain chemicals.

Before you use Alpraline Tablet

– When you must not use it

Do not take Alpraline Tablet:

- If you have sleep apnoea syndrome (temporary stops in breathing during sleep)
- If you have myasthenia gravis (a disease which causes severe muscle weakness)
- If you have severe breathing insufficiency
- If you have severe liver insufficiency
- If you hypersensitive to benzodiazepines or any of the other constituents or ingredient of the tablets listed at the end of this leaflet (see section **Product description**).

– Before you start to use it

You should check with your doctor:-

- if you are pregnant, breastfeeding or plan to become pregnant.
- If you have seizure.
- If you have kidney or liver problem.
- If you plan or are undergoing surgery.
- If you have depression or a history of psychotic illness.
- If you have a history of alcohol or drug abuse.

– Taking other medicines

There are few medicines which may not mix with Alpraline Tablet. It is important to tell your doctor or pharmacist about all the medicines that you are taking including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are on following:-

- Medicines for depression (e.g. fluvoxamine, fluoxetine)
- Other sleeping tablets, sedatives or tranquillisers
- medicines used to treat fungal infections (e.g. ketoconazole and itraconazole, or other azole- type antifungals)
- Opioid painkillers
- Medicines used to control fits
- Sedative antihistamines
- Medicines used to treat viral infections (e.g. ritonavir)

Taking Alpraline 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.

Other medicines not listed above may also interact with Alpraline Tablet. Your doctor and pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

How to use Alpraline Tablet

– How much to use

You should take Alpraline Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Anxiety: the usual daily adult dose ranges from 0.25 mg to 0.5 mg three times daily, increasing if required to a total of 3 mg daily.

If you are elderly, or you are having chronic lung disease or liver problems: a lowered initial dose may be given, and to be gradually increased if needed and as tolerated

Children: Not recommended.

– When to use it

Use Alpraline Tablet as directed by your doctor or pharmacist.

– How long to use it

It is important to take Alpraline Tablet as long as your doctor prescribes. Alpraline Tablet should be taken for short periods only (not more than 8-12 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

– If you forget to use it

Do not take extra tablets to make up for a missed dose. Just take your next dose at usual the time

– If you use too much (overdose)

If you take too many tablets by mistake, contact your doctor immediately or seek medical attention. Symptoms of an overdose may include:

- Sleepiness
- loss of full control of bodily movements
- Diminished reflexes (instantaneous movement in response to a stimulus)
- Coma

While you are using it

– Things you must do

- Take Alpraline Tablet exactly the way as prescribed.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Alpraline Tablet
- Tell your doctor if you become pregnant while taking Alpraline Tablet

– Things you must not do

- Do not share your medicine with others even if they have the same diagnosis as you.

- Do not take Alpraline Tablet for a longer time than your doctor has prescribed. Alpraline Tablet should be taken for short periods only unless advised by your doctor.
- Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely. If you stop taking Alpraline Tablet suddenly, you may experience unpleasant side effects including abdominal and muscle cramps, vomiting, sweating, inability to sleep (insomnia) and seizure (fits).

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Dependence

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Alpraline Tablet for a short a period of time as possible.

Amnesia

You could experience amnesia (total or partial memory loss) when taking this medicine. Amnesia is more likely to occur when taking high doses of Alpraline Tablet.

Psychiatric and 'paradoxical' reactions

Contact your doctor if you experience reactions like restlessness, agitation, irritability, aggressiveness, delusion (firmly held false beliefs), nightmares, hallucinations (hearing voices or seeing things which are not there), and other adverse behavioral effects.

Driving and using machines

Alpraline Tablet may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to Alpraline Tablet before your drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Concomitant use with alcohol

Combining Alpraline Tablet and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.

Complex sleep-related behaviours

Complex sleep-related behaviours which may include sleep driving, making phone calls, preparing and eating food (while asleep) may occur.

Side Effects

Like all medicines, Alpraline Tablet can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The possible side effects are sedation/drowsiness, light-headedness, numbed emotions, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia, double or blurred vision, insomnia, nervousness/anxiety, tremor, change in weight.

Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication

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.moh.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Alpraline Tablet

- Storage

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

- 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

It is a pale pink, oval-shaped, biconvex tablet

- Ingredients

- Active Ingredient

- Alprazolam

- Inactive Ingredients

- Hydroxypropyl Cellulose
- Magnesium Stearate
- Food color red no. 6 (ponceau 4R),
- Corn Starch
- Alcohol 95%
- Avicel 101

-MAL number

MAL07090924AZ

Manufacturer

Taiwan Boitech CO., LTD
22, Chieh Shou Road Taoyuan Taiwan.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
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