

ASOLAN TABLET 0.5MG

Alprazolam 0.5mg

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What [product name] is used for

ASOLAN is used for the short-term treatment of anxiety.

ASOLAN is used for treatment of depression for examples:

- Anxiety with depressive symptoms
- Mixed anxiety-depression (both anxiety and depression occur simultaneously)
- Neurotic or reactive depression (depressed mood or a pervasive loss of interest or pleasure)

ASOLAN is also used to treat panic attacks.

Your doctor may have prescribed ASOLAN for another reason. Ask your doctor if you have any questions about why ASOLAN has been prescribed for you.

How ASOLAN works

ASOLAN is a tranquilliser containing the active ingredient alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical

activity in the brain and impacts central nervous system function like reduction in anxiety and worry.

Before you use ASOLAN

- When you must not use it

ASOLAN is contraindicated in the following conditions:

- myasthenia gravis (a condition where muscles become easily tired and weak)
- chronic obstructive airways disease (lung disease)

Do not take ASOLAN if you have an allergy to:

- Medicines containing alprazolam
- Any other benzodiazepine medicine

Do not take ASOLAN if you are breastfeeding. ASOLAN passes into the breast milk and may cause drowsiness and feeding difficulties in the infant.

Do not take ASOLAN if the packaging is torn or shows signs of tampering.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant. ASOLAN may affect your unborn baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking ASOLAN during pregnancy.

Elderly or debilitated (weak) person may be particularly susceptible to the sedative effects of benzodiazepines.

Tell your doctor if you have any medical conditions, especially the following:

- low blood pressure
- severe muscle weakness
- liver or kidney problems
- lung problems
- blood disorder
- glaucoma (build up of pressure within the eye)
- depression, psychosis or schizophrenia
- epilepsy (fits or convulsions)
-

If you have not told your doctor about any of the above, tell him/her before you start taking ASOLAN.

This preparation may be habit forming on prolonged use

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ASOLAN may interfere with each other.

This include:

- Other sleeping tablets, sedatives or tranquillisers
- Muscle relaxants
- Medicines for depression (eg. Imipramine, desipramine)
- Lithium, a medicine used to treat depression
- Medicines used to treat certain mental and emotional conditions
- Medicines used to treat epilepsy such as barbiturates
- Antihistamines, medicines for allergies, hay fever or colds

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- Some pain relievers such as codeine
- Anaesthetics
- Disulfiram, a medicine commonly used to treat alcohol dependence
- Cimetidine, a medicine commonly used to treat reflux and ulcers
- Some antibiotics such as erythromycin or clarithromycin
- Oral contraceptives (birth control pill)
- HIV protease inhibitors, medicines used to treat HIV infection

These medicines may be affected by ASOLAN or may affect how it works.

Taking Asolan 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.

How to use ASOLAN

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many tablets to take and when to take them. This information is also on the label of the carton the tablets come in.

Do not take your tablets with alcohol.

You will usually start by taking a dose of 0.5 mg to 1 mg. This medicine is taken in divided doses two or three times daily.

The dose may be increased gradually up to a total of 3 mg to 4 mg again taken in divided doses throughout the day.

- When to use it

Use as directed by your doctor or pharmacist.

Adults

Dose should be individualized based upon how severe the symptoms and how the response is by individual patient. When the dose needs to be increased, it is usual to gradually and cautiously increase the dose.

The elderly

If you are an older patient or you have for example kidney or liver problems and you need a lower dose you will normally start on a dose of 250 micrograms twice a day. This dose may be slowly increased if needed and if you don't get any side effects.

Use in children and adolescents

Alprazolam is not recommended for children and adolescents under the age of 18 years

- How long to use it

Asolan tablets are only used for short-term treatment (not more than 12 weeks including a period where the dose is gradually reduced, this is called dose 'tapering'). You will not normally be given a prescription for more than 4 weeks and you will be regularly reviewed by your doctor during this time.

Stopping treatment

Always see your doctor before you stop taking Asolan tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. It is recommended that the daily dosage of alprazolam be decreased by no more than 0.5 mg every 3 days. Some people may also experience 'withdrawal' effects (see Section Side effects – Dependence and withdrawal symptoms). These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

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

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency (Casualty) at the nearest hospital if you think that you or anyone else may have taken too much ASOLAN Tablet.

Do this even if there are no signs of discomfort or poisoning. You may

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need urgent medical attention. The symptoms of overdose:

- drowsiness
- mental confusion
- lethargy
- ataxia (uncoordinated movement)
- hypotonia (poor muscle tone)
- low blood pressure
- breathing difficulty
- coma

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ASOLAN.

If you become pregnant while you are taking ASOLAN tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking ASOLAN.

- Things you must not do

Do not take ASOLAN for longer than your doctor has prescribed.

Do not stop taking ASOLAN or change the dose without checking with your doctor.

Do not take ASOLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how ASOLAN affects you.

This medicine may cause drowsiness, dizziness or lightheadness in some people.

This medicine may cause complex sleep-related behaviors which may include sleep driving, making phone calls, preparing and eating food (while asleep).

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects.

You may not experience any of them. Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, lightheadedness, confusion
- fatigue
- unsteadiness
- anxiety, irritability
- depression
- slurred speech
- blurred vision
- headache
- loss of appetite
- increase or decrease in weight
- irregular menstrual periods

The above list includes the more common or mild side effects of ASOLAN.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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 ASOLAN

- Storage

Store below 30°C. Protect from light. Keep out of reach of children.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product Description

- What it looks like

ASOLAN 0.5mg – A round pink, 7mm diameter tablet with marking, “DUOMA/DUOMA” and “DUO 2”

- Ingredients

- Active ingredient(s)
 - Alprazolam
- Inactive ingredients
 - Carmoisine

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- Cornstarch
- Polyvinylpyrrolidone
- Isopropyl alcohol
- Magnesium stearate
- Silicon dioxide
- Sodium starch glycolate
- Lactose

- MAL number:

MAL20031914AZ

**Product Registration Holder &
Manufacturer**

DUOPHARMA (M) SDN BHD
Lot 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang,
Selangor Darul Ehsan, Malaysia.

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