

ASOLAN TABLET

Alprazolam (0.25mg, 0.5mg, 1mg)

What is in the leaflet?

1. What ASOLAN is used for
2. How ASOLAN works
3. Before you use ASOLAN
4. How to use ASOLAN
5. While you are using it
6. Side effects
7. Storage and Disposal of ASOLAN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What ASOLAN 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 belongs to a group of medicines called benzodiazepines.

These medicines are thought to work by their action on brain chemicals.

Before you use ASOLAN

- When you must not take 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.

There 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
- 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use ASOLAN

- How much to use

The dose varies from patient to patient. Take ASOLAN exactly as directed by your doctor.

Usual starting dosage of each symptom:

- *Anxiety* : 0.5 to 1.5mg daily given in divided doses
- *Anxiety with depressive symptoms*: 1.5mg daily given in divided doses
- *Elderly patients* : 0.5mg to 0.75mg daily given in divided doses
- *Panic – related disorders* : 0.5mg to 1.0mg given at bedtime, increasing at a rate of 0.25mg to 1mg every 3 days until an adequate therapeutic dosage is achieved

Your doctor may gradually increase your dose, depending on how severe your symptoms are, how you respond to this medicine and whether you are taking other medicines.

- When to use it

ASOLAN can be taken with or without food. Food delays the onset of absorption of alprazolam. As a result, side effect such as sleepiness are less pronounced.

- How long to use it

Continue taking ASOLAN as your doctor recommends.

In general, benzodiazepines should be used for short period only (eg. 2-4 weeks)

- 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 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 Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of ASOLAN

- Storage

Keep your tablets in a cool dry place where the temperature stay below 25°C.

Keep it where children cannot reach it.

- 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 0.25mg –light blue, round tablet, marked “DUOMA/DUOMA” on 1 side and “DUO 2” on the other side.
- ASOLAN 0.5mg - pink, round tablet, marked “DUOMA/DUOMA” on 1 side and “DUO 2” on the other side.
- ASOLAN 1mg – apple green, round tablet, marked “DUOMA/DUOMA” on 1 side and “DUO 2” on the other side.

- Ingredients

Active ingredient:

- Alprazolam

Inactive ingredients:

- ASOLAN 0.25mg
- Isopropyl alcohol
 - Cornstarch
 - Polyvinylpyrrolidone
 - Magnesium stearate
 - Sodium starch glycolate
 - Brilliant blue
 - Silicon dioxide (Aerosil)
 - Lactose

ASOLAN 0.5mg

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

ASOLAN 1mg

- Sodium starch glycolate
- Cornstarch
- Quinoline yellow
- Polyvinylpyrrolidone
- Brilliant blue
- Lactose
- Silicon dioxide (Aerosil)
- Isopropyl alcohol
- Magnesium stearate

- MAL numbers

ASOLAN 0.25mg
MAL20031913A

ASOLAN 0.5mg
MAL20031914A

ASOLAN 1mg
MAL20031915A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M)
Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN.
BHD. (42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Date of Revision

04/02/2015

Serial Number

BPFK/(R4/1)300115/00005