# **INZOLAM TABLET**

Triazolam 0.25mg

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## What INZOLAM is used for

Inzolam is used to treat sleeping problems, also called insomnia. It should be used for short-term treatment only.

Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Your doctor, however, may have prescribed this medicine for another reason.

Ask your doctor if you have questions about why it has been prescribed for you.

## How INZOLAM works

Inzolam belongs to a group of medicines called short-acting benzodiazepines. They are thought to work by their action on brain chemicals.

## Before you use INZOLAM

When you must not take it Do not take Inzolam if you:

 have an allergy to triazolam, any other benzodiazepine, or any of the ingredients listed at the end of this leaflet.

- some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- are suffering from depression or are taking nefazodone, a medicine used for treating depression.
- are taking medicines to treat fungal infections (ketoconazole and itraconazole).
- have severe and chronic lung disease.
- suffer from a disease that causes severe muscle weakness known as myasthenia gravis.
- are pregnant or plan to become pregnant. Do not use in future episodes of insomnia unless you are sure you are not pregnant.
- are breastfeeding or plan to breast-feed.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

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

Inzolam is not recommended for use in children. Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of Inzolam has not been established in patients under the age of 18.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

## Before you start to use it

You have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

You have or have had any other medical conditions including:

- liver, kidney, heart or lung disease
- sleep apnoea (when breathing either slows or stops for short periods while sleeping)
- fits or convulsions
- high or low blood pressure
- glaucoma (high pressure in the eye)
- depression, psychosis or schizophrenia

You have an addiction to any drug including alcohol.

Alcohol may increase the effects of Inzolam.

You have experienced an episode of driving, preparing and eating food, making phone calls or other behaviours while not fully awake after having previously taken Inzolam or another sleeping pill.

You are pregnant or intend to become pregnant.

You are breast-feeding or planning to breast-feed.

If you have not told your doctor or pharmacist about any of the above, tell them before you start Inzolam.

## Taking other medicines

Do not have any grapefruit juice if you are taking Inzolam tablets as grapefruit juice may interfere with Inzolam.

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

Tell any health professional who is prescribing a new medicine for you that you are taking Inzolam.

Some medicines and Inzolam may interfere with each other. These include:

- other sleeping tablets, sedatives
- medicines for depression, anxiety or mood disorders
- medicines for allergies, for example antihistamines, or cold tablets
- muscle relaxants
- medicines to control fits
- pain relievers
- antibiotics (erythromycin, clarithromycin)
- cimetidine, a medicine used to treat reflux and ulcers
- medicines used for various heart conditions (verapamil and diltiazem)
- disulfiram, a medicine used to control alcohol problems
- medicines used to treat fungal infection (ketoconazole, itraconazole)

The above medicines may be affected by Inzolam, or may affect how well it works.

You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful of or avoid while taking Inzolam.

### How to use INZOLAM

## How much to use

The usual adult dose is 0.25 mg (2 tablets) before going to sleep.

For elderly or debilitated person, the recommended dose is 0.125mg to 0.25mg.

Sometimes your doctor will recommend you take less than this, rarely they might recommend you take more.

Follow all your instructions from your doctor or pharmacist about how much Inzolam to take.

## When to use it

Inzolam should be taken as recommended by your doctor.

## How long to use it

Do not use Inzolam for a longer period than your doctor says.

Inzolam should be used for short periods only. 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 are unsure whether you should stop taking Inzolam, talk to 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 the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

## If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Inzolam.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Also report any other medicine or alcohol which has been taken.

Symptoms of overdose:

- drowsiness
- mental confusion
- lethargy
- ataxia (disturbances of muscle coordination, resulting in muscle movement becomes irregular)
- hypotonia (instances the lack of tension in the muscles)
- hypotension (low blood pressure)
- respiratory depression
- coma

## While you are using it

## Things you must do

Use Inzolam exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Inzolam. Likewise, tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

Always discuss with your doctor any problems or difficulties, during or after taking Inzolam.

If you become pregnant while taking this medicine, tell your doctor immediately.

Go to your doctor regularly for a check-up.

Your doctor needs to check your progress and see whether you need to keep taking Inzolam.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Inzolam to last for weekends and holidays.

## Things you must not do

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

This medicine is only intended for the use of the patient it has been prescribed for.

Do not use Inzolam to treat any other complaints unless your doctor tells you to.

Do not take Inzolam for a longer time than your doctor has prescribed.

Inzolam should be taken for short periods only unless advised otherwise by your doctor.

Do not change your dose without first checking with your doctor.

Do not stop taking Inzolam without checking with your doctor, even if you are feeling better

If you stop taking Inzolam suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase.

To prevent this, your doctor may gradually reduce the amount of Inzolam you take each day before stopping completely.

Do not take any medicines that cause drowsiness while you are taking Inzolam, unless recommended by your doctor.

## Things to be careful of

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

Inzolam may cause drowsiness or dizziness in some people and therefore may affect alertness.

Even if you take Inzolam at night, you may still be drowsy or dizzy the next day. Caution should be taken when a full night's sleep is not possible. Patients should also take care as pedestrians.

Be careful when drinking alcohol while taking Inzolam.

Combining Inzolam and alcohol can make you more sleepy, dizzy or lightheaded.

Alcohol can increase the risk of sleep-walking or other behaviours such as driving or eating food while asleep. Sometimes these behaviours are not remembered by the person taking Inzolam. The risk of these behaviours occurring is also increased if you take more than the recommended dose.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Inzolam.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

### Side effects

Like all medicines, Inzolam may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Drowsiness or sleepiness during the day
- Tiredness
- Light-headedness and dizziness
- Difficulty concentrating
- Headache

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 Inzolam

## <u>Storage</u>

Keep your tablets in the pack until it is time to take them.

If you take them out of their packaging, they will not keep well

Keep them in a cool, dry place where the temperature stays below 25°C. Protect from light.

Do not store them, or any other medicine in the bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets where young children cannot reach them.

A locked cupboard at least one-and half metres above the ground is a good place to store medicine.

Do not keep Inzolam past its expiry date.

## Disposal

If your doctor tells you to stop taking Inzolam, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

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

Inzolam Tablet 0.25mg is an oval, scored tablet blue in colour with markings 'DUO 861' and 'd/d'.

## **Ingredients**

Active ingredient:

Triazolam

## Inactive ingredients:

- Aerosil
- Avicel
- Promigel
- Corn starch

- Sodium benzoate
- Sodium lauryl sulphate
- Brilliant blue
- Magnesium stearate
- Lactose

MAL number MAL20041071A

#### 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**

25/09/2014

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