ATIVAN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ATIVAN?

ATIVAN contains the active ingredient lorazepam. ATIVAN is used to relieve anxiety.

For more information, see Section 1. Why am I using ATIVAN? in the full CMI.

2. What should I know before I use ATIVAN?

Do not use if you have ever had an allergic reaction to ATIVAN Tablets or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ATIVAN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ATIVAN Tablets and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ATIVAN Tablets?

- The dose of ATIVAN may be different for each person. Your doctor will decide the right dose for you.
- Your ATIVAN Tablet should be swallowed with a drink of water. It may be taken with or without food.

More instructions can be found in Section 4. How do I use ATIVAN Tablets? in the full CMI.

5. What should I know while using ATIVAN?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using ATIVAN. If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.
Things you should not do	 Do not stop taking ATIVAN or lower the dose, without first checking with your doctor. Do not give this medicine to anyone else, even if their symptoms seem similar to yours. Do not take ATIVAN for a longer time than your doctor has prescribed.
Driving or using machines	 This medicine may cause drowsiness or dizziness in some people and therefore may affect alertness. Do not drive or operate machinery until you know how ATIVAN affects you.
Drinking alcohol	 Be careful when drinking alcohol while taking ATIVAN. Combining ATIVAN and alcohol can make you more sleepy, dizzy, or lightheaded.
Looking after your medicine	 Keep ATIVAN in a cool dry place where the temperature stays below 25°C Keep your tablets in their blister pack until it is time to take them

For more information, see Section 5. What should I know while using ATIVAN Tablets? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ATIVAN. Tell your doctor if you notice any of the following common side effects and they worry you: drowsiness, dizziness, sleepiness, clumsiness or unsteadiness, weakness, loss of memory. Less common side effects include skin rashes, feeling sick or vomiting, outbursts of anger and increased excitement, sleep disturbance, nausea and dry mouth. **This is not a complete list of all possible side effects.** For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

ATIVAN

Active ingredient(s): Lorazepam

Consumer Medicine Information (CMI)

This leaflet answers some common questions about ATIVAN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ATIVAN against the benefits this medicine is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

Where to find information in this leaflet:

- 1. Why am I using ATIVAN?
- 2. What should I know before I use ATIVAN?
- 3. What if I am taking other medicines?
- 4. How do I use ATIVAN?
- 5. What should I know while using ATIVAN?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using ATIVAN Tablets?

ATIVAN contains the active ingredient lorazepam. ATIVAN is a benzodiazepines which is thought to work by its action on brain chemicals.

ATIVAN is used to relieve anxiety. However, anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

It is also used before surgery to help relax you.

Your doctor may have prescribed it for another purpose.

This medicine is available only with a doctor's prescription.

2. What should I know before I use ATIVAN Tablets?

Warnings

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.

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of ATIVAN in children under 16 years has not been established.

Do not use ATIVAN Tablets if:

- you are allergic to lorazepam or any of the ingredients listed at the end of this leaflet (See "side effects").
- you are allergic to any other medicine from the benzodiazepine group of medicines.
- you have severe and chronic lung disease.
- you have sleep apnoea, a condition where you have breathing problems when you sleep.
- you are depressed with or without anxiety problems.
 Lorazepam can increase thoughts of death or suicide.
- severe muscle weakness known as myasthenia gravis
- severe liver problems
- the expiry date (EXP) printed on the pack has passed.
 If you take it after the expiry date has passed, it may not work as well or have no effect at all.
- the packaging is torn or shows signs of tampering

Check with your doctor if you:

Have any allergies to:

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

Are pregnant or planning to become pregnant

You have or have had any other medical conditions including:

- liver, kidney, or lung disease
- breathing problems
- blood disorders
- fits or convulsions
- low blood pressure
- glaucoma (high pressure in the eye)
- memory problems
- depression, psychosis or schizophrenia.

Drink alcohol regularly; alcohol may increase the effects of ATIVAN.

If you have not told your doctor about any of the above, tell them before you take any ATIVAN.

See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Do not take ATIVAN if you are pregnant or planning to become pregnant unless you and your doctor have discussed the risks and benefits involved.

ATIVAN may affect the development of newborn babies and cause breathing difficulty, muscle stiffness, a drop in body temperature or yellowing of the skin.

Babies born to mothers who take ATIVAN throughout their pregnancy may be at risk of withdrawal symptoms. The baby may require ventilation at birth.

Do not take ATIVAN if you are breastfeeding or planning to breastfeed unless you and your doctor have discussed the risks and benefits involved.

Use in Children

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of ATIVAN in children under 16 years has not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with ATIVAN. These include:

- other sleeping tablets, sedatives, or tranquillisers
- medicines for depression or mental illness
- medicines for allergies for example antihistamines or cold and flu tablets
- theophylline or aminophylline which are medicines for breathing problems
- pain relievers
- muscle relaxants
- · medicines to control fits.

These medicines may increase the effects of ATIVAN.

Do not use ATIVAN with these medicines or alcohol. It may increase the risk of heart or breathing problems.

You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking ATIVAN.

4. How do I use ATIVAN Tablets?

How much to take / use

The dose of ATIVAN may be different for each person. Your doctor will decide the right dose for you.

For anxiety, the usual daily dose is 2 to 3 mg administered in divided doses. However, the daily dose can range from 1 to 10 mg.

For sleeping problems (insomnia) due to anxiety, a dose of 1 to 2 mg taken at bedtime is usually prescribed.

If you are taking ATIVAN before surgery the usual dose is 2 to 4 mg the night before surgery. Another dose of 2 to 4 mg may also be given 1 to 2 hours before surgery.

Elderly people may need a lower dose.

When to take / use ATIVAN Tablets

Your doctor will tell you how many times during the day you need to take ATIVAN.

Do not take ATIVAN for longer than your doctor says.

ATIVAN is usually used for short periods only (for example 2-4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Continue taking ATIVAN as long as your doctor recommends it.

How to take ATIVAN Tablets

Swallow ATIVAN with a glass of water. It may be taken with or without food.

If you forget to use ATIVAN

ATIVAN should be used regularly at the same time each day.

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 it as you would normally.

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

If you have missed more than two doses in a row, speak to your doctor or pharmacist.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you are taking ATIVAN for insomnia due to anxiety and forget to take ATIVAN before you go to bed, do not take any ATIVAN if you wake up late in the night or early morning.

Taking ATIVAN late at night or early in the morning may make it hard for you to wake in the morning. If you have any questions about this, ask your doctor or pharmacist.

If you take too much (overdose)

If you think that you or anyone else may have taken too much ATIVAN, you may need urgent medical attention.

If you take too much ATIVAN you may feel drowsy, confused, tired, dizzy, have low muscle strength, low blood pressure, difficulty breathing, lack coordination, feel weak or become unconscious. It can be rarely fatal.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using ATIVAN Tablets?

Things you should do

Take ATIVAN exactly as your doctor has prescribed.

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

Tell your doctor if you feel ATIVAN is not helping your condition.

If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.

This will help your doctor to determine the best treatment for you.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking ATIVAN.

Always discuss with your doctor any problems or difficulties you have during or after taking ATIVAN.

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 ATIVAN to last weekends and holidays.

Remind any doctor, dentist or pharmacist you visit that you are using ATIVAN.

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.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Things you should not do

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

ATIVAN should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.

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

Do not stop taking ATIVAN or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted withdrawal effects. This is more common in patients that have taken high doses over longer periods of time.

Withdrawal symptoms may include insomnia, anxiety, unusual mood, fast heartbeat, panic attacks, dizziness, lack of normal movement, light sensitivity, increased sound and touch sensitivity, abnormal body sensations (e.g. feels of motion, metallic taste), confusion, hallucinations, vomiting, sweating and loss of short-term memory.

Your doctor will slowly reduce your dose before you can stop taking it completely. This will minimise these unwanted withdrawal symptoms.

Do not suddenly stop taking ATIVAN if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give ATIVAN to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ATIVAN affects you.

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

Make sure you know how you react to ATIVAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take ATIVAN at night, you may still be drowsy or dizzy the next day.

Driving alcohol

Be careful when drinking alcohol while taking ATIVAN.

Combining ATIVAN 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 ATIVAN.

Looking after your medicine

Keep ATIVAN in a cool dry place where the temperature stays below 25 $^{\circ}\text{C}.$

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

If you take the tablets out of the box or the blister pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 drowsiness dizziness sleepiness clumsiness or unsteadiness muscle weakness, tiredness dry mouth, excessive drooling 	Speak to your doctor if you notice any of the following side effects and they worry you.

Serious side effects

Serious side effects	What to do
 skin rashes nausea, feeling sick or vomiting change in appetite outbursts of anger and increased excitement confusion or depression headache slurred speech sleep disturbances vision problems such as blurred vision low blood pressure breathing difficulty loss of memory tremor reduced alertness loss of consciousness impotence hypothermia (low body temperature) 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Other less common or rare side effects include:

- dry mouth
- excessive salivation
- changes in appetite

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What ATIVAN Tablets Contains

Active ingredient (main ingredient)	 Each ATIVAN 1 mg tablet contains 1 mg lorazepam. Each ATIVAN 2.5 mg tablet contains 2.5 mg lorazepam.
Other ingredients (inactive ingredients)	 magnesium stearate cellulose-microcrystalline polacrilin potassium lactose monohydrate
Potential allergens	• lactose

ATIVAN does not contain gluten, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What ATIVAN looks like

ATIVAN 1 mg tablets are white to off white, round tablets with a breakbar on one side and "C11" on the other.

ATIVAN 2.5 mg tablets are white to off white, round tablets with a breakbar on one side and "C18" on the other.

ATIVAN 1 mg and 2.5 mg tablets are supplied in blister packs or glass bottles in Australia. Each pack contains 50 tablets.

ATIVAN 1 mg and 2.5 mg tablets are supplied in glass bottles in New Zealand. ATIVAN 1 mg bottles contain 250 tablets and ATIVAN 2.5 mg bottles contain 100 tablets.

Australian Registration Numbers:

1 mg tablets: AUST R 10387 (blister pack); AUST R 237801 (bottle)

2.5 mg tablets: AUST R 10388 (blister pack); AUST R 237802 (bottle).

Who distributes ATIVAN

In Australia:

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street, St. Leonards NSW 2065 Australia

In New Zealand:
Pharmacy Retailing (NZ) Ltd t/a
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
AUCKLAND

This leaflet was revised in February 2025.