

Package leaflet: Information for the patient

Ativan® 1mg tablets lorazepam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Ativan Tablets are and what they are used for**
- 2. What you need to know before you take Ativan Tablets**
- 3. How to take Ativan Tablets**
- 4. Possible side effects**
- 5. How to store Ativan Tablets**
- 6. Contents of the pack and other information**

1. What Ativan Tablets are and what they are used for

The name of your medicine is Ativan Tablets. Ativan Tablets contain the active substance lorazepam. Ativan Tablets are a member of a group of medicines called benzodiazepines. It can help to relieve anxiety.

Ativan Tablets may be prescribed as short-term therapy for anxiety or sleeping difficulties due to anxiety which is significantly affecting normal daily life.

It may also be used as a sedative before surgery or operative dental treatment.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Ativan Tablets

Do not take Ativan Tablets:

- If you are allergic to lorazepam, other benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- If you have severe breathing or chest problems
- If you have 'myasthenia gravis' (very weak or tired muscles)
- If you have serious liver problems
- If you suffer from 'sleep apnoea' (breathing problems when you are asleep)

If any of the above apply to you, do not take Ativan Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ativan Tablets

- If you are pregnant or trying to become pregnant
- If you abuse or have in the past abused drugs or alcohol
- If you have a personality disorder. If so, you have a greater chance of becoming dependent on Ativan Tablets

- If you have any kidney or liver problems
- If you are elderly or debilitated (weak)
- If you have suffered from depression before since it could re-occur during treatment with Ativan Tablets
- If you are suffering from depression, since Ativan Tablets may increase any suicidal feelings which you may have
- If you have a history of psychotic illness
- If you have a history of convulsions/seizures
- If you suffer from breathing problems
- If you suffer from an eye problem called glaucoma
- If you are taking any other medicines, including those which have not been prescribed by a doctor, since they may affect the way Ativan Tablets works. Ativan Tablets may also affect the way other drugs work

Other medicines and Ativan Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular

- barbiturates - sedatives, anti-anxiety drugs
- antidepressants
- strong pain killers (e.g. opioids- keep the dosages and duration of the medicine to a minimum as recommended by your doctor). Taking Ativan with these pain killers may make you more sleepy and in rare cases can cause breathing difficulty and death.
- drugs for epilepsy (e.g. sodium valproate)
- antihistamines
- anti-psychotic drugs for mood or mental disorders (e.g. loxapine or clozapine)
- anaesthetics – drugs that cause anaesthesia – reversible loss of sensation
- drugs for asthma (theophylline, aminophylline)
- probenecid (a drug to treat gout)

The dose of these drugs may need to be reduced before you can take Ativan Tablets.

Ativan Tablets with food, drink and alcohol

Alcohol will increase the sedative effects of Ativan Tablets and should therefore be avoided. Please refer to section 3.

Things to note before taking Ativan Tablets

Tell your doctor or pharmacist that you are taking Ativan Tablets before taking any other medicine or if you enter hospital for treatment.

Some elderly patients may feel dizzy after taking Ativan Tablets and may be in danger of falling.

Tolerance and dependence

Tolerance to benzodiazepines may occur. Therefore the beneficial effect of Ativan Tablets may be less apparent after several weeks of use.

Lorazepam may have abuse potential, especially in patients with a history of drug and/or alcohol abuse.

Dependence is unlikely to occur but the risk increases with higher doses and longer-term use and is further increased in patients with a history of alcoholism, drug abuse or in patients with personality disorders. Therefore use in individuals with a history of alcoholism or drug abuse should be avoided.

Dependence may lead to withdrawal symptoms, especially if treatment is discontinued abruptly. Therefore, the drug should always be discontinued gradually.

If you are given Ativan Tablets for more than 4 weeks, your doctor might want to take blood samples occasionally to check your blood and liver, since drugs like Ativan Tablets have occasionally affected liver function.

Dependence on benzodiazepines may occur following prolonged treatment. Therefore Ativan Tablets are usually prescribed for short courses of treatment, lasting from a few days to 4 weeks including a dose reduction at the end. This reduces the risk of becoming dependent on Ativan Tablets, or suffering unpleasant effects when you stop taking it. (See section 3 'If you stop taking Ativan Tablets', below).

Increases in the dosage of lorazepam should be made gradually to help avoid adverse effects. The evening dose should be increased before the daytime doses.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Benzodiazepines, including Ativan Tablets may cause damage to the foetus if taken during early pregnancy. If you take this medicine during late pregnancy or during labour, your baby, when born, may be less active than other babies, have a low body temperature, be floppy or have breathing or feeding difficulties for a while. Your baby's response to the cold might be temporarily impaired also. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms after birth.

Ativan should not be given to breastfeeding mothers unless the expected benefit to the mother outweighs the potential risk to the infant, as the drug may pass into breast milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ativan Tablets may make you sleepy or affect your concentration. This may affect your performance at skilled tasks e.g. driving and operating machinery, particularly if you have not had enough sleep.

Ativan Tablets contain lactose monohydrate

Ativan Tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ativan Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

If you have been given Ativan Tablets for anxiety or sleeping problems, treatment will usually last from a few days to 4 weeks and will usually include a dose reduction at the end.

You will be prescribed the lowest effective dose for the shortest possible time.

Ativan Tablets should be swallowed with water.

The recommended dose is:

Adults (and children over 13 years of age)

Anxiety:	1 to 4 mg daily in divided doses. Your doctor will tell you how often to take your tablets. Ativan is not recommended for the treatment of anxiety in children under 12 years of age.
Sleeping Problems:	1 to 2 mg before going to sleep. You should make sure that you will be able to sleep for 7 to 8 hours before taking your tablets.
Before Surgery:	2 to 3 mg the night before your operation and 2 to 4 mg one or two hours before your operation.

Children (between 5 and 13 years of age)

Before Surgery:	The dose is usually between 0.5 and 2.5 mg (depending on your child's weight) at least one hour before your child's operation.
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Ativan Tablets are not recommended for the treatment of anxiety or sleeping problems in children. Nor is it recommended for children below 5 years of age.

Elderly

Elderly and debilitated (weak) patients may be given lower doses. They may respond to half the usual adult dose or less. However, this lower dose may be adjusted if needed.

Patients with Renal or Hepatic Impairment

Lower doses may be sufficient in patients with impaired renal function or mild to moderate hepatic insufficiency. Use in patients with severe hepatic insufficiency is contraindicated.

If you take more Ativan Tablets than you should

If anyone has taken an overdose of Ativan Tablets (that is more than the doctor has prescribed), seek medical help immediately, either by calling your doctor, or going to the nearest casualty department. Always take the labelled medicine container with you, even if there are no tablets left.

If you forget to take Ativan Tablets

If you forget to take a tablet for anxiety and if it is less than 3 hours since your usual time, you should take it as soon as you remember. If more than 3 hours has passed from when you usually take your tablet, don't worry; just take your next tablet when it is due. Do not take a double dose to make up for a forgotten tablet.

If you forget to take a tablet for sleeping problems, only take it if you will be able to sleep for 7 to 8 hours afterwards.

If you stop taking Ativan Tablets

After you have finished your prescribed treatment with Ativan Tablets, your doctor will decide whether or not you need further treatment.

The number of Ativan Tablets and how often you take them should always be reduced slowly before you stop taking them altogether. This allows your body to get used to being without your tablets, and reduces the risk of unpleasant effects when you stop taking them. Your doctor will tell you how to do this.

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

Withdrawal Symptoms

On stopping Ativan Tablets, you may experience withdrawal symptoms such as headaches, muscle pain, anxiety, tension, depression, restlessness, dizziness, nausea, diarrhoea, loss of appetite, confusion, irritability, agitation, shaking, stomach pain, changes in heart rate, short-term memory loss,

high body temperature and sweating. Your original sleeplessness may also return. If you suffer from any of these symptoms, ask your doctor for advice.

Do not stop taking your tablets suddenly. This could lead to more serious withdrawal symptoms such as a loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have experienced numbness or tingling of the arms or legs, vomiting, tinnitus (ringing sounds in your ears), twitching, hallucinations, convulsions and hypersensitivity to light, sound and touch. If you suffer from any of these symptoms, ask your doctor for advice immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Benzodiazepines, including lorazepam, may lead to potentially fatal breathing problems.

Severe allergic reactions can occur with benzodiazepine use, even after the first dose. Symptoms include swelling of the tongue or throat, shortness of breath, throat closing, nausea or vomiting. In such cases, immediate medical attention should be sought.

Occasionally, you may have unwanted effects whilst taking Ativan 1mg Tablets. These are usually not serious and do not last long. However, you should tell your doctor if any of your symptoms are severe or become troublesome:

Other side effects that may occur are:

Very common: may affect more than 1 in 10 people

- Sedation
- Fatigue
- Drowsiness

Common: may affect up to 1 in 10 people

- Muscle weakness
- Asthenia (loss of strength)
- Ataxia (poor muscle control)
- Confusion
- Depression
- Unmasking of depression (revealing signs of depression that were previously hidden)
- Dizziness

Uncommon: may affect up to 1 in 100 people

- Nausea
- Change in libido
- Impotence
- Decreased orgasm

Not known: frequency cannot be estimated from the available data

- Increased sensitivity to light, sound and touch
- Convulsions/fits
- Constipation, yellowing of the skin and eyes
- Shaking
- Problems with vision (double and blurred vision)
- Slurred speech
- Headache
- Memory loss
- Heightened emotions
- Coma
- Impaired attention/concentration
- Loss of inhibitions

- Thoughts or attempts of suicide
- Increase in specific liver enzymes (bilirubin, liver transaminases and alkaline phosphatase)
- Anxiety, excitation, hostility, aggression, sexual arousal
- Balance disorder
- Difficulty breathing
- Difficulty breathing when you are asleep
- Worsening of lung disease
- Allergic skin reactions (e.g. rash, swelling)
- Alopecia (loss of hair from the head or body)
- Hypersensitivity reactions
- Angioedema (swelling of the face, hands and feet)
- SIADH - syndrome of inappropriate antidiuretic hormone hypersecretion (a condition in which the body produces too much antidiuretic hormone (ADH). Increased ADH may cause too much water to remain inside your body.)
- Hyponatremia (low level of sodium in the blood which can cause tiredness and confusion, muscle twitching, fits and coma)
- Hypothermia
- Lowering of blood pressure
- Thrombocytopenia (unexplained bruising, nosebleeds and/or bleeding gums), agranulocytosis (severe infection), pancytopenia (bleeding, bruising easily, fatigue, shortness of breath, and weakness)
- Vertigo
- Problems sleeping

The following side effects may be more likely to occur in children and elderly patients:

- Restlessness
- Agitation
- Irritability
- Aggressiveness
- Violent anger
- Nightmares
- Hallucinations
- Personality changes
- Abnormal behaviour
- False beliefs

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.
Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

Malta

ADR Reporting: www.medicinesauthority.gov.mt/adrportal

5. How to store Ativan Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label, blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store Ativan Tablets above 25°C. Blisters should be stored in the original package and bottles should be kept tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Ativan Tablets contains

The active ingredient is lorazepam. Each tablet contains 1mg of lorazepam. The other ingredients are lactose monohydrate (see section 2 “Ativan Tablets contain lactose monohydrate”), microcrystalline cellulose, polacrillin potassium and magnesium stearate .

What Ativan Tablets looks like and the contents of the pack

Ativan Tablets are round, flat, white, bevelled-edged tablets impressed with “1.0” on one side, and a breakbar on the other.

Supplied in PVC blister packs of 30 and 100 tablets/ Strips of aluminium foil with PE-film strips of 10, 20 or 100 tablets or amber glass bottles with screw caps of 100 or 500 tablets. However, your doctor may prescribe a different number of tablets for you.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

Manufacturer:

Pfizer Ireland Pharmaceuticals
Little Connell
Newbridge
Co. Kildare
Republic of Ireland

Or

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
D-79090 Freiburg
Germany

Company Contact Address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

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