

## 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.

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.

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.

### **Development of tolerance and dependence, withdrawal reactions and drug abuse**

You may experience a reduction in the efficacy of this medicine (tolerance) after continued use. This medicine is recommended for short term treatment.

Treatment with this medicine also increases the sensitivity of the effects of alcohol and other medicines that affect brain function. Therefore, talk to your doctor if you are using alcohol or this type of medicines.

The use of benzodiazepines, including Ativan, may lead to dependence. The risk of dependence is increased with higher doses and continuous use. It is also increased if you have a history of alcohol or drug abuse and in patients with significant personality disorders.

You must tell your doctor if

- you have used or currently use any illegal drugs
- you regularly consume alcohol, or have in the past frequently consumed large quantities of alcohol
- you have had in the past or currently have a craving to take large amounts of medicines
- you have a personality disorder, e.g difficulties interacting with other people or various situations in life, even if you were not always aware of these problems.

In principle, benzodiazepines should only be used for short periods and discontinued gradually. You and your doctor should agree for how long you will take the medicine before starting the treatment.

If you stop taking the drug abruptly or reduce the dosage rapidly, withdrawal reactions can occur. Do not stop taking this medicine suddenly. Ask your doctor for advice on how to discontinue the treatment.

Some withdrawal reactions can be life-threatening.

Withdrawal reactions can range from mild depressed mood and sleeplessness to a major syndrome with cramps in the muscles and abdomen, vomiting, sweating, trembling and convulsions. More severe withdrawal signs and symptoms, including life threatening reactions, can include delirium tremens, depression, hallucinations, mania, psychosis, seizures, and suicidality. Convulsions/seizures may occur more often if you have preexisting seizure disorders or take other drugs that lower the convulsive threshold, such as antidepressants.

Other withdrawal reactions can include: headache, anxiety, restlessness, tension, confusion and irritability, depressed mood, feeling dizzy, feeling of detachment or alienation from oneself and the outside world, excessive perception of noise, tinnitus, tingling and numbness in the limbs, increased sensitivity to light, noise and physical contact / changes in perception, involuntary movements, feel sick to the stomach, lack of appetite, diarrhoea, panic attacks, muscle pain, states of excitation, increased perception of heartbeat (palpitations), faster heartbeat (tachycardia), feeling of losing balance, exaggerated reflexes, loss of ability to remember recent events and increase in body temperature.

Your symptoms for which this medicine was prescribed may also return for a short time (rebound phenomena).

You must not give Ativan Tablets to family or friends. Store this medicine safely so it does not cause harm to others.

### **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**

The dose and duration of administration should be adjusted to your individual situation. Your doctor will advise you on the dose and the number of times a day to take the medicine and the duration of your treatment with Ativan Tablets, so that you take the lowest dose possible for the shortest possible time. You should not change or exceed the dose prescribed for you. To discontinue the treatment, the dose should be gradually reduced in consultation with your doctor. This reduces the risk of withdrawal reactions, which can be life threatening in some cases (see section 2).

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.

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.

### **Duration of use**

The duration of treatment is determined by your doctor. You will be prescribed the lowest effective dose for the shortest possible time as there is a risk of becoming addicted (dependent). Your doctor will assess your treatment frequently.

Stopping taking this medicine or reducing the dose must be carried out slowly and supervised by your doctor to prevent any withdrawal reactions (see section 2).

### **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**

Do not stop taking this medicine suddenly unless you suspect a serious side effect, because the doses have to be reduced gradually. Your doctor will tell you how to discontinue treatment. If you think you experience a serious side effect, talk to your doctor immediately.

If you stop taking Ativan Tablets or reduce the dose suddenly, you may develop temporary withdrawal symptoms or rebound symptoms (see section 2).

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

## **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
- Drug abuse

- Drug dependence
- Drug withdrawal syndrome

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, pharmacist or nurse. 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. Website: [www.hpra.ie](http://www.hpra.ie).

### **Malta**

ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://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 this medicine please contact: Pfizer Medical Information on 1800 633 363 or at [medical.information@pfizer.com](mailto:medical.information@pfizer.com). For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

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