

Package leaflet: Information for the patient

ATIVAN® 4mg/ml SOLUTION FOR INJECTION

lorazepam

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it onto 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Ativan 4 mg/ml Solution for Injection - this medicine will be referred to as Ativan Injection in the rest of this leaflet.

What is in this leaflet

1. What Ativan Injection is and what it is used for.
2. What you need to know before you use Ativan Injection.
3. How to use Ativan Injection.
4. Possible side effects.
5. How to store Ativan Injection.
6. Contents of the pack and other information.

1. What Ativan Injection is and what it is used for

Ativan Injection contains lorazepam, which is a member of a group of medicines called benzodiazepines. It helps to relieve anxiety and muscle tension.

Ativan Injection is usually prescribed as pre-medication to help you to relax before an operation or before uncomfortable or prolonged investigations. It may also be used to relieve short periods of anxiety, excitement or agitation, and in the control of convulsions.

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

Ativan Injection is not recommended for use in children under the age of 12 years except for status epilepticus.

2. What you need to know before you use Ativan Injection

You should not be given Ativan Injection:

- If you have severe breathing or chest problems.
- If you are allergic to benzodiazepines, including lorazepam or any of the other of this medicine (listed in section 6).
- If you have myasthenia gravis (a disease causing weakened muscles and excessive tiredness).
- If you have serious liver problems.
- If you suffer from sleep apnoea (breathing problems when you are asleep).

If you are an out-patient you should not be given Ativan Injection unless you have somebody to take you home.

Ativan Injection contains benzyl alcohol and should not be used in infants or young children up to 3 years old.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ativan Injection if:

- You are pregnant or trying to become pregnant.
- You are breast-feeding, since the drug may pass into breast milk.
- You abuse or have in the past abused drugs or alcohol.
- You have a personality disorder. If so, you have a greater chance of becoming dependent on lorazepam.
- You have any kidney or liver problems.
- You have suffered from depression in the past since it could re-occur during treatment with lorazepam.
- You are currently suffering from depression, since lorazepam may increase any suicidal feelings, which you may have.
- You suffer from breathing problems.
- You suffer from an eye problem called glaucoma.
- You enter hospital for treatment.

Other medicines and Ativan Injection

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, since they may affect the way Ativan Injection works. Ativan Injection may also affect the way other drugs work.

In particular, you should tell your doctor if you are taking any other sedative, anti-anxiety drugs, antidepressants, strong pain killers (e.g. opioids, methadone), drugs for epilepsy, antihistamines, drugs for mood or mental disorders (e.g. chlorpromazine, clozapine and haloperidol), drugs for respiratory diseases, drugs for gout (probenecid). The dose of these drugs may need to be reduced before you can take Ativan Injection. You should also tell your doctor if you are taking a drug called scopolamine, which may be used for gut problems or before an operation.

Use of Ativan at the same time as opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, use of Ativan at the same time as opioids should only be considered when other treatment options are not possible.

However if your doctor does prescribe Ativan together with opioids the dose and duration of treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Ativan Injection with food, drink and alcohol

You should avoid alcohol for at least 24 to 48 hours after receiving Ativan Injection. Please refer to section 3.

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 Injection, 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.

The drug may pass into breast milk.

Driving and using machines

Do not drive or use machinery within 24 to 48 hours of receiving Ativan Injection.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Ativan Injection contains polyethylene glycol and propylene glycol

Toxic effects (including seizures) caused by the ingredients contained in Ativan Injection (polyethylene glycol and propylene glycol) have been reported following very high doses of Ativan Injection.

Ativan Injection contains 20.9mg/ml benzyl alcohol and must not be given to premature babies and babies less than one month old. This preservative may cause allergic and toxic reactions in young children up to three years old.

Propylene glycol may cause alcohol like symptoms.

3. How to use Ativan Injection

Your doctor will give you Ativan Injection, by injecting it into one of your veins (intravenously) or into one of your muscles. Ativan Injection may be diluted with water or saline just before it is given to you. The amount of Ativan Injection you are given will depend on how much you weigh and why it is being given to you:

The recommended dose is:

- Before an operation or investigation, you will usually be given 0.05 mg of Ativan Injection for each kilogram that you weigh (e.g. if you weigh 70 kilograms you will receive 3.5 mg of Ativan Injection).
- For anxiety or excitement, the usual dose is 0.025 to 0.03 mg for each kilogram that you weigh (e.g. if you weigh 70 kilograms you will probably receive 1.75 to 2.1 mg of Ativan Injection).
- When Ativan Injection is used to control convulsions a dose of 4 mg is usually given intravenously to adults. A lower dose of 2 mg given intravenously is usually given to control convulsions in children.

Your doctor may prescribe a different dose or length of treatment, especially if you are elderly.

Some people feel sleepy after receiving Ativan Injection. Therefore, you may need to stay in hospital for at least 8 hours, or overnight, after receiving your injection. If you are to leave hospital shortly after receiving Ativan Injection you should have someone with you.

Ativan Injection is usually only prescribed for one or two doses, or for a short course of treatment. This reduces the risk of becoming dependent on Ativan Injection, or suffering unpleasant effects when you stop taking it (See 'If you stop using Ativan Injection', below).

If you stop using Ativan Injection:

- After you have finished your prescribed treatment with Ativan Injection, your doctor will decide whether or not you need further treatment.
- Following a course of treatment your dose of Ativan Injection may be reduced slowly. This allows your body to get used to being without Ativan Injection, and reduces the risk of unpleasant effects.
- On stopping Ativan Injection, you may experience symptoms such as headaches, muscle or stomach pains, anxiety, tension, depression, restlessness, sweating, sleep problems, confusion or irritability. If these symptoms do occur, they do not usually last for long. If you suffer from any of these symptoms, ask your doctor for advice.
- If you suffer from any of the following symptoms; loss of the sense of reality, tinnitus (ringing sounds in your ears), numbness or tingling of your arms or legs, vomiting, twitching, hallucinations, convulsions, or effects on sight, hearing or touch, ask your doctor for advice immediately.

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

4. Possible side effects

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

Reasons for stopping Ativan Injection

It is very important that you immediately contact your doctor if you develop any of the following symptoms:

- Anaphylactic (severe allergic) reactions such as swelling of the face, tongue, lips or throat (angioedema), which may cause difficulty breathing; swelling of the extremities (hands or feet)
- A serious allergic reaction which causes swelling of your face or throat (angioedema)
- Develop signs of jaundice (yellowing of the skin or the whites of the eyes)
- Difficulty breathing
- Thoughts of harming or killing yourself
- Changes in your mental state.

Other side effects that may occur are:

Very common: may affect more than 1 in 10 people

- Drowsiness, sedation
- Tiredness.

Common: may affect up to 1 in 10 people

- Confusion, depression, unmasking of depression

- Lack of muscle coordination, dizziness
- Muscle weakness
- Lack of energy.

Uncommon: may affect up to 1 in 100 people

- Nausea
- Changes in sex drive, impotence, decreased orgasm.

Not known: frequency cannot be estimated from available data

Contact your doctor if you develop any of the following symptoms:

- Blood disorders which can include lower levels of red blood cells, white blood cells and platelets (known as blood dyscrasias). Symptoms of this include unexplained bruising, bleeding, pale skin, weakness and/or breathlessness, mouth ulcers and/or frequent infections.
- Allergic (hypersensitivity) reactions
- Abnormally concentrated urine
- Low levels of sodium in the blood
- Loss of inhibitions, feelings of great happiness or well-being (euphoria), thoughts or attempts of suicide
- Anxiety, agitation, excitation, hostility, aggression, rage, sleep disturbances/insomnia, sexual arousal, and hallucinations
- Extrapyramidal symptoms, involuntary trembling, vertigo, visual disturbances (including double vision and blurred vision), slurred speech, headache, vomiting, fits, memory loss, coma
- Low blood pressure
- Reduced breathing rate, shortness of breath, temporary cessation of breathing, including during sleep, worsening of sleep
- Worsening of chronic obstructive lung disease
- Constipation
- Increases in liver enzymes, which may affect the way your liver works (will be detected by blood tests)
- Allergic skin reactions, hair loss
- Hypothermia
- Pain or redness at the injection site.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Ativan Injection

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 carton or bottle after 'EXP'. The expiry date refers to the last day of that month.

Ativan Injection should be stored and transported refrigerated (2°C to 8°C).

Keep ampoule in the outer carton to protect from light.

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. Contents of the pack and other information

What Ativan Injection contains

The active ingredient in Ativan Injection is lorazepam, and there are 4 mg of lorazepam in each 1 ml of the injection.

The other ingredients in Ativan Injection are polyethylene glycol, benzyl alcohol and propylene glycol (see section 2 “Ativan Injection contains polyethylene glycol and propylene glycol”).

What Ativan Injection looks like and contents of the pack

Ativan Injection is a clear, colourless solution supplied in small clear glass bottles (called ampoules) and each ampoule contains 1 ml of Ativan Injection.

Ativan Injection is supplied in packs of 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich
Kent,
CT13 9NJ
United Kingdom

Manufacturer:

Haupt Pharma Livron
1 rue Comte de Sinard
26 250 Livron Sur Drome
France

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.

This leaflet was last revised in 09/2018

Ref: AT 8_2

The following information is intended for medical or healthcare professionals only:

Posology and method of administration

Posology

Dosage and duration of therapy should be individualised. The lowest effective dose should be prescribed for the shortest time possible.

Treatment in all patients should be withdrawn gradually to minimise possible withdrawal symptoms (see section 4.4).

Method of administration

Ativan Injection can be given intravenously or intramuscularly. However, the intravenous route is to be preferred. Care should be taken to avoid injection into small veins and intra-arterial injection.

Absorption from the injection site is considerably slower if the intramuscular route is used and as rapid an effect may be obtained by oral administration of lorazepam.

Ativan should not be used for long-term chronic treatment.

Preparation of the injection

Ativan Injection is slightly viscid when cool.

Intramuscular administration:

A 1:1 dilution of Ativan Injection with normal saline or Sterile Water for Injection BP is recommended in order to facilitate intramuscular administration.

Intravenous administration:

For intravenous administration, Ativan Injection should always be diluted with saline or Sterile Water for Injection BP as a 1:1 dilution.

Ativan Injection is presented as a 1ml solution in a 2ml ampoule to facilitate dilution.

Ativan Injection should not be mixed with other drugs in the same syringe.

Dosage:

1. Premedication:

Adults: 0.05mg/kg (3.5mg for an average 70kg man). By the intravenous route the injection should be given 30-45 minutes before surgery when sedation will be evident after 5-10 minutes and maximal loss of recall will occur after 30-45 minutes.

By the intramuscular route the injection should be given 1-1½ hours before surgery when sedation will be evident after 30-45 minutes and maximal loss of recall will occur after 60-90 minutes.

Paediatric population: Ativan Injection is not recommended in children under 12.

2. Acute Anxiety

Adults: 0.025-0.03mg/kg (1.75-2.1mg for an average 70kg man). Repeat 6 hourly.

Paediatric population: Ativan Injection is not recommended in children under 12.

3. Status epilepticus

Adults: 4mg intravenously

Paediatric population: 2mg intravenously

Elderly: The elderly may respond to lower doses and half the normal adult dose may be sufficient.

Patients with Renal or Hepatic impairment:

Lower doses may be sufficient in these patients (see section 4.4). Use in patients with severe hepatic insufficiency is contraindicated.

Incompatibilities

Not Applicable.

Shelf life

1 year.

Special precautions for storage

Store and transport refrigerated (2°C to 8°C).

Keep ampoule in the outer carton to protect from light.

Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.