PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

ATIVAN INJECTION

Read all of this leaflet carefully before ATIVAN INJECTION is administered to you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ATIVAN INJECTION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ATIVAN INJECTION CONTAINS

The active substance is lorazepam.

Each 1 ml of ATIVAN INJECTION contains 4 mg of lorazepam.

The other ingredients are benzyl alcohol, polyethylene glycol, propylene glycol.

Preservative: Benzyl alcohol 2 % *v/v*

Sugar free

WHAT ATIVAN INJECTION IS USED FOR

ATIVAN is used for the following:

- As pre-medication to help you to relax before an operation or before uncomfortable or prolonged investigations.
- To relieve short periods of anxiety, excitement or agitation.
- To control convulsions (fits).

BEFORE YOU RECEIVE ATIVAN INJECTION

You should not be given ATIVAN INJECTION

- if you are allergic (hypersensitive) to lorazepam or any of the ingredients contained in ATIVAN INJECTION.
- if you have pre-existing central nervous system (CNS) depression (decreased rate of breathing, decreased heart rate and loss of consciousness).
- if you have severe breathing or chest problems.
- 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 should not be given to children under 12 years of age.
- if you are pregnant or trying to become pregnant.

Tell your doctor or healthcare provider before being given ATIVAN INJECTION if you:

- drink alcohol or take medicines called Central nervous system (CNS) depressants as your tolerance to them may decrease in the presence of ATIVAN INJECTION.
- have suffered from depression in the past, as this may re-occur during treatment with

ATIVAN INJECTION.

- are currently suffering from depression, since ATIVAN INJECTION may increase any suicidal feelings which you may have.
- have a condition that affects your breathing (e.g. chronic obstructive pulmonary disease (COPD)) as concomitant use of ATIVAN INJECTION may cause you to stop breathing and/or your heart to stop.
- suffer from an eye problem called glaucoma (increased pressure in the eye).
- suffer from anxiety that is related to another condition which you suffer from.
- have hepatic encephalopathy (worsening of brain function that occurs when the liver is no longer able to remove toxic substances in the blood), as your condition may worsen with concomitant ATIVAN INJECTION use.
- have impaired kidney function.

Pregnancy and breastfeeding

If you are pregnant or might become pregnant ATIVAN INJECTION should not be administered to you.

You should not breastfeed while you are receiving ATIVAN INJECTION.

If you are pregnant or breastfeeding please consult your healthcare provider for advice before receiving ATIVAN INJECTION.

Important information about some of the ingredients of ATIVAN INJECTION

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.

Taking other medicines with ATIVAN INJECTION

Always tell your healthcare professional if you are taking any other medication (this includes complementary or traditional medicines).

The effects of other medicines might be influenced if you receive ATIVAN INJECTION. Tell your doctor if you are taking any of the following medicines:

- any other sedative, anti-anxiety medicines, antidepressants, strong pain killers (e.g. opioids or morphine).
- medicine for epilepsy, antihistamines.
- medicine for mood or mental disorders (e.g. chlorpromazine, clozapine and haloperidol).
- medicine for respiratory diseases, medicine for gout (probenecid).
- hyoscine butyl bromide, which may be used for gut problems or before an operation.
- medicine for asthma (e.g. theophylline or aminophylline).

The dose of these medicines may need to be reduced before you receive ATIVAN INJECTION.

HOW TO RECEIVE ATIVAN INJECTION

Your doctor will give you ATIVAN INJECTION, by injecting it into one of your veins (intravenously) or into one of your muscles (intramuscularly). ATIVAN INJECTION will 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.

You may feel sleepy after receiving ATIVAN INJECTION. Therefore, you may need to stay in hospital for at least 24 hours, or preferably overnight, after receiving your injection. If you are to leave hospital shortly after receiving ATIVAN INJECTION you should have someone

with you and you should not drive motor vehicles.

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.

ATIVAN INJECTION should not be used in children under 12 years of age.

If you have a problem with your kidneys or liver, your doctor may decide to reduce your dose.

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

POSSIBLE SIDE EFFECTS

ATIVAN INJECTION can cause side effects.

Not all side effects reported for ATIVAN INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ATIVAN INJECTION, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ATIVAN INJECTION:

- Anaphylactic (severe allergic) reactions (such as itchy rash, swelling of face, tongue or throat and difficulty breathing)
- Develop signs of jaundice (yellowing of the skin or the whites of the eyes)
- Thoughts of harming or killing yourself
- Changes in your mental state

- Anxiety, agitation, aggression, anger, sleeping difficulties.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ATIVAN INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you develop any of the following side effects:

Frequent:

- Drowsiness, sedation
- Tiredness
- Confusion, depression, unmasking of depression
- Lack of muscle coordination, dizziness
- Muscle weakness
- Lack of energy.

Less frequent:

- 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
- Changes in vision
- Nausea, vomiting
- Changes in appetite
- Changes in salivation
- Lack of ability to urinate or involuntary leakage of urine
- Change in sexual drive, inability to achieve and maintain an erection, decreased orgasm

- Allergic reactions
- Abnormally concentrated urine
- Low levels of sodium in the blood
- Anxiety, agitation, excitation, hostility, aggression, rage, sleep disturbances/insomnia, sexual arousal, and hallucinations
- Loss of inhibitions, euphoria, thoughts or attempts of suicide
- Involuntary trembling, vertigo, slurred speech, headache, vomiting, convulsions/seizures, memory loss, coma
- Low blood pressure
- Reduced breathing rate, shortness of breath, temporary cessation of breathing, including during sleep
- Worsening of chronic obstructive lung disease
- Constipation
- Increase in specific liver enzymes (bilirubin, liver transaminases and alkaline phosphatase)
- Allergic skin reactions, hair loss
- Stinging or painful sensation at the injection site
- Hypothermia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ATIVAN INJECTION

Store at 2 °C to 8 °C (in a refrigerator).

Protect from light.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ATIVAN INJECTION

5 x 2 ml amber Type I glass ampoules, each containing 1 ml of ATIVAN (lorazepam) solution equivalent to 4 mg lorazepam, are packed in a transparent polyvinyl chloride tray. The ampoules, one tray (5 ampoules) or two trays (10 ampoules), are packed into an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

IDENTIFICATION OF ATIVAN INJECTION

A clear colourless solution free from particulate matter.

REGISTRATION NUMBER

JX/2.6/295

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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