LORAZEPAM SXP

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.
WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given LORAZEPAM SXP?

LORAZEPAM SXP contains the active ingredient lorazepam. It is used in adults to treat epilepsy, for the short-term relief of excessive anxiety or agitation and also to relax a patient before surgery or sedation for prolonged procedures. This medicine may be given to your child to treat epilepsy, if your child is more than 6 years of age.
For more information, see Section 1. Why am I being given LORAZEPAM SXP? in the full CMI.

2. What should I know before I am given LORAZEPAM SXP?

Do not use if you have ever had an allergic reaction to lorazepam 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 am given LORAZEPAM SXP? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LORAZEPAM SXP 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 am I given LORAZEPAM SXP?

- Your doctor will decide what dose of LORAZEPAM SXP injection you will receive and how long you will receive it. This depends on your medical condition and other factors, such as weight.
- LORAZEPAM SXP injection must be diluted with an equal amount of diluent prior to intravenous injection into a vein. The injection should be made slowly.

More instructions can be found in Section 4. How am I given LORAZEPAM SXP? in the full CMI.

5. What should I know while being given LORAZEPAM SXP?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are being given LORAZEPAM SXP. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• You may need assistance to get out of bed after you have been given this medicine. • If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. • Avoid consuming alcohol for at least 48 hours after being given this medicine.
Driving or using machines	• Do not drive or operate machinery until 48 hours after you have been given LORAZEPAM SXP.
Looking after your medicine	• LORAZEPAM SXP will be stored in the refrigerator at the surgery, pharmacy or ward of the medical facility where the temperature stays below 8°C.

For more information, see Section 5. What should I know while I am being given LORAZEPAM SXP in the full CMI.

6. Are there any side effects?

All medicines have side effects, likewise this medicine may have unwanted side effects. Sometimes these are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Common side effects are confusion, depression, dizziness, drowsiness, sleepiness, insomnia, unsteadiness or lack of balance or co-ordination, disorientation, slurred speech, muscle weakness, dry mouth, increased saliva, cough, or lack of energy. Serious side effects include difficulty breathing, excessive sleepiness or loss of consciousness, convulsions, fits or seizures, depression, anxiety, suicidal thoughts, tremor, slurred speech, impaired concentration, visual disturbances, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. Tell your doctor immediately if you notice any of the serious symptoms above.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

FOR ACUTE USE ONLY. CONTAINS BENZYL ALCOHOL AND PROPYLENE GLYCOL. CHRONIC USE OR EXCESSIVE DOSAGE RISKS TOXICITY. NOT FOR USE IN NEONATES, INFANTS AND CHILDREN LESS THAN 6 YEARS OF AGE.

LORAZEPAM SXP

Active ingredient(s): *Lorazepam* (law-raz-uh-pam)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LORAZEPAM SXP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LORAZEPAM SXP**.

Where to find information in this leaflet:

1. Why am I being given LORAZEPAM SXP?
2. What should I know before I am given LORAZEPAM SXP?
3. What if I am taking other medicines?
4. How am I given LORAZEPAM SXP?
5. What should I know while being given LORAZEPAM SXP?
6. Are there any side effects?
7. Product details

1. Why am I being given LORAZEPAM SXP?

LORAZEPAM SXP contains the active ingredient lorazepam. LORAZEPAM SXP is a benzodiazepine which are thought to work by action on the brain chemicals.

LORAZEPAM SXP is used to treat epilepsy. Epilepsy is a condition which causes different types of seizures. Lorazepam injection is used to treat epilepsy where there are a number of rapidly repeated seizures.

LORAZEPAM SXP is also used for the short-term relief of excessive anxiety in patients. It is also used for the short-term relief of excessive agitation.

It is also used to relax a patient before surgery or for sedation for prolonged investigations.

2. What should I know before I am given LORAZEPAM SXP?

Warnings

You should not be given LORAZEPAM SXP if you:

- are allergic to benzodiazapines, lorazepam, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have severe and chronic lung disease or severe breathing difficulties
- have a condition where you temporarily stop breathing while you sleep
- have severe liver disease
- have a condition of the nerves and muscles
- have recently consumed alcohol
- are under 6 years of age

Check with your doctor if you:

- Have any other medical conditions such as
  - acute narrow-angle glaucoma, a high pressure in the eye
  - breathing difficulties
  - liver problems
  - kidney problems
  - depression or psychosis
  - have benzodiazepine, opioid or alcohol dependence
  - or are over 65 years or less than 18 years of age
- Take any medicines for any other condition
- Are unsure whether you should be given this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

LORAZEPAM SXP contains benzyl alcohol and propylene glycol. This medicine contains 21 mg benzyl alcohol in each 1 ml of solution for injection.

Benzyl alcohol may cause allergic reactions.

Ask your doctor for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children

This medicine also contains 840 mg propylene glycol in each 1 ml of solution for injection.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not recommended that lorazepam is given to pregnant or breastfeeding women.

3. What if I am taking other medicines?

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

Medicines that may interact with Lorazepam injection may interfere with each other:

- Opioids, medicines used to treat anxiety or pain, such as morphine or oxycodone
- Probenecid, a medicine used to treat gout
- Valproate, a medicine used to treat epilepsy
- Other sleeping tablets, sedatives or tranquilisers
- Scopolamine, a medicine used to treat nausea
- Medicines used to treat mental illness and depression, such as clozapine.
- Haloperidol, an antipsychotic medication.

These medicines may be affected by LORAZEPAM SXP injection or may affect how well it works. You may need different amounts of your medicines or may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LORAZEPAM SXP.

4. How am I given LORAZEPAM SXP?

How much you will be given

Your doctor will decide what dose or LORAZEPAM SXP Injection you will receive and how long you will receive it. This depends on your medical condition and other factors, such as weight.

When you are given LORAZEPAM SXP

LORAZEPAM SXP injection must only be given by a doctor or nurse on the ward or at the surgery.

Your doctor will decide when you should be given LORAZEPAM SXP.

How LORAZEPAM SXP is injected

LORAZEPAM SXP is given as a slow injection into the muscle or vein.

If you forget to be given LORAZEPAM SXP

Your doctor will decide the correct time for you to be given LORAZEPAM SXP injection as necessary for your condition. You must keep all of your appointments.

If you are given too much LORAZEPAM SXP

Your doctor will decide how much you will be given based on a range of factors including weight, and other conditions.

If you think that you have been given too much LORAZEPAM SXP, you may need urgent medical attention.

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.

5. What should I know while being given LORAZEPAM SXP?

Things you should do

Call your doctor straight away if you:

- Experience symptoms of drowsiness, mental confusion and lethargy.
- If you experience poor coordination, decreased muscle tone, low blood pressure, hypnosis or coma, seek medical attention.

Remind any doctor, dentist or pharmacist you visit that you are being given LORAZEPAM SXP.

Things you should not do

- You may need assistance to get out of bed for at least 8 hours after you have been given this medicine. Getting out of bed without help may result in a fall or injury. Elderly patients have a greater risk of a fall.
- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from chairs, will help your body get used to change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Do not drive or operate machinery until 48 hours after use.

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

LORAZEPAM SXP may cause dizziness, and drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol is not to be consumed for at least 48 hours after this medicine is given.

Looking after your medicine

Your medicine will be stored in the surgery, pharmacy or ward of a hospital. The injection should be stored in the refrigerator where the temperature stays below 8^{o}C and protected from light.

When to discard your medicine

As this medicine is stored in the surgery, pharmacy or ward, the pharmacist will dispose of any unused medicine.

LORAZEPAM SXP Injection will be opened for use on you. It will be used only once and then it will be discarded

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
• Dizziness • Drowsiness • Sleepiness • Unsteadiness • Forgetfulness • Insomnia • Lack of balance or co-ordination • Disorientation • Cough • Dry mouth or increased saliva	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Moderately serious side effects

Moderately serious side effects	What to do
• Headache • Slow or fast breathing • Apnoea • Weakness • Chills • Nausea, vomiting, constipation • Agitation, confusion, abnormal thinking, hallucinations • Worsened asthma • Sore muscles	**Speak to your doctor if you have any of these moderately serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Difficulty breathing • Excessive sleepiness or loss of consciousness • Convulsions, fits or seizures • Depression, anxiety, suicidal thoughts, tremor, slurred speech, impaired concentration and visual disturbances. • Allergic reactions. Symptoms may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.	**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.**

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

Other side effects not listed here 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

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

What LORAZEPAM SXP contains

Active ingredient (main ingredient)	lorazepam
Other ingredients (inactive ingredients)	polyethylene glycol macrogol 400 benzyl alcohol

You should not be given this medicine if you are allergic to any of these ingredients.

What LORAZEPAM SXP looks like

LORAZEPAM SXP is a clear colourless or almost colourless solution, available in 2 strengths (2 mg/mL and 4 mg/mL) in packs of 5 or 10 ampoules.

2 mg/mL: AUST R 465433

4 mg/mL: AUST R 352550

Who distributes LORAZEPAM SXP

Southern XP Pty Ltd
Unit 5, 118 Church Street
Hawthorn VIC 3122
Australia

Sponsor:
Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn, 3122, Victoria
Australia

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