

Fentanyl-hameln Injection

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine. [Include if applicable]

1. Why am I being treated with Fentanyl-hameln Injection?

Fentanyl-hameln Injection contains the active ingredient fentanyl (as citrate). Fentanyl-hameln Injection is a short-term pain reliever that belongs to a group of medicines called opioid analgesics. It is most commonly used to relieve severe pain. It may also be used just before, or during, an operation, to help the anaesthetic work better.

For more information, see Section [1. Why am I being treated with Fentanyl-hameln Injection?](#) in the full CMI.

2. What should I know before treatment with Fentanyl-hameln Injection?

Do not use if you have ever had an allergic reaction to fentanyl 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 treatment with Fentanyl-hameln Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fentanyl-hameln Injection 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 is Fentanyl-hameln Injection given?

Your doctor will decide what dose of fentanyl you will receive. This depends on your age, physical condition and other factors, such as your weight.

More instructions can be found in Section [4. How is Fentanyl-hameln Injection given?](#) in the full CMI.

5. What should I know during treatment with Fentanyl-hameln Injection?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are being given fentanyl.If you become pregnant while you are being treated with fentanyl, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly. If you have been using fentanyl for more than two weeks, you may experience unpleasant feelings if you stop fentanyl suddenly.
Driving or using machines	<ul style="list-style-type: none">Do not drive a car, operate machinery, or do anything else that could be dangerous until until your doctor tells you it is safe to do so. Fentanyl may cause drowsiness and impair coordination.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol while you are being treated with fentanyl.
Looking after your medicine	<ul style="list-style-type: none">If you are being given Fentanyl-hameln Injection while in hospital, it will be stored in the pharmacy or on the ward. Store below 30°C and keep container in outer carton to protect from light.

For more information, see Section [5. What should I know during treatment with Fentanyl-hameln Injection?](#) in the full CMI.

6. Are there any side effects?

Common side effects include sweating, dizziness, faintness, nausea or vomiting. Tell your doctor immediately if you notice slow or troubled breathing, muscle stiffness, slowed heart rate, blurred vision, spasm of the larynx (voice box) or itching. If you experience serious side effects such as allergic reactions, agitation, hallucinations, twitching or loss of coordination, severe dizziness and weakness, irregular heart rate, changes in blood pressure, skin turning blue or unconsciousness, you may need urgent medical attention or hospitalisation.

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. 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.

WARNING:

Limitations of use

Fentanyl-hameln Injection should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Fentanyl-hameln Injection poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening breathing problems

Fentanyl-hameln Injection can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting fentanyl and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using fentanyl

Using fentanyl with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using fentanyl.

Fentanyl-hameln Injection

Active ingredient(s): fentanyl (as citrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fentanyl-hameln Injection. **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 Fentanyl-hameln Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with Fentanyl-hameln Injection?](#)
- [2. What should I know before treatment with Fentanyl-hameln Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Fentanyl-hameln Injection given?](#)
- [5. What should I know during treatment with Fentanyl-hameln Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with Fentanyl-hameln Injection?

Fentanyl-hameln Injection contains the active ingredient **fentanyl (as citrate)**. Fentanyl-hameln Injection is a short-term pain reliever that belongs to a group of medicines called opioid analgesics. Fentanyl acts in the brain and

spinal cord. It works quickly to reduce pain and its effects wear off quickly.

Fentanyl may be used alone but is usually used in hospital with other anaesthetics or with a sedative.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.

2. What should I know before treatment with Fentanyl-hameln Injection?

Warnings

Do not use Fentanyl-hameln Injection if you:

- are allergic to fentanyl, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction 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.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - kidney or liver problems
 - lung or breathing problems
 - severe asthma
 - severe bronchitis
 - emphysema
 - slow or irregular heartbeats;
 - heart problems
 - snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
 - recent head injury
 - are undergoing treatment with monoamine oxidase (MAO) inhibitors (e.g. phenelzine, tranylcypromine, moclobemide or selegiline) or have stopped MAO inhibitor treatment during the last fourteen days
 - have myasthenia gravis (severe muscle weakness)
 - have long-standing pain not related to cancer.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Fentanyl-hameln Injection.

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?](#)

Pregnancy and breastfeeding

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

If Fentanyl-hameln is used during labour, there is a risk that the newborn infant will experience breathing problems and signs of withdrawal.

Prolonged use of Fentanyl-hameln during pregnancy may cause drug dependence in the newborn infant and neonatal withdrawal syndrome.

Fentanyl-hameln given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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

Fentanyl-hameln passes into human breast milk and may cause sedation and breathing problems in the newborn infant. breastfeeding is not recommended for 24 hours following use of Fentanyl-hameln. Your doctor or pharmacist will discuss the possible risks and benefits of being given Fentanyl-hameln during breastfeeding.

Children

Fentanyl-hameln Injection should not be given to children under the age of 2 years. There is not enough information to recommend the use of this medicine for children under the age of 2 years.

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.

Some medicines may interfere with Fentanyl-hameln Injection and affect how it works. These include:

- antidepressants or medicines for anxiety disorders such as:
 - selective serotonin re-uptake inhibitors (SSRIs)
 - serotonin norepinephrine reuptake inhibitors (SNRIs)
 - monoamine oxidase (MAO) inhibitors (e.g. phenelzine, tranylcypromine and moclobemide)
- MAO inhibitors used to treat Parkinson's disease e.g. selegiline, rasagiline and safinamide.

Medicines that may increase the effect of Fentanyl Injection include:

- macrolide antibiotics (e.g. erythromycin)
- azole-antifungal agents (e.g. ketoconazole)
- protease inhibitors or medication for HIV (e.g. ritonavir)
- barbiturates
- general anaesthetics and strong pain killers (e.g. opioid analgesics)
- sedating antipsychotics (e.g. droperidol, chlorpromazine, fluphenazine and thioridazine)
- centrally-active anti-emetics (e.g. metoclopramide and promethazine)
- benzodiazepines
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, sedatives, tranquilisers, hypnotics and muscle relaxants
- Gabapentinoids e.g. gabapentin, pregabalin

Medicines that may reduce the effect of Fentanyl Injection include:

- Rifampin (anti-tuberculosis medication)
- Carbamazepine
- Phenytoin

These medicines may be affected by Fentanyl-hameln Injection or may affect how well it works. You may need different amounts of your medicine, or different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fentanyl-hameln Injection.

4. How is Fentanyl-hameln Injection given?

How much is given

- Your doctor will decide what dose you will receive. This depends on your age, physical condition and other factors, such as your weight.

How is it given

- Your doctor or nurse will usually give Fentanyl-hameln Injection to you.

- Fentanyl-hameln Injection is given as an injection into a vein or muscle.

If you are given too much Fentanyl-hameln Injection (overdose)

Fentanyl-hameln Injection is administered under the care of a highly trained doctor so overdose rarely occurs.

If you think that you or somebody else has been given too much Fentanyl-hameln, 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

Symptoms of an overdose may include:

- slow, unusual or difficult breathing causing skin to turn blue
- severe drowsiness, dizziness or unconsciousness
- slow or weak heartbeat, decreases in heart rate and blood pressure
- nausea or vomiting
- convulsions or fits
- severe weakness or muscle stiffness

5. What should I know during treatment with Fentanyl-hameln Injection?

Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are being given Fentanyl-hameln Injection.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Fentanyl-hameln Injection.
- If you plan to have surgery that needs a local or general anaesthetic, tell your doctor or dentist you are being given Fentanyl-hameln Injection.
- If you become pregnant while you are being treated with Fentanyl-hameln Injection, tell your doctor or pharmacist.
- Tell your doctor, pharmacist or nurse if you have any concerns about being given Fentanyl-hameln Injection.

Addiction

You can become addicted to fentanyl even if you use it exactly as prescribed. Fentanyl may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you using fentanyl. Using it for a long time (i.e. more than two weeks) may result in

physical dependence (i.e. it can be habit-forming or addictive). Physical dependence means that you may experience withdrawal symptoms if you stop using fentanyl suddenly, so it is important to use it exactly as directed by your doctor.

However, it is also important to keep your pain under control. Your doctor can advise you on how to manage this.

Tolerance

Tolerance to fentanyl may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue using your medicine for as long as your doctor tells you. If you stop using this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fentanyl-hameln Injection affects you.

Fentanyl-hameln Injection may cause feelings of weakness, dizziness, drowsiness and impairment of coordination in some people. Do not drive a car, operate machinery, or do anything else that could be dangerous until your doctor says it is safe to do so.

Drinking alcohol

Tell your doctor if you drink alcohol.

Fentanyl-hameln can increase the effect of alcohol.

Looking after your medicine

If you are being given Fentanyl-hameln Injection while in hospital, it will be stored in the pharmacy or in a locked cupboard on the ward.

Fentanyl-hameln Injection should be stored in a cool, dry place, protected from light where the temperature stays below 30°C.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date.

Fentanyl-hameln Injection should not be given to you if the packaging is torn or shows signs of tampering.

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
<ul style="list-style-type: none"> sweating dizziness faintness nausea vomiting headache difficulty swallowing drowsiness weakness hiccups excessive sweating an unusual sense of well being restlessness vein pain or inflammation chills, shivering, or lowered body temperature visual disturbance allergic reactions itching 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Cardiovascular related</p> <ul style="list-style-type: none"> increase or decrease in blood pressure slow, fast or irregular heart rate <p>Neurological and behaviour related</p> <ul style="list-style-type: none"> drowsiness severe dizziness and weakness confusion unconsciousness blurred vision agitation hallucinations <p>Breathing</p> <ul style="list-style-type: none"> skin turning blue and clammy swelling of the face, neck or throat slow or troubled breathing spasm of the larynx (voice box) <p>Other</p> <ul style="list-style-type: none"> uncontrolled movement of the body or eyes muscle stiffness or twitching loss of coordination convulsions or fits short periods of depression imaginary events 	<p>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.</p>

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.

Tell your doctor immediately if you have unwanted side effects which continue after your treatment has stopped.

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 Fentanyl-hameln Injection contains

Active ingredient (main ingredient)	Fentanyl citrate
Other ingredients (inactive ingredients)	Sodium hydroxide Hydrochloric acid Sodium chloride Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

Fentanyl-hameln Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Fentanyl-hameln Injection looks like

Fentanyl-hameln Injection is a sterile, aqueous, preservative-free, colourless or almost colourless solution in glass ampoules or vials.

It is available in the following strengths and pack sizes:

- 100 micrograms/2 mL x 5 or 10 ampoules (AUST R 434650)
- 500 micrograms/10 mL x 5 or 10 ampoules (AUST R 434651)

Who distributes Fentanyl-hameln Injection

hameln pharma Pty Ltd
Level 3, 302 Burwood Rd
Hawthorn, Victoria 3122
Australia

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