

Fentanyl GH

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.

1. Why am I being given Fentanyl GH?

Fentanyl GH contains the active ingredient fentanyl citrate. Fentanyl GH is used to provide short-term pain relief and to help anaesthesia when you have an operation.

For more information, see Section [1. Why am I being given Fentanyl GH?](#) in the full CMI.

2. What should I know before I am given Fentanyl GH?

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 or pharmacist 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 Fentanyl GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fentanyl GH 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 GH given?

- Your doctor will decide what dose of Fentanyl GH 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 GH given?](#) in the full CMI.

5. What should I know while being given Fentanyl GH?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are being given Fentanyl GH.If you become pregnant while you are being treated with Fentanyl GH, tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">Do not drive a car or operate machinery until your doctor tells you it is safe to do so. Fentanyl GH may cause drowsiness and impair co-ordination, and have a negative impact on your alertness.
Driving or using machines	<ul style="list-style-type: none">Do not drive a car or operate machinery until your doctor tells you it is safe to do so. Fentanyl GH may cause drowsiness and impair co-ordination, and have a negative effect on your alertness.
Drinking alcohol	<ul style="list-style-type: none">Fentanyl GH can increase the effect of alcohol. Do not drink alcohol while you are being treated with Fentanyl GH.
Looking after your medicine	<ul style="list-style-type: none">Fentanyl GH should be stored below 25°C. Protect from light.

For more information, see Section [5. What should I know while being given Fentanyl GH?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: dizziness; faintness; nausea; vomiting; Serious side effects include: slow or troubled breathing; muscle stiffness; slowed heart rate; blurred vision; spasm of the larynx (voice box); itching; allergic reactions; agitation; hallucinations; twitching or loss of co-ordination; severe dizziness and weakness; irregular heart rate; changes in blood pressure.

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.

WARNING:**Limitations of use**

Fentanyl GH 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 GH 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 GH 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 GH

Using Fentanyl GH with other medicines that can make you feel drowsy, such as sleeping tablets (eg. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (eg. 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 GH.

Fentanyl GH

Active ingredient(s): fentanyl citrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fentanyl GH. **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 GH.**

Where to find information in this leaflet:

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

1. Why am I being given Fentanyl GH?

Fentanyl GH contains the active ingredient fentanyl citrate. Fentanyl GH belongs to a group of medicines called opioid analgesics. It relieves pain by blocking the nerves in the brain that recognise pain messages from the body.

Fentanyl GH is used to [insert indication].

Fentanyl GH is a drug used to provide short-term pain relief and to help anaesthesia when you have an operation. It is a strong painkiller for use in hospitals.

Your doctor may have prescribed Fentanyl GH for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Fentanyl GH may be addictive. Addiction is unlikely in patients who receive it under medical supervision.

2. What should I know before I am given Fentanyl GH?

Warnings

Do not use Fentanyl GH if:

- you have an allergy or known intolerance to fentanyl, other strong pain killers 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.

- you suffer from asthma.
- you are particularly prone to breathing difficulties (for example, in the case of head injury, coma or brain tumour).
- you have taken a type of medicine known as monoamine oxidase inhibitors (MAOIs) within the last 14 days. These include phenelzine, moclobemide and tranylcypromine (for depression) and selegiline (for Parkinson's disease).
- you suffer from a condition known as myasthenia gravis which causes constant weakness of muscles.
- the packaging is torn or shows signs of tampering.

- if the expiry date on the pack has passed. The anaesthetist will inspect Fentanyl GH before use to determine that it is still within its use by date.

Check with your doctor if you:

- have, or have had, any other medical conditions, especially the following:
 - lung disease;
 - breathing problems;
 - severe asthma;
 - severe bronchitis;
 - emphysema;
 - brain disorder;
 - slow or irregular heartbeat;
 - kidney or liver problems;
 - snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep).
- you or someone in your family have a history of drug and alcohol abuse or mental illness.
- you have an underactive thyroid gland.
- you take any medicine that slows down your reactions (such as CNS depressants), especially benzodiazepines or related drugs.
- you take any medicines for any other condition.

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

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 or pharmacist if you are pregnant or intend to become pregnant.

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

Prolonged use of Fentanyl GH during pregnancy may cause withdrawal syndrome in the newborn.

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

Fentanyl passes into human breast milk and may cause sedation and breathing problems in the newborn infant.

Use in children

Fentanyl GH 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.

For children aged 2-12 years old, your doctor will give the appropriate dose based on age and body weight.

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.

Fentanyl GH may interfere with some medicines and affect how they work. These include:

- antidepressants or medicines for anxiety disorders such as:
 - selective serotonin re-uptake inhibitors (SSRIs) (eg. fluoxetine, sertraline and citalopram),
 - serotonin norepinephrine reuptake inhibitors (SNRIs) (eg. venlafaxine),
 - monoamine oxidase inhibitors (MAOIs) (eg. phenelzine, tranylcypromine, moclobemide, and selegiline). MAOIs should be stopped for 14 days before treatment with Fentanyl GH;
- MAOIs used to treat Parkinson's disease (eg. selegiline, rasagiline and safinamide). MAOIs should be stopped for 14 days before treatment with Fentanyl GH.

Medicines that may increase the effect of Fentanyl GH include:

- macrolide antibiotics (eg. erythromycin);
- azole-antifungal agents (eg. ketoconazole);
- protease inhibitors or medication for HIV (eg. ritonavir);
- barbiturates;
- general anaesthetics and strong pain killers (eg. opioid analgesics);
- sedating antipsychotics (eg. droperidol, chlorpromazine, fluphenazine and thioridazine);
- centrally-active antiemetics (eg. metoclopramide and promethazine);
- benzodiazepines (and other medicines) to treat anxiety, acute stress reactions, agitation, tremor, such as diazepam, alprazolam, lorazepam or midazolam;
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, sedatives, tranquilisers, hypnotics and muscle relaxants;
- gabapentin and pregabalin.

The dose of both medicines may need to be lowered to reduce the risk of potentially serious side effects such as breathing difficulties, slow or shallow breathing, severe drowsiness and decreased awareness, coma and death.

Medicines that may reduce the effect of Fentanyl GH include:

- rifampin;
- carbamazepine;
- phenytoin.

These medicines may be affected by Fentanyl GH or may affect how well it works. You may need different amounts of your medicine, or 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 Fentanyl GH.

4. How is Fentanyl GH given?

How much is given

- Your doctor will decide how much Fentanyl GH you need. This will depend on your age, body weight, medical conditions and history.
- In adults the usual dose of Fentanyl GH ranges from 25 micrograms to 100 micrograms depending on what it is being used for. Repeat doses may be given in some cases.
- If you are elderly or if you have problems with your kidneys, you may be given a lower dose of Fentanyl GH.
- In children 2 to 12 years of age, the usual dose ranges from 20 micrograms to 30 micrograms per 10 kg of body weight.

How Fentanyl GH is given

- Your doctor or nurse will usually give Fentanyl GH to you.
- Fentanyl GH is given as an injection into a vein or muscle

If you are given too much Fentanyl GH

The doctor or the anaesthetist giving you Fentanyl GH will be experienced in its use, so it is unlikely that you will be given too much.

If you think that you or someone else has been given too much Fentanyl GH, 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, drowsiness, dizziness or unconsciousness;
- slow or weak heartbeat;
- nausea or vomiting;
- convulsions or fits;
- muscle stiffness;
- lowering of blood pressure;
- lowering of heart rate;
- a brain disorder (known as toxic leukoencephalopathy).

If these symptoms occur, you may be administered another medicine (eg. naloxone) to help reverse the effects.

5. What should I know while being given Fentanyl GH?

Things you should do

- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Fentanyl GH.
- If you plan to have surgery that needs a local or general anaesthetic, tell your doctor or dentist you are being given Fentanyl GH.
- Tell your doctor, pharmacist or nurse if you have any concerns about being given Fentanyl GH.

Addiction

You can become addicted to Fentanyl GH even if you use it exactly as prescribed. Fentanyl GH 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 GH.

Using it for a long time (ie. more than two weeks) may result in physical dependence (ie. 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. 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.

It may also lead to dependence and abuse which may result in life-threatening overdose. If you have any concern that you may become dependent on Fentanyl GH, it is important that you speak to your doctor.

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.

Sleep-related breathing disorders

Fentanyl GH can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include

breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.

Hepatobiliary disorders

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Driving or using machines

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

Fentanyl GH can have a negative effect on your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.

Drinking alcohol

Tell your doctor if you drink alcohol.

Fentanyl GH can increase the effect of alcohol.

Looking after your medicine

- Fentanyl GH will be kept in a locked cupboard in the hospital pharmacy or operating theatre.
- Fentanyl GH ampoules should be kept in the pack until use, protected from light, in a cool dry place where the temperature stays below 25°C.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

The hospital staff looking after you will dispose of any remaining Fentanyl GH appropriately.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Dizziness. • Hiccups. • Blurred vision. • Nausea. • Vomiting. • Excessive sweating. • Itching. • An unusual sense of wellbeing. • Sedation. • Headaches. • Weakness. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Post-operative confusion or agitation. • Neurological or airway complications of anaesthesia. • Vein pain or inflammation. • Chills or lowered body temperature. • Visual disturbance. • Drowsiness. • Restlessness. • Difficulty in swallowing. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Difficulty in breathing (abnormally slow and/or weak breathing or increased breathing rate or a temporary cessation of breathing). • Muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements. • Slow, fast or irregular heartbeat or cardiac arrest. • A feeling of choking which is caused by the spasm of the muscles around the voice box. • Allergic reactions such as skin rash, redness and swelling of the face, neck or throat. • Severe drowsiness. • Convulsions. • Loss of consciousness. • Adrenal insufficiency symptoms such as weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. • Androgen deficiency symptoms such as loss of libido, impotence, erectile dysfunction or your menstrual cycle stops. • Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time. 	<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.

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 GH contains

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

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

Fentanyl GH does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Fentanyl GH looks like

Fentanyl GH 100 microgram in 2 mL injection is a clear, colourless to almost colourless solution available in 2 mL Type 1 clear glass ampoules (AUST R 201872).

Fentanyl GH 500 microgram in 10 mL injection is a clear, colourless to almost colourless solution available in 10 mL Type 1 clear glass ampoules (AUST R 201871).

Who distributes Fentanyl GH

Generic Health Pty Ltd

Suite 2, Level 2

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Box Hill, VIC, 3128

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