

Fentanyl GH Injection

Fentanyl (as citrate) 0.05 mg/mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fentanyl GH Injection.

It does not contain all the available information.

It does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your treatment using Fentanyl GH Injection against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Fentanyl GH Injection is used for

The name of your medicine is Fentanyl GH Injection. It contains the active ingredient called Fentanyl (as citrate). It belongs to a group of medicines known as narcotic analgesics or opioids. Fentanyl GH Injection 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.

Fentanyl relieves pain by blocking the nerves in the brain that recognise pain messages from the body.

Your doctor will have explained why you are being treated with

Fentanyl GH Injection and told you what dose you will be given.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

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

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

Before You Are Given Fentanyl GH Injection

When you must not be given Fentanyl GH Injection

Fentanyl GH Injection should not be used:

- if you have an allergy to Fentanyl GH Injection, other strong pain killers or any of the ingredients. See **Product Description** at the end of this leaflet for a list of ingredients.
- if you suffer from asthma or if you are particularly prone to breathing difficulties (for example, in the case of head injury, coma or brain tumour).
- if 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).

- if you suffer from a condition known as myasthenia gravis which causes constant weakness of muscles.
- in children less than two years old.

Fentanyl GH Injection should not be used if the packaging is torn or shows signs of tampering. It should not be used beyond the expiry date (month and year) printed on the pack.

If you are not sure whether you should start using Fentanyl GH Injection, talk to your doctor.

Before you are given this medicine

You must tell your doctor if:

- you are pregnant or planning to become pregnant.
- you are breast feeding or wish to breastfeed. Fentanyl is excreted in human milk.
- you have a lung disease or breathing problems.
- you have a brain disorder.
- you know you have a slow or irregular heart beat.
- you have or have ever had kidney or liver diseases.
- you are an alcoholic.
- you have an underactive thyroid gland.

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

Your doctor will decide whether or not to treat you with Fentanyl GH

Injection or whether to adjust the dose or alter your treatment.

Taking other medicines

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

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines which make you feel drowsy or slow to react, such as, sleeping tablets, tranquillisers or strong pain-killers.
- medicines for mental disorders or a group of medicine called monoamine oxidase inhibitors (MAOIs). These include phenelzine, moclobemide and tranylcypromine (for depression) and selegiline (for Parkinson's disease). They should be stopped for 14 days before Fentanyl GH Injection is given.
- medicines for depression known as selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs). These include fluoxetine, paroxetine, sertraline and venlafaxine.
- ritonavir (a protease inhibitor used to treat HIV).

These medicines may be affected by Fentanyl GH Injection or may affect how well Fentanyl GH Injection works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Effect on driving and operating machinery

Fentanyl GH Injection 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.

Effect of alcohol

Fentanyl GH Injection can increase the effect of alcohol.

How Fentanyl GH Injection is given

Fentanyl GH Injection is given by your doctor as an injection into a muscle or a vein. Your doctor will decide how much Fentanyl GH Injection you need. This will depend on your age, body weight, medical conditions and history.

Adults

The usual dose of Fentanyl GH Injection 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, you may be given a lower dose of Fentanyl GH Injection.

Children 2 to 12 years old

The usual dose ranges from 20 micrograms to 30 micrograms per 10 kg of body weight.

Fentanyl GH Injection is not recommended for use in children under 2 years.

If you are given too much (overdose)

Immediate medical care is required. The main symptom is markedly weakened breathing.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Fentanyl GH Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are given Fentanyl GH Injection

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant.
- Tell your doctor or pharmacist if you are about to start taking a new medicine.

Things you must not do

- Do not use Fentanyl GH Injection to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- 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 heart beat 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.

Tell your doctor if you experience any of the following:

- dizziness;
- low or high or variable blood pressure which may cause headache, weakness or dizziness;
- hiccups;
- blurred vision;
- nausea, vomiting;
- excessive sweating;
- itching;
- an unusual sense of well being;
- sedation;
- headaches;
- postoperative confusion or agitation;
- neurological or airway complications of anaesthesia;
- vein pain or inflammation;
- chills or lowered body temperature;
- visual disturbance.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using Fentanyl GH Injection

Storage

Store unopened Fentanyl GH Injection ampoules in the pack and in a cool dry place, where the temperature stays below 25°C. Protect from light.

Fentanyl GH Injection will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Fentanyl GH Injection should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect Fentanyl GH Injection before use to determine that it is still within its use by date.

Disposal

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

Product Description

What it looks like

Fentanyl GH Injection is a clear, colourless to almost colourless solution.

Fentanyl GH Injection is available in two size glass ampoules: a 2 mL and a 10 mL ampoule.

A carton of Fentanyl GH Injection contains 1, 5 or 10 ampoules. Not all pack sizes may be marketed.

The 2 mL ampoule contains 100 micrograms of fentanyl (as citrate).

The 10 mL ampoule contains 500 micrograms of fentanyl (as citrate).

Ingredients

Fentanyl GH Injection contains:

Active ingredient

- Fentanyl (0.05 mg/mL, as citrate)

Other ingredients

- Sodium chloride
- Sodium hydroxide
- Water for injections

Distributor

Generic Health Pty
LtdLevel 1, 1102 Toorak Road
Camberwell VIC 3124

100 mcg/2 mL AUST R 201872

500 mcg/10 mL AUST R 201871

This leaflet was prepared in March 2014.