

Fentanyl Injection

Consumer Medicine Information

Fentanyl Injection

Fentanyl
50 micrograms/mL injection

What is in this leaflet

Please read this leaflet carefully before you are given Fentanyl Injection.

This leaflet answers some common questions about Fentanyl Injection. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.gov.nz.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about receiving Fentanyl Injection ask your doctor or pharmacist.

Keep this leaflet with your medicine.
You may need to read it again.

What Fentanyl Injection is used for

Fentanyl Injection is used to provide short-term pain relief and to help anaesthesia when you have an operation. It can be given with droperidol injection which is a tranquilliser.

Fentanyl Injection contains a medicine called fentanyl. It belongs to a group of medicines known as opioid analgesics. Fentanyl relieves pain by blocking the nerves in the brain that recognise pain messages from the body.

Your doctor may have prescribed fentanyl for another reason.

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

Fentanyl Injection is only available with a doctor's prescription.

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



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You may be at more risk of addiction if:

- You or someone in your family have a history of drug and alcohol abuse or mental illness
- You require repeated injections of Fentanyl Injection
- You need increasingly larger doses of Fentanyl Injection to control your pain.

Before you are given Fentanyl Injection

Fentanyl Injection is not suitable for everyone.

When you must not be given Fentanyl Injection

Fentanyl Injection must not be given:

- if you have an allergy to fentanyl, 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 injuries, 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 Injection must not be used if the packaging is torn or shows signs of tampering. It must not be used beyond the expiry date (month and year) printed on the pack.

Before you are given Fentanyl Injection

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

You must tell your doctor if you:

- are pregnant or planning to become pregnant
- are breast-feeding or wish to breast-feed
- have lung diseases or breathing problems
- have a brain disorder
- are particularly prone to breathing difficulties (for example, in the case of head injury, coma or brain tumour)
- have a slow or irregular heart beat
- have or have ever had kidney or liver diseases
- or someone in your family have a history of drug and alcohol abuse or mental illness
- have an underactive thyroid gland
- if you take any medicines that slows down your reactions (CNS depressants), especially benzodiazepines or related medicines
- if you are taking certain antidepressants (e.g MAOI, SSRIs, SNRIs and tricyclic antidepressants) as you may experience Serotonin Syndrome. Symptoms include

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confusion, extreme agitation, mood changes, diarrhoea, stiffness, increased body temperature, sweating, changes in blood pressures, nausea, vomiting, involuntary muscle jerk, involuntary shaking or movement in one or more parts of body, difficult movement coordination, disturbances in mental abilities and coma

Tell your doctor if you have ever abused or been dependent on opioids, alcohol, prescription medicines, or illegal drugs.

- Repeated use of the product may result in the drug being less effective (you become accustomed to it) or becoming dependent on it.
- If your treatment is stopped withdrawal symptoms may occur. Please tell your doctor or nurse if you think this is happening to you (see also section Side effects).

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

Your doctor will decide whether or not to treat you with Fentanyl 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 any that you get without a prescription from a pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are using Fentanyl Injection.

Some medicines and Fentanyl Injection may interfere with each other. These include:

- medicines which make you feel drowsy or slow to react (CNS depressants), such as benzodiazepines or related medicines, sleeping tablets, tranquillisers, alcohol, illegal drugs or strong pain killers. This also includes a group of medicines called neuroleptics, for example droperidol. The dose of Fentanyl Injection used may need to be lower if taking these medicines. If you are prescribed a benzodiazepine or other CNS depressant after receiving Fentanyl Injection after surgery, the dose of the CNS depressant may need to be reduced to lower the risk of potentially serious side effects such as breathing difficulties (slow or shallow breathing), severe drowsiness and decreased awareness, coma and death.
- medicines for mental disorders or a group of medicines called monoamine oxidase inhibitors (MAOIs). These include phenelzine, moclobemide and tranylcypromine (for depression) and selegiline (for Parkinson's disease). These medicines should be stopped 14 days before Fentanyl 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.
- fluconazole or voriconazole (antifungal medicines).
- ritonavir (used to treat AIDS).

These medicines may be affected by Fentanyl Injection or may affect how well it works. You may need different amounts of Fentanyl Injection or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while you are given Fentanyl Injection.

Effects on driving and operating machinery

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Do not drive or operate machinery until your doctor says it is safe.

Fentanyl Injection can affect your alertness and ability to drive and operate machinery.

Effects of alcohol

Fentanyl Injection can increase the effects of alcohol.

How Fentanyl Injection is given

How it is given

Fentanyl Injection is given by your doctor as an injection into a muscle or a vein.

How much will be given

Adults

The usual dose of Fentanyl Injection ranges from 25 micrograms to 100 micrograms depending on what it is being used for. Repeat doses may be given in some cases. Doses greater than 200 micrograms are only for use in anaesthesia, as higher doses may cause difficulty in breathing.

If you are elderly, overweight or if you have problem with your kidneys, you may be given a lower dose of Fentanyl Injection.

Children 2 to 12 years old

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

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

Your doctor will know how much Fentanyl Injection you should be given.

The need for more doses will depend on how well your body responds to the treatment. Your doctor will decide how many injections you need, and how often you should receive them.

While you are given Fentanyl 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 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.

In case of overdose

If you are given too much (overdose)

As Fentanyl Injection is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Tell your doctor immediately if you experience any of the following:

- muscle stiffness, breathing difficulties that may cause your skin to turn blue. This is followed by unconsciousness.
- decrease in heart rate
- low blood pressure
- a fall in body temperature.

In such cases, immediate medical care is required.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are given Fentanyl Injection.

Like, all medicines, Fentanyl Injection may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Tell your doctor or nurse if you experience any of the following and they worry you:

- 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
 - post-operative confusion or agitation
 - neurological or airway complications of anaesthesia
 - vein pain or inflammation
 - chills or lowered body temperature
 - visual disturbance.
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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 sudden muscle twitches
- 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
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating).

When a sedating medicine such as droperidol injection is used with Fentanyl Injection, the following can occur:

- chills, shivering
- restlessness
- seeing, feeling or hearing things that are not there after an operation
- short periods of mental depression
- uncontrolled movements of the body or eyes which may occur up to 24 hours after an operation.
- low blood pressure
- drowsiness.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After you have been given Fentanyl Injection

Storage

- Keep Fentanyl Injection in the pack until use.
- Keep Fentanyl Injection in a cool dry place where the temperature stays below 25°C.
- Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.
- Do not store Fentanyl Injection, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Product description

What it looks like

Fentanyl Injection is a clear, colourless sterile solution. It is available in 2 mL and 10 mL clear glass ampoules. The ampoules are available in boxes of 10.

Ingredients

Fentanyl Injection contains 50 micrograms of fentanyl per mL.

The 2 mL ampoule contains 100 micrograms of fentanyl.

The 10 mL ampoule contains 500 micrograms of fentanyl.

The solution also contains sodium chloride, sodium hydroxide and water for injections.

Sponsor details

Boucher & Muir (NZ) Ltd t/a Mercury Pharma (NZ)
39 Anzac Road
Browns Bay
Auckland 0753

Ph: 0800 565 633

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