

DBL™ Fentanyl Injection

Fentanyl Citrate (FEN-tah-nil SIT-trate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Fentanyl Injection.

It does not contain all the available information.

It 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 being given fentanyl against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place.

You may need to read it again.

What DBL™ Fentanyl Injection is used for

Fentanyl is a 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 such as droperidol (*dro-PER-ee-dol*) before an operation to provide an anaesthetic effect and during an operation to help continue the anaesthesia.

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 may produce physical dependence (ie it can be habitforming or addictive), if used for a long time. Physical dependence means you may experience unpleasant feelings if you stop fentanyl suddenly.

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

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

There is not enough information to recommend the use of this medicine for children under the age of 2 years.

Before you are given DBL™ Fentanyl Injection

When you must not be given it

You should not be given fentanyl if you have an allergy to fentanyl or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to fentanyl 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.

You should not be given Fentanyl if:

- you suffer from bronchial asthma
- you are prone to breathing difficulties
- you are undergoing treatment with monoamine oxidase (MAO) inhibitors (eg phenelzine, tranylcypromine, moclobemide or selegiline) or have

stopped MAO inhibitor treatment during the last fourteen days

- you suffer from Myasthenia gravis (severe muscle weakness).

Do not use DBL™ Fentanyl Injection after the expiry date (EXP) printed on the pack.

If this medicine is used after the expiry date has passed it may not work as well.

Do not use DBL™ Fentanyl Injection if the packaging is torn or shows signs of tampering

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

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

As fentanyl crosses the placenta, your doctor or pharmacist will discuss the possible risks and benefits of you being given DBL™ Fentanyl Injection during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

As fentanyl may pass into breast milk, breastfeeding is not recommended for 24 hours following use of DBL™ Fentanyl Injection. Your doctor or pharmacist will discuss the possible risks and benefits of using DBL™ Fentanyl Injection during breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- kidney or liver problems
- lung or breathing problems
- slow or irregular heart beats.

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

Taking other medicines

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

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

- barbiturates
- strong pain killers
- alcohol
- sedating drugs such as droperidol, chlorpromazine, fluphenazine, metoclopramide, thioridazine, and promethazine
- antidepressants which belong to the group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRI)
- antidepressants which belong to the group of medicines called Serotonin Norepinephrine Re-uptake Inhibitors (SNRI)
- antidepressants which belong to the group of medicines called monoamine oxidase (MAO) inhibitors (ie

phenelzine, tranylcypromine and moclobemide)

- selegiline, a monoamine oxidase (MAO) inhibitor used to treat Parkinson's disease
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, medicines to treat mental disorders, other strong pain killers and some antihistamines

These medicines may be affected by fentanyl, 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.

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

How DBL™ Fentanyl Injection is 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 it is given

DBL™ Fentanyl Injection is given as an injection into a vein or a muscle. It must only be given by a doctor or nurse.

If you take too much (overdose)

DBL™ Fentanyl Injection is administered under the care of a highly trained doctor so overdose rarely occurs. **However, if you experience any severe side effects after being given DBL™ Fentanyl Injection, tell your doctor immediately or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.**

Symptoms of overdose include severe drowsiness and weakness, decreases in heart rate, blood pressure and breathing, causing skin to turn blue and muscle stiffness followed by unconsciousness.

In case of overdose, immediately contact the Poisons Information Centre for advice (In Australia, call 13 11 26. In New Zealand, call 0800 764 766),

While you are being given DBL™ Fentanyl Injection

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are being given DBL™ Fentanyl Injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL™ Fentanyl Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist you are being given DBL™ Fentanyl Injection.

Things you must not do

Do not give DBL™ Fentanyl Injection to anyone else, even if they have the same condition as you.

Do not use DBL™ Fentanyl Injection to treat any other complaints unless your doctor tells you to.

Do not stop using fentanyl, or lower the dosage, without checking with your doctor or pharmacist.

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist who knows you are being treated with fentanyl.

Things to be careful of

Feelings of weakness, dizziness, or nausea. Avoid smoking or taking other drugs unless your doctor tells you to.

Be careful driving or operating machinery until you know how fentanyl affects you.

Fentanyl may cause drowsiness and impairment of co-ordination, in some people.

Do not drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or feeling uncoordinated.

Do not drink alcohol, while you are undergoing treatment with fentanyl, unless otherwise advised by your doctor or pharmacist, as drowsiness and co-ordination impairment may be worse.

Tell your doctor, pharmacist or nurse if you have any concerns about being given fentanyl.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving fentanyl.

Fentanyl helps most people but it may have unwanted side effects in a few people. 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 of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sweating
- dizziness, faintness
- nausea, vomiting

These are the more common side effects of Fentanyl Injection.

Tell your doctor or pharmacist immediately if you notice any of the following:

- slow or troubled breathing
- muscle stiffness
- a slowed heart rate
- blurred vision
- spasm of the larynx (voice box)
- itching

These are less common side effects of fentanyl.

The following side effects may occur when a sedating medicine (eg droperidol) is used with fentanyl:

- chills, shivering
- restlessness
- drowsiness
- short periods of depression
- imaginary events

- uncontrolled movement of the body or eyes.

Your doctor will be able to treat you for these symptoms so tell your doctor immediately if you experience any of these symptoms.

If any of the following happen, tell your doctor, pharmacist or nurse immediately, or go to the Accident and Emergency department at your nearest hospital:

- agitation, hallucinations
- slow or troubled breathing
- muscle stiffness, twitching or loss of coordination
- severe dizziness and weakness
- increase or decrease in heart rate
- decrease in blood pressure
- skin turning blue and clammy
- unconsciousness

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Other side effects not listed may also occur in some patients.

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

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

You may not experience any of them.

Allergic reactions may also occur.

After being given DBL™ Fentanyl Injection

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

Storage

If you are being given DBL™ Fentanyl Injection while in hospital, it will be stored in the pharmacy or on the ward.

DBL™ Fentanyl Injection should be stored in a cool, dry place, protected from light where the temperature stays below 25°C.

Do not store DBL™ Fentanyl Injection or any medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using DBL™ Fentanyl Injection or the injections are passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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

Ingredients

Active ingredient:

- fentanyl citrate

Other ingredients:

- sodium hydroxide or sodium citrate (used to adjust the acidity of the product)

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

Sponsor

DBL™ Fentanyl Injection is supplied in Australia by:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3,
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Fentanyl Injection is available in the following strengths and pack sizes:

- 100 microgram / 2mL x 5 ampoules
AUST R 107025
- 500 microgram / 10mL x 5 ampoules
AUST R 107027

This leaflet was updated in September 2014.