

# DBL™ Fentanyl Injection

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## 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.

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

## 1. Why am I being treated with DBL Fentanyl Injection?

DBL Fentanyl Injection contains the active ingredient fentanyl citrate. DBL Fentanyl 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 DBL Fentanyl Injection?](#) in the full CMI.

## **2. What should I know before treatment with DBL Fentanyl 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 DBL Fentanyl Injection?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with DBL Fentanyl 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 DBL Fentanyl 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 DBL Fentanyl Injection given?](#) in the full CMI.

## 5. What should I know during treatment with DBL Fentanyl Injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are being given fentanyl.</li><li>• If you become pregnant while you are being treated with fentanyl, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive a car, operate machinery, or do anything else that could be dangerous until you know how fentanyl affects you. Fentanyl may cause drowsiness and impair coordination.</li></ul>

<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>Do not drink alcohol while you are being treated with fentanyl.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>If you are being given DBL Fentanyl Injection while in hospital, it will be stored in the pharmacy or on the ward. Store below 25°C.</li> </ul>

For more information, see Section [5. What should I know during treatment with DBL Fentanyl 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.



**WARNING:****Limitations of use**

DBL Fentanyl 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**

DBL Fentanyl 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**

DBL Fentanyl 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.

## DBL™ Fentanyl Injection

**Active ingredient(s):** *fentanyl citrate*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Fentanyl 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 DBL Fentanyl Injection.**

**Where to find information in this leaflet:**

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

## **1. Why am I being treated with DBL Fentanyl Injection?**

**DBL Fentanyl Injection contains the active ingredient fentanyl citrate.** DBL Fentanyl 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 such as droperidol before an operation to provide an anaesthetic effect and during an operation to help continue the anaesthesia.

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.

## **2. What should I know before treatment with DBL Fentanyl Injection?**

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



## Warnings

### Do not use DBL Fentanyl 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.

- have bronchial asthma or severe disease relating to the lungs
- have breathing difficulties or shallow breathing
- 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.

### 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
- slow or irregular heartbeats; heart problems
- snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
- recent head injury
- mental health conditions (e.g. depression, anxiety or personality disorder)
- or anyone in your family have abused or are dependent on alcohol, prescription medicine or other illegal substances (addiction)
- are a smoker
- 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 DBL Fentanyl 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.

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.

Talk to your doctor if you are breastfeeding or intend 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 being given DBL Fentanyl Injection during breastfeeding.

## **Children**

DBL Fentanyl 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.

## **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.

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

### 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 DBL Fentanyl Injection and affect how it works. These include:**

- barbiturates
- general and local anaesthetics (e.g. lidocaine)
- strong pain killers (e.g. opioid analgesics)
- sedating antipsychotics (e.g. droperidol, chlorpromazine, fluphenazine and thioridazine) and centrally-active anti-emetics (e.g. 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
- 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 inhibitor used to treat Parkinson's disease e.g. selegiline, rasagiline and safinamide.
- medicines to treat mental disorders
- medicines to treat seizures (gabapentinoids e.g. gabapentin, pregabalin)

**Medicines that may increase the effect of DBL Fentanyl Injection include:**

- macrolide antibiotics (e.g. erythromycin)
- azole-antifungal agents (e.g. ketoconazole)
- protease inhibitors or medication for HIV (e.g. ritonavir)

**Medicines that may reduce the effect of DBL Fentanyl Injection include:**

- rifampin (anti-tuberculosis medication)
- carbamazepine and phenytoin, medicines used to control fits or seizures.

These medicines may be affected by DBL Fentanyl 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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given this medicine.

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

## **4. How is DBL Fentanyl 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 DBL Fentanyl Injection to you.
- DBL Fentanyl Injection is given as an injection into a vein or muscle.

### **If you are given too much (overdose)**

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

However, if you or someone else receive too much (overdose), and experience one or more of the symptoms below, urgent medical attention is required. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used DBL Fentanyl Injection that was prescribed for you.

Symptoms of an overdose may include:

- slow, unusual or difficult breathing causing skin to turn blue

- severe drowsiness, dizziness or unconsciousness
- confusion, memory loss, impairment of vision or coordination
- slow or weak heartbeat, decreases in heart rate and blood pressure
- nausea or vomiting
- convulsions or fits
- severe weakness or muscle stiffness

**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.**

## **5. What should I know during treatment with DBL Fentanyl Injection?**

### **Things you should 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 local or general anaesthetic, tell your doctor or dentist you are being given DBL Fentanyl Injection.
- If you become pregnant while you are being treated with DBL Fentanyl Injection, tell your doctor or pharmacist.
- Tell your doctor, pharmacist or nurse if you have any concerns about being given DBL Fentanyl Injection.

### **Things you should 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 DBL Fentanyl Injection, 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 prescribed or recommended by a doctor or pharmacist who knows you are being treated with DBL Fentanyl Injection.
- Avoid smoking or taking other drugs unless your doctor tells you to.

### **Driving or using machines**

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

DBL Fentanyl 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 if you are drowsy or feeling uncoordinated.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

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

## **Looking after your medicine**

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 it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

Do not use this medicine after the expiry date.

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

## Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, take it to any pharmacy for safe disposal.

## 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.

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"><li>• sweating</li><li>• dizziness, faintness</li><li>• nausea, vomiting</li></ul>	<b>Speak to your doctor if you have any of these common side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● agitation, hallucinations</li> <li>● slow or troubled breathing</li> <li>● muscle stiffness, twitching or loss of coordination</li> <li>● severe dizziness and weakness</li> <li>● slow, fast or irregular heart rate</li> <li>● blurred vision</li> <li>● increase or decrease in blood pressure</li> <li>● skin turning blue and clammy</li> <li>● unconsciousness</li> <li>● spasm of the larynx (voice box)</li> <li>● allergic reactions</li> <li>● itching</li> </ul> <p><b>The following side effects may occur when a sedating medicine (e.g. droperidol) is used with DBL Fentanyl Injection</b></p>	<p><b>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.</b></p> <p>Tell your doctor immediately if you experience any of these symptoms. You may need urgent medical attention or hospitalisation.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● chills, shivering</li> <li>● restlessness</li> <li>● drowsiness</li> <li>● short periods of depression</li> <li>● imaginary events</li> <li>● uncontrolled movement of the body or eyes</li> </ul>	

**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](http://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 DBL Fentanyl Injection contains

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

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

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

### What DBL Fentanyl Injection looks like

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

It is available in the following strengths and pack sizes:

- 100 micrograms / 2 mL x 5 ampoules AUST R 107025

- 500 micrograms / 10 mL x 5 ampoules AUST R 107027

## **Who distributes DBL Fentanyl Injection**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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