

FENTANYL MEDSURGE

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 treated with FENTANYL MEDSURGE?

FENTANYL MEDSURGE contains the active ingredient fentanyl citrate. FENTANYL MEDSURGE 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 FENTANYL MEDSURGE?](#) in the full CMI.

2. What should I know before treatment with FENTANYL MEDSURGE?

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 FENTANYL MEDSURGE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FENTANYL MEDSURGE 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 MEDSURGE 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 FENTANYL MEDSURGE given?](#) in the full CMI.

5. What should I know during treatment with FENTANYL MEDSURGE?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are being given fentanyl. If you become pregnant while you are being treated with fentanyl, tell your doctor immediately.
Driving or using machines	Do not drive a car or operate machinery until your doctor tells you it is safe to do so. FENTANYL MEDSURGE may cause drowsiness and impair coordination.
Drinking alcohol	FENTANYL MEDSURGE can increase the effect of alcohol. Do not drink alcohol while you are being treated with FENTANYL MEDSURGE.

For more information, see Section [5. What should I know during treatment with FENTANYL MEDSURGE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include 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, 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

FENTANYL MEDSURGE 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 MEDSURGE 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 MEDSURGE 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.

FENTANYL MEDSURGE

Active ingredient(s): *fentanyl citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FENTANYL MEDSURGE. **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 MEDSURGE.**

Where to find information in this leaflet:

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

1. Why am I being treated with FENTANYL MEDSURGE?

FENTANYL MEDSURGE contains the active ingredient **fentanyl citrate**. FENTANYL MEDSURGE is 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 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.

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.

The use of FENTANYL MEDSURGE poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

2. What should I know before treatment with FENTANYL MEDSURGE?

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

Warnings

Do not use FENTANYL MEDSURGE 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 disease
 - breathing problems
 - severe asthma
 - severe bronchitis
 - emphysema
 - slow or irregular heartbeats
 - heart problems
 - snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
 - recent head injury
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.
- you or someone in your family have a history of drug and alcohol abuse or mental illness.
- you have an underactive thyroid gland
- if you take any medicine that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs.
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

If FENTANYL MEDSURGE is used during labour, there is a risk that the newborn infant will experience breathing problems and signs of withdrawal.

Prolonged use of FENTANYL MEDSURGE during pregnancy may cause drug dependence in the newborn infant and neonatal withdrawal syndrome.

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

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

FENTANYL MEDSURGE passes into human breast milk and may cause sedation and breathing problems in the

newborn infant. breastfeeding is not recommended for 24 hours following use of FENTANYL MEDSURGE. Your doctor or pharmacist will discuss the possible risks and benefits of being given FENTANYL MEDSURGE during breastfeeding.

Children

FENTANYL MEDSURGE 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 MEDSURGE 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) e.g. fluoxetine, sertraline and citalopram
 - serotonin norepinephrine reuptake inhibitors (SNRIs) e.g. venlafaxine
 - monoamine oxidase (MAO) inhibitors e.g. phenelzine, tranylcypromine, moclobemide, and selegiline should be stopped for 14 days before treatment with FENTANYL MEDSURGE.
- MAO inhibitors used to treat Parkinson’s disease e.g. selegiline, rasagiline and safinamide.

Medicines that may increase the effect of FENTANYL MEDSURGE include:

- barbiturates
- general anaesthetics and strong pain killers (e.g. opioid analgesics)
- sedating antipsychotics (e.g. droperidol, chlorpromazine, fluphenazine and thioridazine) and centrally-active antiemetics (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.
- 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, with slow or shallow breathing, severe drowsiness and decreased awareness, coma and death.

- erythromycin
- ketoconazole
- ritonavir

Medicines that may reduce the effect of FENTANYL MEDSURGE include:

- rifampin
- carbamazepine
- phenytoin

These medicines may be affected by FENTANYL MEDSURGE 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 MEDSURGE.

4. How is FENTANYL MEDSURGE 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 FENTANYL MEDSURGE to you.
- FENTANYL MEDSURGE is given as an injection into a vein or muscle.

If you are given too much (overdose)

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

If you think that you or somebody else has been given too much FENTANYL MEDSURGE, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Information Centre (**in New Zealand telephone 0800 POISON or 0800 764 766**)
- 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 causing skin to turn blue
- severe drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- severe weakness or muscle stiffness

5. What should I know during treatment with FENTANYL MEDSURGE?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are being given FENTANYL MEDSURGE.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given FENTANYL MEDSURGE.

If you plan to have surgery that needs a local or general anaesthetic, tell your doctor or dentist you are being given FENTANYL MEDSURGE.

If you become pregnant while you are being treated with FENTANYL MEDSURGE, tell your doctor or pharmacist. Tell your doctor, pharmacist or nurse if you have any concerns about being given FENTANYL MEDSURGE.

Addiction

You can become addicted to FENTANYL MEDSURGE even if you use it exactly as prescribed. FENTANYL MEDSURGE 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 MEDSURGE.

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. 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 MEDSURGE, 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FENTANYL MEDSURGE affects you.

FENTANYL MEDSURGE 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 until your doctor says it is safe.

Drinking alcohol

Tell your doctor if you drink alcohol.

FENTANYL MEDSURGE can increase the effect of alcohol.

Looking after your medicine

FENTANYL MEDSURGE will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

FENTANYL MEDSURGE should be kept in the pack until use, protected from light, in a cool dry place where the temperature stays below 30°C.

Keep it where young children cannot reach it.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• sweating• dizziness• faintness• nausea• vomiting• headache• weakness• hiccups• excessive sweating• an unusual sense of well being• vein pain or inflammation• chills or lowered body temperature• visual disturbance• drowsiness• restlessness• itching• chills• shivering• short period of depression• imaginary event	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Cardiovascular related</p> <ul style="list-style-type: none">• increase or decrease in blood pressure• slow, fast or irregular heart rate <p>Neurological and behavior related</p> <ul style="list-style-type: none">• severe dizziness and weakness• confusion• unconsciousness• blurred vision• agitation,• hallucinations• uncontrolled movement of the body or eyes <p>Breathing and Allergy related</p> <ul style="list-style-type: none">• allergic reactions• skin turning blue and clammy• swelling of the face, neck or throat• slow or troubled breathing• spasm of the larynx (voice box) <p>Other</p> <ul style="list-style-type: none">• muscle stiffness,• twitching or loss of coordination• convulsions or fits	<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.

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

Reporting side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions

<https://nzphvc.otago.ac.nz/reporting/>

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 MEDSURGE contains

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

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

FENTANYL MEDSURGE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What FENTANYL MEDSURGE looks like

FENTANYL MEDSURGE is a clear colourless solution in glass ampoules.

It is available in the following strengths and pack sizes:

- 100 micrograms /2 mL x 5 ampoules and 10 ampoules
- 500 micrograms /10 mL x 5 ampoules and 10 ampoules

Who distributes FENTANYL MEDSURGE

New Zealand Sponsor

Medsurge Pharma Limited
P O Box 331054
Takapuna
Auckland 0622

Marketed and distributed by Medsurge Healthcare Pty Ltd.

Telephone: 0800 788 261
Website: www.medsurgehc.com

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