

# Fentanyl Sandoz®

## 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 using Fentanyl Sandoz?

Fentanyl Sandoz contains the active ingredient fentanyl. Fentanyl Sandoz is used for the long-term management of severe pain that requires daily around-the-clock pain relievers, when other treatment options are not able to effectively manage your pain, or you cannot tolerate them. Fentanyl Sandoz is only used in people who have previously been using other opioid-based pain relief.

For more information, see Section [1. Why am I using Fentanyl Sandoz?](#) in the full CMI.

### 2. What should I know before I use Fentanyl Sandoz?

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 I use Fentanyl Sandoz?](#) in the full CMI.

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

Some medicines may interfere with Fentanyl Sandoz 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 do I use Fentanyl Sandoz?

- Fentanyl Sandoz is available in five different patches, each with a different size and strength. Your doctor will decide which patch, or combination of patches, is suitable to control your pain. The lowest effective strength should be used.

More instructions can be found in Section [4. How do I use Fentanyl Sandoz?](#) in the full CMI.

### 5. What should I know while using Fentanyl Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Fentanyl Sandoz.</li><li>Always follow your doctor's instructions carefully. <b>Accidental exposure or improper use including Fentanyl Sandoz patches sticking to another person can be life-threatening.</b></li><li>Tell your doctor if you develop a fever.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine suddenly.</li><li>Do not expose the patch to direct heat. Direct exposure to such heat may cause an increase in the amount of fentanyl absorbed by the skin, resulting in possible overdose and death.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Fentanyl Sandoz can affect your alertness and ability to drive and operate machinery. Be careful before you drive or use any machines or tools until you know how Fentanyl Sandoz affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>You must not drink alcohol while using Fentanyl Sandoz. Their combined effect may cause severe drowsiness, decreased awareness, breathing problems, coma and death.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Fentanyl Sandoz patches in the sealed pouch until it is time to apply them.</li><li>Keep the patches in a dry place where temperature stays below 25°C.</li><li>Store this medicine securely, where other people cannot access it. It may harm people who may take this medicine by accident, or intentionally.</li></ul>

For more information, see Section [5. What should I know while using Fentanyl Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

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

**Life threatening respiratory depression**

Fentanyl Sandoz can cause life-threatening or fatal breathing difficulties (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 Sandoz 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.

**Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol**

Using Fentanyl Sandoz 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 Sandoz.

# Fentanyl Sandoz®

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

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fentanyl Sandoz. **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 Sandoz.**

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

- [1. Why am I using Fentanyl Sandoz?](#)
- [2. What should I know before I use Fentanyl Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Fentanyl Sandoz?](#)
- [5. What should I know while using Fentanyl Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Fentanyl Sandoz?

**Fentanyl Sandoz contains the active ingredient fentanyl.** Fentanyl Sandoz is an opioid analgesic which are a group of strong pain relievers. Fentanyl relieves pain by blocking the nerves that recognise pain messages from the body.

Fentanyl Sandoz is used for the long-term management of pain that is severe enough to require daily around-the-clock pain relievers, when other treatment options are not able to effectively manage your pain or you cannot tolerate them. Fentanyl Sandoz is only used in people who have previously been using other opioid-based pain

relief. Fentanyl Sandoz is not used to treat pain that you only have once in a while.

Each patch is applied onto the skin every three days (72 hours). The patch releases a continuous amount of fentanyl that is absorbed through the skin in contact with the patch.

## 2. What should I know before I use Fentanyl Sandoz?

### Warnings

Opioids can be abused and misused, and you are at risk for opioid addiction, even if you take your dose as prescribed. Opioid addiction, abuse and misuse can lead to overdose and death.

Fentanyl Sandoz may become habit-forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Fentanyl Sandoz patches may be retrieved and abused or misused illegally. Please ensure that used patches are concealed and disposed of carefully. Return unused patches to the pharmacy (see Getting rid of any unwanted medicine at the end of this leaflet).

Keep used and unused patches where children cannot reach them. A patch may be tempting to a child. Accidental exposure or ingestion of used or unused Fentanyl Sandoz patches, particularly in children, may result in breathing difficulties, with slow or shallow breathing, that could lead to death. Improper use

**including Fentanyl Sandoz patches sticking to another person can be life-threatening.**

Fentanyl Sandoz can cause sleep apnoea (stopping breathing from time to time while sleeping) which can lead to low levels of oxygen in the blood. **Tell your doctor if you have a history of sleep apnoea or if anyone notices you stop breathing from time to time whilst sleeping.**

Opioids can cause a high level of the hormone 'prolactin' and low levels of sex hormones in the blood. The effects of these hormone changes may include:

- In females – unexpected production of breast milk; loss of menstrual periods
- In males – enlarged breasts; difficulty getting and keeping an erection (impotence)
- In females or males – decreased sex drive; infertility.

Tell your doctor if you notice any of these symptoms. You may need blood tests, and your doctor may tell you to stop using Fentanyl Sandoz.

Opioids can cause a decreased level of hormones in the blood caused by a problem with the adrenal glands. The effects of these hormone changes may include:

- Nausea, vomiting, loss of appetite, feeling very tired and weak, feeling dizzy, or low blood pressure.

Tell your doctor if you notice any of these symptoms. You may need blood tests, and your doctor may tell you to stop using Fentanyl Sandoz.

### **Tolerance**

As with all opioid analgesics, Fentanyl Sandoz may lead to tolerance with continued use. Tolerance means that the effect of the medicine may decrease and more is needed to produce the same effect. Therefore, it is possible your doctor will prescribe a higher dose of Fentanyl Sandoz after some time to produce the same result.

### **Dependence and withdrawal**

As with all other opioids, your body may become used to you taking Fentanyl Sandoz after several days to weeks of continued use resulting in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Fentanyl Sandoz suddenly. Some examples of withdrawal symptoms include feeling uneasy and unwell, restless, agitated, anxious, increased pain, sweating, chills, weakness, stomach cramps, problems sleeping, nausea, vomiting, diarrhoea, increased blood pressure, fast breathing and fast heartbeat.

Fentanyl Sandoz must be stopped by decreasing the dose gradually. Your doctor will tell you how to do this, and will regularly monitor and support any increase in pain or withdrawal symptoms.

### **Increased sensitivity to pain**

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

### **Do not use Fentanyl Sandoz:**

- If you are allergic to fentanyl, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- for acute pain or pain following surgery
- for mild or intermittent pain
- at a starting dose greater than 25 micrograms/hour
- if you have any lung condition or breathing difficulties
- if you have not used any opioid analgesics in the past. This is because you may be more likely to experience some of the side effects.

Do not use Fentanyl Sandoz if the packaging is torn or shows signs of tampering.

Do not use Fentanyl Sandoz beyond the expiry date (month and year) printed on the pack.

### **Check with your doctor if you:**

- have any other medical conditions, particularly:
  - have or have ever had problems with your liver or kidney
  - have or have ever had problems with your lungs or breathing difficulties
  - have sleep apnoea or if anyone notices you stop breathing from time to time while sleeping
  - have or have ever had problems with your heart
  - have or have ever had a brain tumour or head injuries
  - have problems with your stomach or intestines such as bowel blockage
  - have problems with your immune system or medical conditions which lower your resistance to diseases.
- take any medicines for any other condition
- (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs or have a mental illness. Your doctor will advise you whether or not to use Fentanyl Sandoz or if you need to adjust the dose or adapt your treatment.

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.**

Your doctor will decide whether you may use Fentanyl Sandoz if you are pregnant or plan to become pregnant.

Fentanyl Sandoz should not be used during childbirth as the medicine can slow the breathing of the newborn child. Prolonged use of Fentanyl Sandoz during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognised and treated.

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

If you are breast feeding, you should not use Fentanyl Sandoz since it may be present in your milk. See your doctor.

### Use in children and adolescents

Fentanyl Sandoz should not be used in children under 12 years of age or in adolescents under 18 years of age who weigh less than 50 kg.

### 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 Fentanyl Sandoz and affect how it works.**

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

- medicines that slow down your central nervous system, for example:
    - medicines that makes you sleepy, reduce anxiety such as sedatives, hypnotics, sleeping tablets, tranquillisers (benzodiazepines)
    - other opioid medicines
    - medicines used for surgery (anesthetics) and muscle relaxants
    - antihistamines or allergy medicine that makes you drowsy
    - gabapentinoid medicines used to treat epilepsy or nerve pain such as gabapentin and pregabalin
    - alcohol, cannabis or some illegal drugs.
- Taking these medicines with Fentanyl Sandoz may make you even more drowsy, slow down your ability to react, have decrease awareness, breathing difficulties with slow or shallow breathing, coma and death.

A change in dose by your doctor may be required if Fentanyl Sandoz is used with these medicines:

- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs). Fentanyl Sandoz should not be used together with MAOIs as this may cause severe serotonin syndrome which is a potentially life-threatening condition. Signs and symptoms can include confusion, restlessness, fever, heavy sweating, fast or irregular heart rate, diarrhoea, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, seizures and unconsciousness. Do not use Fentanyl Sandoz if you have taken a MAOI in the last 14 days.
- other antidepressant medicines belonging to the class selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine re-uptake inhibitors (SNRIs) or tricyclic antidepressants (TCAs) and nefazodone. Combination of these medicines with Fentanyl Sandoz may increase the risk of serotonin syndrome.
- medicines used to treat mental illness or psychotic conditions and to relieve severe nausea and vomiting, such as phenothiazines.

- certain antibiotics used to treat infections such as erythromycin, clarithromycin and troleandomycin.
- certain medicines to treat fungal infections such as fluconazole, ketoconazole, itraconazole and voriconazole.
- ritonavir and nelfinavir (used to treat AIDS). Do not take ritonavir or nelfinavir while using Fentanyl Sandoz, unless you are closely monitored by your doctor.
- if taking rifampicin, carbamazepine, phenobarbital or phenytoin, careful monitoring by your doctor and dose adjustment may be required.
- idelalisib (cancer treatment)
- certain medicines that act on the heart and blood vessels such as calcium-channel blockers like verapamil and diltiazem, nicardipine.
- certain medicines used to treat arrhythmias such as amiodarone.

**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 Sandoz.**

### 4. How do I use Fentanyl Sandoz?

#### How much to use

- Fentanyl Sandoz is available in five different patches, each with a different size and strength. Your doctor will decide which patch, or combination of patches, is suitable to control your pain. The lowest effective strength should be used.

#### Using it for the first time

- The first patch may take up to a day to take effect after it is applied onto the skin. This is because fentanyl is slowly absorbed through the skin into the blood. Your doctor may prescribe additional medicines to control the pain for the first day.

#### Applying the patch

1. **Find an intact and hairless spot of skin on the upper part of your body or on your upper arm. Do not place the patch onto skin that is red, burnt or damaged.** The skin should be healthy and undamaged.
2. **Trim any excess hair with scissors. Do not shave the hair off since this may affect the skin. If you need to wash the skin before applying the patch, use clean water only. Do not use soap, oils or lotions.** The skin should be completely dry before applying the patch.
3. **Open the pouch and remove the Fentanyl Sandoz patch. Do not apply the patch if it looks damaged in any way. Never cut or divide the patch.**
4. **Remove the protective film.** Avoid touching the adhesive side of the patch.
5. **Apply the patch to the skin and press with the palm of the hand for about 30 seconds. Make sure all of the patch is in contact with skin and the corners are stuck tightly.**
6. **Wash your hands after applying or removing the patch.**

You can now leave the patch on the skin for three days (72 hours).

You may have a bath, shower or swim.

**Always write the date and time you applied the patch on the pack.**

It will help you to use Fentanyl Sandoz correctly and remember when the next patch is due.

## Changing the patch

1. **After three days (72 hours), remove the patch.**
2. **Fold the used patch in half so that the adhesive side sticks to itself. Wrap the folded patch and carefully dispose of it in the garbage.**
3. **Apply a new patch straight away to a different area of the skin, following the steps under 'Applying the patch'.**

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

If your pain continues, see your doctor who may prescribe additional medicines to help control the pain or change the dose of Fentanyl Sandoz. Your doctor may advise you initially to change the patch every two days (48 hours) instead of every three days (72 hours) to achieve adequate pain relief.

## How to long to use Fentanyl Sandoz

- Continue using your medicine for as long as your doctor tells you.

## If you forget to use Fentanyl Sandoz

If you forget to apply a patch, and are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to apply each patch, ask your pharmacist for some hints.

## If you use too much Fentanyl Sandoz

If you think that you have used too much Fentanyl Sandoz, you may need urgent medical attention.

**You should immediately remove the patch(es) and phone triple zero (000) in Australia or triple one (111) in New Zealand for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then.**

Also,

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), 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 with Fentanyl Sandoz may include:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness

- Slow or weak heart beat
- Nausea or vomiting
- Convulsions or fits

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

## 5. What should I know while using Fentanyl Sandoz?

### Things you should do

- Always follow your doctor's instructions carefully.
- If you are pregnant or plan to become pregnant, you should inform your doctor, who will decide whether you may use Fentanyl Sandoz.
- If your pain continues or returns, see your doctor. You may need additional medicines to control the pain or a change in the strength of the Fentanyl Sandoz patch.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Fentanyl Sandoz.

### Call your doctor straight away if you:

- develop a fever. At high temperatures, the amount of fentanyl absorbed by the skin increases. Your doctor may need to adjust your Fentanyl Sandoz dose.

Remind any doctor, dentist or pharmacist you visit that you are using Fentanyl Sandoz.

### Things you should not do

- **Do not stop using this medicine suddenly** unless your doctor advises you to do so. If you have been using Fentanyl Sandoz for a long period of time but stop using it suddenly without your doctor's advice, you may experience withdrawal symptoms such as:
  - trouble sleeping, nervousness, restlessness, agitation 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 sweatingSeek your doctor's advice if you experience these symptoms.
- **DO NOT expose the patch to direct heat** from electric blankets, heat pads, heated water beds, heat or tanning lamps, intensive sunbathing, hot water bottles, long hot baths, saunas or hot spa baths while you are using Fentanyl Sandoz. Direct exposure to such heat may cause an increase in the amount of fentanyl absorbed by the skin, resulting in possible overdose and death.
- **Do not cut, break, chew, crush, dissolve, snort or inject Fentanyl Sandoz.** This can result in serious side effects and death.

- Do not change your dose without first checking with your doctor
- Do not give the patches to anyone else, even if their symptoms seem similar to yours as they could die from taking it.

### Things to be careful of

- If the patch accidentally sticks to another person (for example a family member sharing the same bed) or is accidentally swallowed (for example by a child),
- remove the patch and phone triple zero (000) in Australia or triple one (111) in New Zealand. Do this even if there are no signs of discomfort or drowsiness.
- Different brands of fentanyl patches may vary in size, shape, colour or adhesiveness.
- **DO NOT switch brands of fentanyl patches unless your doctor and pharmacist authorise it.**

### Driving or using machines

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

Fentanyl Sandoz can affect your alertness and ability to drive and operate machinery. Do not drive or operate machinery until you know how this medicine affects you.

### Drinking alcohol

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

You must not drink alcohol while using Fentanyl Sandoz since their combined effect may cause severe drowsiness, decreased awareness, breathing problems, coma and death.

### Looking after your medicine

- Keep the patches in a dry place where temperature stays below 25°C.
- Store this medicine securely, where other people cannot access it. It may harm people who may take this medicine by accident, or intentionally when it has not been prescribed for them.
- Keep Fentanyl Sandoz patches in the sealed pouch until it is time to apply them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, 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.**

### Getting rid of any unwanted medicine

**The contents of Fentanyl Sandoz patches may be retrieved and abused or misused illegally.**

**Fold used patches so that the adhesive side of the patch sticks to itself, then wrap and dispose of it carefully.**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 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
<b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• nausea, vomiting, constipation, dry mouth, diarrhoea, uncomfortable feeling in stomach or belching after eating, indigestion, blockage in the bowel, problem with the movement of food or drink through the food pipe.</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Blood pressure-related:</b> <ul style="list-style-type: none"> <li>• low blood pressure, headache, weakness or dizziness, high blood pressure, being less alert or aware, or loss of consciousness.</li> <li>• blurred vision</li> </ul>	
<b>Sleep-related:</b> <ul style="list-style-type: none"> <li>• sleepiness, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, pins and needles.</li> <li>• stopping breathing from time to time whilst sleeping (sleep apnoea).</li> </ul>	
<b>Skin-related:</b> <ul style="list-style-type: none"> <li>• skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed).</li> <li>• thinning or redness where the patch has been on the skin; ulcer (sore) where the patch has been on the skin.</li> </ul>	
<b>Other:</b> <ul style="list-style-type: none"> <li>• unusual tiredness or weakness, feeling of body temperature</li> </ul>	

change; swelling of the feet, ankles and hands. <ul style="list-style-type: none"> <li>nausea, vomiting, diarrhoea, anxiety and shivering may occur initially when you are switched from other opioid analgesics to Fentanyl Sandoz or if therapy is stopped suddenly.</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<b>Heart-related:</b> <ul style="list-style-type: none"> <li>slow heartbeat</li> <li>fast heartbeat</li> </ul> <b>Breathing-related:</b> <ul style="list-style-type: none"> <li>breathing slows or weakens</li> <li>temporarily stopped breathing</li> <li>difficulty in breathing</li> </ul> <p><i>The risk of breathing problems is higher if you:</i></p> <ul style="list-style-type: none"> <li>have an existing lung condition</li> <li>have a small physique</li> <li>are an elderly patient</li> <li>have kidney or liver disease</li> <li>are given a high Fentanyl Sandoz dose</li> <li>you have not used opioid pain relief before.</li> </ul> <b>Nervous system-related:</b> <ul style="list-style-type: none"> <li>numbness; seizures or fits.</li> <li>involuntary muscle movements including muscle spasms.</li> <li>sweating or trouble urinating</li> </ul> <b>Allergy-related:</b> <ul style="list-style-type: none"> <li>sudden life-threatening allergic reaction.</li> </ul> <p><i>Symptoms may include:</i></p> <ul style="list-style-type: none"> <li>rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul>	<b>REMOVE the Fentanyl Sandoz patch and phone triple zero (000) in Australia or triple one (111) in New Zealand or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b> <p><b>Make sure that you are with someone who can keep you awake by talking to you or gently shaking you every now and then.</b></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.

## 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) or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Fentanyl Sandoz contains

<b>Active ingredient (main ingredient)</b>	fentanyl
<b>Other ingredients (inactive ingredients)</b>	polyethylene terephthalate acrylic-vinylacetate copolymer siliconised polyethylene terephthalate

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

### What Fentanyl Sandoz looks like

Fentanyl Sandoz patches are transparent rounded oblong patches. They are individually packed in sachets and are available in packs containing 5 sachets.

- Fentanyl Sandoz 12 mcg/h - 12 microgram fentanyl released per hour (AUST R 152572)
- Fentanyl Sandoz 25 mcg/h - 25 microgram fentanyl released per hour (AUST R 152569)
- Fentanyl Sandoz 50 mcg/h - 50 microgram fentanyl released per hour (AUST R 152571)
- Fentanyl Sandoz 75 mcg/h - 75 microgram fentanyl released per hour (AUST R 152568)
- Fentanyl Sandoz 100 mcg/h - 100 microgram fentanyl released per hour (AUST R 152576)

### Who distributes Fentanyl Sandoz

Fentanyl Sandoz is distributed in Australia by:

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia

Tel 1800 726 369

Fentanyl Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited  
12 Madden Street  
Auckland 1010  
New Zealand  
Tel: 0800 726 369

This leaflet was prepared in June 2025.

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