

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Fentanyl Sandoz.

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 taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT FENTANYL SANDOZ IS USED FOR

This medicine is used to relieve chronic or long-lasting pain, which requires strong painkillers.

It contains the active ingredient fentanyl.

Fentanyl belongs to a group of medicines called opioid analgesics.

It works by blocking the nerves that recognise pain messages from the body.

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

Your doctor may have prescribed it for another reason.

This medicine may be addictive.

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

Warning

FENTANYL patches may be retrieved and abused by addicts.

Please ensure that used patches are concealed and disposed of carefully. Return unused patches to the pharmacy (see Disposal at the end of this leaflet).

Keep used and unused patches where children cannot reach them.

BEFORE YOU USE FENTANYL SANDOZ

When you must not use it

Do not use this medicine if you have an allergy to:

- fentanyl, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.
- any other similar medicines.
Some of the 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.

Do not use this medicine if you have or had any of the following medical conditions:

- acute pain or pain following surgery
- mild or intermittent pain.

Do not use any Fentanyl Sandoz strength other than the 25 micrograms/hour patch if you have never had opioid analgesics for pain relief before.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

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

Tell your doctor if you have or have had any of the following medical conditions:

- liver or kidney disease
- lung disease
- brain lesions or head injuries
- heart disease
- medical conditions which lower your resistance to diseases.

Unless you are being treated for cancer pain, you must tell your doctor if you have not used any opioid analgesics in the past. You may be more likely to experience some of the side effects.

Tell your doctor if you (or a family member) have a history of drug, alcohol or prescription medicines abuse.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or wish to breastfeed.

Children

FENTANYL 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.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Fentanyl Sandoz.

Taking other medicines

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

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

- other strong analgesics used to manage pain such as morphine, codeine, methadone, oxycodone, pethidine or buprenorphine
- ritonavir and nelfinavir, medicines used to treat HIV infections. 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.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs), selective serotonin re-uptake inhibitors (SSRIs), or serotonin norepinephrine re-uptake inhibitors (SNRIs) including moclobemide, phenelzine sulfate and tranylcypromine sulphate. Fentanyl Sandoz should not be

used concurrently with these medicines and should be initiated 14 days after cessation of MAOIs.

Combination of these medicines with Fentanyl Sandoz may increase the risk of serotonin syndrome, a potentially life-threatening condition.

- certain medicines used to treat depression such as nefazodone
 - medicines that slow down your central nervous system (for example medicines that makes you sleepy, reduce anxiety or decrease awareness, such as sedatives, hypnotics, sleeping tablets, tranquillisers, strong pain killers (opioids), medicines used for surgery (anaesthetics), muscle relaxants, allergy medicine that makes you drowsy, alcohol or some illegal drugs).
- Combination of these medicines with FENTANYL may increase the sedative effect of these drugs or slow down your ability to react, breathing difficulties with slow or shallow breathing, coma and death. A change in dose by your doctor may be required if FENTANYL is used with these medicines.
- medicines used as sedatives, sleeping tablets, tranquillisers or muscle relaxants
 - medicines used to treat mental illness or psychotic conditions
 - medicines used to relieve severe nausea and vomiting, such as phenothiazines
 - certain antibiotics used to treat infections such as clarithromycin and troleandomycin
 - certain medicines used to treat fungal infections such as ketoconazole and itraconazole
 - medicines used as antihistamines that are sedating
 - certain medicines that act on the heart and blood vessels such as calcium-channel blockers like verapamil and diltiazem
 - certain medicines used to treat arrhythmias such as amiodarone.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Tolerance

As with all opioid analgesics, FENTANYL may lead to tolerance with combined use. Your doctor may, therefore, prescribe a higher dose of FENTANYL after some time to continue to give you pain relief.

HOW TO USE FENTANYL SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to use

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly which patch or patches to use.

Follow the instructions they give you.

If you use the wrong dose, Fentanyl Sandoz may not work as well in controlling your pain.

Fentanyl Sandoz is available in five different sizes. Your doctor will decide which patch, or combination of patches, is suitable to control your pain.

Each patch is applied onto the skin and lasts for three days (72 hours). After three days, remove the patch and apply a new patch to the skin at a different place.

You should not use more than one patch at a time, unless your doctor authorises otherwise (for example to obtain a dose that cannot be achieved with a single patch). The old patch should be removed before the new patch is applied.

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.

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 your 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.
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'.

How long to use Fentanyl Sandoz

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

If you forget to use it

Apply a new patch as soon as you remember, and continue to use Fentanyl Sandoz as you would normally.

If it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

The most important sign of overdose is difficulty in breathing. If a person using FENTANYL has abnormally slow or weak breathing, remove the patch. Keep the person awake by talking to them or gently shaking them every now and then.

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Fentanyl Sandoz. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The most important symptom of an overdose is difficulty in breathing.

If a person using Fentanyl Sandoz has abnormally slow or weak breathing, remove the patch. Keep the person awake by talking to them or gently shaking them every now and then.

WHILE YOU ARE USING FENTANYL SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Fentanyl Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

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.

Tell your doctor 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.

Things you must not do

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.

Do not use Fentanyl Sandoz to treat any other complaints unless your doctor tells you to.

Do not give the patches to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are using before stopping completely. This may help reduce the possibility of withdrawal symptoms such as:

- nausea, loss of appetite, vomiting, diarrhoea
- anxiety, depression
- sweating, shivering.

Things to be careful of

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

This medicine may affect your alertness and cause dizziness in some people. Do not drive, operate machinery or do anything else that could be dangerous until your doctor tells you that it is safe.

Avoid drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness may be worse.

If the patch accidentally adheres to another person (for example a family member sharing the same bed), remove the patch and contact your doctor. 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.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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:

- nausea, vomiting, constipation, stomach pain or discomfort, dry mouth, diarrhoea, uncomfortable feeling in stomach or belching after eating, indigestion, blockage in the bowel

- low blood pressure, headache, light-headedness, weakness or dizziness, fainting, high blood pressure
- drowsiness, sleepiness, trouble sleeping, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, tingling or numbness of the hands or feet, seizures or fits, tremor or shaking
- blurred vision
- sweating or trouble in urinating
- runny or blocked nose, flu-like symptoms, generally feeling unwell
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- swelling of hands, ankles or feet
- skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed).
- involuntary muscle contractions
- irregular heart beat
- unusual tiredness or weakness, feeling of body temperature change.

Tell your doctor as soon as possible if you notice any of the following:

- convulsions, fits or seizures
- slow heart beat
- fast heart beat.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, remove the Fentanyl Sandoz patch and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- breathing slows or weakens
- temporarily stopped breathing
- difficulty in breathing

Make sure that you are with someone who can keep you awake by talking to you or gently shaking you every now and then.

- sudden life-threatening allergic reaction. Symptoms of an allergic reactions are 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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. Tell your doctor if you experience any of these effects.

Medicines like Fentanyl Sandoz can lead to addiction. This is unlikely when this medicine is used correctly.

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

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

Some of the side effects (for example high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

AFTER USING FENTANYL SANDOZ

Storage

Keep your medicine in the original sealed pouch.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Fentanyl Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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

The contents of Fentanyl Sandoz patches may be retrieved and abused by addicts.

Fold used patches so that the adhesive side of the patch sticks to itself, wrap and dispose of carefully in the garbage.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

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

Ingredients

Active ingredients:

- Fentanyl Sandoz 12mcg/h - 12 microgram fentanyl released per hour
- Fentanyl Sandoz 25mcg/h - 25 microgram fentanyl released per hour
- Fentanyl Sandoz 50mcg/h - 50 microgram fentanyl released per hour
- Fentanyl Sandoz 75mcg/h - 75 microgram fentanyl released per hour
- Fentanyl Sandoz 100mcg/h - 100 microgram fentanyl released per hour

Inactive ingredients:

- polyethylene terephthalate
- acrylic-vinylacetate copolymer
- siliconised polyethylene terephthalate.

This medicine does not contain lactose monohydrate, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park, NSW 2113
 Australia
 Tel: 1800 634 500
 Novartis New Zealand Ltd
 PO Box 99102
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Australian Register Numbers

12mcg/h transdermal patch: AUST R 152572

25mcg/h transdermal patch: AUST R 152569

50mcg/h transdermal patch: AUST R 152571

75mcg/h transdermal patch: AUST R 152568

100mcg/h transdermal patch: AUST R 152576