

## APO-Fentanyl

fentanyl transdermal patches

### Consumer Medicine Information

#### 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 risk 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.

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about APO-Fentanyl patches. 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 using APO-Fentanyl against the benefits this medicine is expected to have for you.

**If you have any concerns about using APO-Fentanyl, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### WHAT APO-FENTANYL IS USED FOR

APO-Fentanyl 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.

APO-Fentanyl is only used in people who have previously been using other opioid-based pain relief. APO-Fentanyl is not used to treat pain that you only have once in a while.

APO-Fentanyl patches contains a medicine called fentanyl. This strong pain reliever belongs to a group of medicines known as opioid analgesics. Fentanyl relieves pain by blocking the nerves that recognise pain messages from the body.

Each patch is applied on 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.

Your doctor may have prescribed APO-Fentanyl for another reason.

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

#### BEFORE YOU USE APO-FENTANYL

##### Warning

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.

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

APO-Fentanyl 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 Disposal 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 APO-Fentanyl patches, particularly in children, may result in breathing difficulties, with slow or shallow breathing, that could lead to death. Improper use including APO-Fentanyl patches sticking to another person can be life-threatening.

APO-Fentanyl 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.

##### Tolerance

As with all opioid analgesics, APO-Fentanyl 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 APO-Fentanyl after some time to produce the same result.

##### Dependence and withdrawal

As with other opioids, your body may become used to you taking APO-Fentanyl 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 APO-Fentanyl 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.

APO-Fentanyl 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.

##### When you must not use it

##### Do not use APO-Fentanyl

- if you have an allergy to fentanyl, or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- 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 APO-Fentanyl if the packaging is torn or shows signs of tampering. Do not use APO-Fentanyl beyond the expiry date (month and year) printed on the pack.**

##### Before you start to use it

You must tell your doctor if you

- are pregnant or planning to become pregnant
- are breast feeding or wish to breastfeed
- have or have ever had liver or kidney disease
- have or have ever had lung disease or breathing difficulties
- have sleep apnoea or if anyone notices you stop breathing from time to time while sleeping
- have or have ever had heart disorders
- have or have ever had brain lesions or head injuries
- have problems with your stomach or intestine such as bowel blockage
- have problems with your immune system or medical conditions which lower your resistance to diseases.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given APO-Fentanyl.

**Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription**

## medicines, illegal drugs or have a mental illness.

Your doctor can advise you whether or not to use APO-Fentanyl if you need to adjust the dose or adapt your treatment.

### Children

**APO-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.**

### Taking other medicines

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

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 or decrease awareness, such as sedatives, hypnotics, sleeping tablets, tranquillisers (benzodiazepines)
  - other opioid medicines
  - medicines used for surgery (anaesthetics) 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.Combination of these medicines with APO-Fentanyl may increase the sedative effect of these drugs or 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 APO-Fentanyl is used with these medicines.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs). APO-Fentanyl 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 APO-Fentanyl 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 APO-Fentanyl may increase the risk of serotonin syndrome, a potentially life-threatening condition.
- 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 clarithromycin and troleandomycin.
- certain medicines used 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 APO-Fentanyl, 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, diltiazem and nifedipine.
- certain medicines used to treat arrhythmias such as amiodarone.

Your doctor and pharmacist can tell you what to do if you are taking any of these medicines.

### Effect of alcohol

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

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## HOW TO USE APO-FENTANYL

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### How to use the patch

#### Adults

APO-Fentanyl 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.

- 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.**

#### Children

APO-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.

### 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 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. The skin should be healthy and undamaged. Do not place the patch onto skin that is red, burnt or damaged.
2. Trim any excess hair with scissors. Do not shave the hair 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 APO-Fentanyl patch. Do not apply the patch if it looks damaged in any way. Never cut or divide the patch. Do not use a patch that has been divided, cut or damaged in any way.
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 carton. It will help you to use APO-Fentanyl 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 APO-Fentanyl. 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.

### If you forget to use it

If you forgot 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 receive too much (overdose)

The most important sign of overdose is difficulty in breathing. If a person using APO-Fentanyl has abnormally slow or weak breathing, remove the patch(es) and phone triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then.

Also, telephone your doctor or the Poisons Information Centre for advice, or go to the Accident and Emergency Department at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning. The person may need urgent medical attention.

Poisons Information Centre telephone number:

- Australia: 13 11 26

Keep this telephone number handy.

You should also follow the above steps if someone other than you have accidentally used APO-Fentanyl that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heart beat
- Nausea or vomiting
- Convulsions or fits

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.

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## WHILE YOU ARE USING APO-FENTANYL

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### Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you plan to or become pregnant while using APO-Fentanyl, who will then decide whether you may use APO-Fentanyl. APO-Fentanyl should not be used during childbirth as the medicine can slow the breathing of the newborn child. Prolonged use of APO-Fentanyl during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognised and treated. If you are breastfeeding, you should not use APO-Fentanyl since it may be present in your milk. See your doctor.
- 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 APO-Fentanyl 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 APO-Fentanyl dose.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using APO-Fentanyl.

### 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, saunas or hot spa baths while you are using APO-Fentanyl. 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 use APO-Fentanyl to treat any other complaint unless your doctor says so.
- Do not give the patches to anyone else, even if their symptoms seem similar to yours.
- Do not stop using APO-Fentanyl unless your doctor advises you to do so. If you have been using APO-Fentanyl 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 sweating

Seek your doctor's advice if you experience these symptoms.

- **Do not cut, break, chew, crush, dissolve, snort or inject APO-Fentanyl.** This can result in serious side effects and death.

### Things to be careful of

- If the patch accidentally adheres 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). Do this even if there are no signs of discomfort or drowsiness.
- APO-Fentanyl 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.
- Different brands of fentanyl patches may vary in size, shape, colour or adhesiveness.

**DO NOT switch brands of fentanyl patches unless your doctor or pharmacist authorise it.**

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## SIDE EFFECTS

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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 this list of possible side effects. You may not experience any of them.

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

### Tell your doctor if you experience any of the following:

- nausea, vomiting, constipation, dry mouth, diarrhoea, uncomfortable feeling in stomach or belching after eating, indigestion, blockage in the bowel.
- low blood pressure, headache, weakness or dizziness, high blood pressure, being less alert or aware, or loss of consciousness.
- blurred vision
- sleepiness, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, pins and needles
- stopping breathing from time to time whilst sleeping (sleep apnoea)
- skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed)
- thinning or redness where the patch has been on the skin; ulcer (sore) where the patch has been on the skin
- unusual tiredness or weakness, feeling of body temperature change; swelling of the feet, ankles and hands.

**Tell your doctor immediately if you notice any of the following as you may need urgent medical care:**

- slow heartbeat.
- fast heartbeat.

**REMOVE the APO-Fentanyl patch and phone triple zero (000) or go to the Emergency Department at your nearest hospital if the following happens:**

- breathing slows or weakens
- temporarily stopped breathing
- difficulty in breathing
- numbness; seizures or fits
- involuntary muscle movements including muscle spasms.
- sweating or trouble in urinating.
- sudden life-threatening allergic reaction
- sudden signs of allergy such as 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.

Make sure that you are with someone who can keep you awake by talking to you or gently shaking you every now and then. The risk of breathing problems is higher if you:

- have an existing lung condition
- have a small physique
- are an elderly patient
- have kidney or liver disease
- are given a high APO-Fentanyl dose
- you have not used opioid pain relief before.

Your doctor will carefully select the most appropriate dose for you.

Nausea, vomiting, diarrhoea, anxiety and shivering may occur initially when you are switched from other opioid analgesics to APO-Fentanyl or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects.

Other side effects not listed above such as sexual dysfunction and withdrawal symptoms may also occur in some people. Tell your doctor if you notice any other effects.

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## AFTER USING APO-FENTANYL

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### Storage

Keep APO-Fentanyl patches in the sealed pouch until it is time to apply them. If you take it out of its original container it may not keep well.

Keep the patches in a cool dry place where the 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 your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store APO-Fentanyl patches or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

### Disposal

The contents of APO-Fentanyl patches may be retrieved and abused or misused illegally.

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

If your doctor tells you to stop using APO-Fentanyl, or the patches have passed their

expiry date, return the patches to your pharmacist.

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## Product description

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### *What it looks like*

APO-Fentanyl patches are transparent rounded oblong patches. They are individually packed in sachets and are available in packs containing 1\*, 2\*, 3\*, 4\*, 5, 7\*, 8\* or 10\* sachets.

\* Not all strengths, pack types and/or pack sizes may be available.

### *Ingredients*

Active ingredients:

- APO-Fentanyl 12 µg/h – 12 microgram fentanyl released per hour
- APO-Fentanyl 25 µg/h – 25 microgram fentanyl released per hour
- APO-Fentanyl 50 µg/h – 50 microgram fentanyl released per hour
- APO-Fentanyl 75 µg/h – 75 microgram fentanyl released per hour
- APO-Fentanyl 100 µg/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.

### *Australian Register Numbers*

APO-Fentanyl 12 µg/h transdermal patch:  
AUST R 152577

APO-Fentanyl 25 µg/h transdermal patch:  
AUST R 152574

\*APO-Fentanyl 37 µg/h transdermal patch:  
AUST R 152566

APO-Fentanyl 50 µg/h transdermal patch:  
AUST R 152573

APO-Fentanyl 75 µg/h transdermal patch:  
AUST R 152570

APO-Fentanyl 100 µg/h transdermal patch:  
AUST R 152575

\*Not currently marketed in Australia.

### *Supplier*

Apotex Pty Ltd  
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Macquarie Park NSW 2113

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