

APO-Fentanyl

fentanyl transdermal patches

Consumer Medicine Information (CMI)

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 to relieve chronic or long-lasting pain, which requires strong painkillers.

APO-Fentanyl patches contains a medicine call 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.

Warning

APO-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 APO-FENTANYL

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 never had opioid analgesics for pain relief.

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
- have or have ever had heart disorders
- have or have ever had brain lesions or head injuries
- have medical conditions which lower your resistance to diseases.

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

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 or illegal drugs.

Your doctor can advise you whether or not to use APO-Fentanyl or 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:

- other strong analgesics used to manage pain such as opioids and general anaesthetics.

- 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.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs), selective serotonin re-uptake inhibitors (SSRIs), or serotonin norepinephrine re-uptake inhibitors (SNRIs). APO-Fentanyl should not be used in combination with these medicines. APO-Fentanyl should be initiated 14 days after stopping treatment with MAOIs. Combination of these medicines with APO-Fentanyl 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 APO-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 APO-Fentanyl is used with these medicines.

- 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 ketoconazole and itraconazole.
- sedating antihistamines.
- 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.

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

Effect of alcohol

Avoid alcohol when using APO-Fentanyl since their combined effect may cause drowsiness.

Tolerance

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

HOW TO USE APO-FENTANYL

How to use the patch

Adults

APO-Fentanyl 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.

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.

Your doctor may prescribed additional pain relievers to control occasional outbreaks of pain.

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. 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 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.

WHILE YOU ARE USING APO-FENTANYL

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while using APO-Fentanyl.
- 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 nausea, vomiting, diarrhoea, anxiety and shivering). Seek your doctor's advice if you experience these symptoms.

Things to be careful of

- 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.
- 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.

SIDE EFFECTS

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
- 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.

- skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed).
- 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 tell your doctor immediately or go to the Emergency Department at your nearest hospital if the following happens:

- 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.

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.

Medicines like APO-Fentanyl can lead to addiction. This is unlikely when APO-Fentanyl is used correctly.

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.

AFTER USING APO-FENTANYL

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 25C.

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 by addicts.

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.

Product description

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 12mcg/h - 12 microgram fentanyl released per hour
- APO-Fentanyl 25mcg/h - 25 microgram fentanyl released per hour
- APO-Fentanyl 50mcg/h - 50 microgram fentanyl released per hour

- APO-Fentanyl 75mcg/h - 75 microgram fentanyl released per hour
- APO-Fentanyl 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.

Australian Register Numbers

APO-Fentanyl 12mcg/h transdermal patch:

AUST R 152577

APO-Fentanyl 25mcg/h transdermal patch:

AUST R 152574

*APO-Fentanyl 37mcg/h transdermal patch:

AUST R 152566

APO-Fentanyl 50mcg/h transdermal patch:

AUST R 152573

APO-Fentanyl 75mcg/h transdermal patch:

AUST R 152570

APO-Fentanyl 100mcg/h transdermal patch:

AUST R 152575

*Not currently marketed in Australia.

Supplier

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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