

## MYLAN FENTANYL PATCH

### *Fentanyl Transdermal Patch*

**12.5, 25, 50, 75 & 100 micrograms per hour**



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### What is in this leaflet

This leaflet answers some common questions about Mylan Fentanyl Patch. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. Your doctor has weighed the risks of you using Mylan Fentanyl Patch against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist. Keep this leaflet with your medicine. You may need to read it again.

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### What Mylan Fentanyl Patch is used for

Mylan Fentanyl Patch is used to relieve chronic or long-lasting pain, which requires strong painkillers. The patches contain 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 recognize pain messages from the body.

Each patch is applied onto the skin every 72 hours (3 days). The patch releases a continuous amount of fentanyl that is absorbed through the skin in contact with the patch (see **Fentanyl Patch Diagram**).

Your doctor may have prescribed Mylan Fentanyl Patch for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

### Warning

**Mylan Fentanyl Patch 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.**

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### Before you use Mylan Fentanyl Patch

#### *When you must not use it*

You should not use Mylan Fentanyl Patch:

- 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.
- other than 12.5 or 25 micrograms/hour patch if you have never had opioid analgesics for pain relief.
- if you have difficulties breathing.
- if your central nervous system is severely impaired, e.g. brain or spinal injury.

Do not use Mylan Fentanyl Patch if the packaging is torn or shows signs of tampering. Do not use Mylan Fentanyl Patch after 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 breastfeeding or wish to breast feed.
- have or have ever had liver or kidney problems.
- have or have ever had lung problems.
- have or have ever had heart problems.
- 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 Mylan Fentanyl Patch.

Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs. Mylan Fentanyl Patch may lead to physical or psychological dependence with continued or repeated use.

Your doctor will advise you whether or not to use Mylan Fentanyl Patch or if you need to adjust the dose or adapt your treatment.

### Taking other medicines

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

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

- other strong pain medicines such as morphine, codeine, methadone, oxycodone, pethidine or buprenorphine.
- ritonavir or nelfinavir (used to treat AIDS). Do not take ritonavir or nelfinavir while using Mylan Fentanyl Patch, unless you are closely monitored by a doctor.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs) including moclobemide, phenelzine sulfate and tranylcypromine sulfate. Mylan Fentanyl Patch should not be used at the same time as these medicines and should only be started 14 days after stopping treatment with a MAOI.
- SSRI (selective serotonin reuptake inhibitor) medicines for anxiety and depression.
- certain medicines to treat depression such as nefazodone.
- 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.
- certain antibiotics used to treat infections such as clarithromycin, troleandomycin and rifampicin.
- certain medicines 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.
- medicines used in the treatment of convulsions or seizures such as carbamazepine, phenytoin, phenobarbital.

Mylan Fentanyl Patch can increase the effect of medicines that are sedating, or slow down your ability to react. A change in dose may be required if Mylan Fentanyl Patch is used with these medicines. Your doctor or pharmacist can tell you

what to do if you are taking any of these medicines.

### **Effect on driving and operating machinery**

Mylan Fentanyl Patch can affect your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.

### **Effect of alcohol**

Avoid alcohol when using Mylan Fentanyl Patch since their combined effect may cause drowsiness or side effects.

### **Tolerance**

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

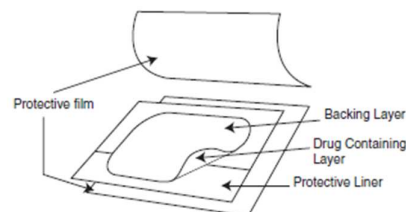
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## **Using Mylan Fentanyl Patch**

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### **Fentanyl Patch Diagram**

(not to scale)



Each Mylan Fentanyl Patch is packaged with an additional piece of protective film (plastic) above and below the patch and is sealed in its own protective pouch.

The Mylan Fentanyl Patch should be applied to the chosen skin site immediately after it is taken out of the sealed pouch.

**Never cut or divide the patch. Do not use a patch that has been divided, cut, or damaged in any way.**

## **How much to use**

### **Adults**

Mylan Fentanyl Patch 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 old 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 authorizes 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**

Mylan Fentanyl Patch 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 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. This 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 as 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. To open the pouch, locate the pre-cut notch indicated by the scissors. Carefully tear the pouch along the edge and then

- fully open the pouch by folding it open like a book.
- Remove the Mylan Fentanyl Patch from the pouch. Discard the pieces of protective film.  
**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.**
  - Each Mylan Fentanyl Patch has a clear plastic protective (release) liner that covers the sticky side of the Mylan Fentanyl Patch. The protective liner can be peeled off in two pieces. Carefully peel off each part of the protective liner separately, and discard the liner.  
**Avoid touching the adhesive (sticky) side of the patch.**
  - 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.
  - Always wash hands after applying or removing the patch.

You can now leave the patch on for three days (72 hours). You may have a bath, shower or swim. Always write on the pack the date and time you applied the patch. It will help you to use Mylan Fentanyl Patch correctly and remember when the next patch is due.

If the Mylan Fentanyl Patch does not stick properly, first aid tape may be applied around the edges of the patch. If the adhesion problem persists, the Mylan Fentanyl Patch may be overlaid with a transparent adhesive film dressing, eg. OpSite™ Flexigrid™, or OpSite™ Flexifix™. **Never fully cover a Mylan Fentanyl Patch with any other bandage or tape.**

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

### **Changing the patch**

- After three days (72 hours), remove the patch.
- 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 rubbish.

- 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 Mylan Fentanyl Patch.

### **If you forget to use it**

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 receive too much (overdose)**

The most important sign of overdose is difficulty in breathing. If a person using Mylan Fentanyl Patch 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 National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to the Emergency department at the nearest hospital, if you think you or anyone else may have used too much Mylan Fentanyl Patch. Do this even if there are no signs of discomfort or poisoning.**

You or the person may need urgent medical attention.

Keep the number of these facilities handy.

**Information for the doctor in case of overdose: inject with naloxone and transfer patient to hospital.**

**Please refer to full Product Information for details on appropriate management of overdose.**

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## **While you are using Mylan Fentanyl Patch**

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### **Things you must do**

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while using Mylan Fentanyl Patch.
- 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 Mylan 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 Mylan Fentanyl Patch dose.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Mylan Fentanyl Patch.

### **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 Mylan Fentanyl Patch. 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 Mylan Fentanyl Patch 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 Mylan Fentanyl Patch unless your doctor advises you to do so. If you have been using Mylan Fentanyl Patch for a long period of time but stop 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, family member sharing the same bed), remove the patch and contact your doctor or Poisons Centre. 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.

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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 treatment 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 the stomach or belching after eating, indigestion, blockage in the bowel.
- low blood pressure, headache, weakness or dizziness, high blood pressure.
- sleepiness, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, pins and needles.
- sweating or trouble urinating.
- 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.
- sudden signs of allergy such as rash, itching or hives on the skin.

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

- slow heart beat.
- fast heart beat.
- convulsion or seizure.

### **REMOVE the Mylan 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.
- sudden allergic reaction, which includes swelling of the face, lips, tongue or other parts of the body, shortness of breath or wheezing.

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 Mylan Fentanyl Patch or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects.

Medicines like Mylan Fentanyl Patch can lead to addiction. This is unlikely when Mylan Fentanyl Patch is used correctly.

Other side effects not listed above, 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 Mylan Fentanyl Patch**

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### **Storage**

Keep the patch in the sealed pouch until it is time to apply it.

Keep the patches in a dry place where the temperature stays below 25°C.

Keep the patches where young 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 Mylan Fentanyl Patch 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 Mylan Fentanyl Patch 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 rubbish.**

If your doctor tells you to stop using Mylan Fentanyl Patch, or your 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**

Mylan Fentanyl Patches are available in 5 sizes.

Each carton contains 5 patches.

The patches are rectangular and transparent, imprinted with the strength:

'Fentanyl 12.5 mcg/hr' in white for the 12.5 micrograms/hour strength.

'Fentanyl 25 mcg/hr' in white for the 25 micrograms/hour strength.

'Fentanyl 50 mcg/hr' in white for the 50 micrograms/hour strength.

'Fentanyl 75 mcg/hr' in white for the 75 micrograms/hour strength.

'Fentanyl 100 mcg/hr' in white for the 100 micrograms/hour strength.

The number beneath the name Mylan Fentanyl Patch refers to the amount of fentanyl in micrograms

(one thousandth of a milligram)  
released by the patch per hour.

### ***Ingredients***

The patches contain the active  
ingredient fentanyl.

The patch is made of a silicone  
adhesive, dimeticone, polyolefin  
film, white ink and a polyester  
release liner.

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### **If you want to know more**

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Should you have any questions  
regarding this product, please  
contact your pharmacist or doctor.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Limited  
PO Box 11-183  
Ellerslie  
Auckland, NZ.

Phone: (09) 579 2792

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### **Date of information**

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19 January 2016  
(Based on datasheet dated 19  
January 2016).