PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S6

Fendermal® 25 µg/h (transdermal patch (matrix))

Fendermal® 50 µg/h (transdermal patch (matrix))

Fendermal® 75 µg/h (transdermal patch (matrix))

Fendermal® 100 µg/h (transdermal patch (matrix))

Fentanyl

Read all of this leaflet carefully before you start using FENDERMAL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FENDERMAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FENDERMAL is and what it is used for
2. What you need to know before you use FENDERMAL
3. How to use FENDERMAL
4. Possible side effects
5. How to store FENDERMAL
6. Contents of the pack and other information

1. What FENDERMAL is and what it is used for

FENDERMAL belongs to a group of strong painkillers called opioids. The painkiller, fentanyl, slowly passes from the patch, through the skin and into the body.

FENDERMAL relieves severe long-lasting pain, which can only adequately be managed with strong painkillers (opioids).

2. What you need to know before you use FENDERMAL

Do not use FENDERMAL:

- If you are hypersensitive (allergic) to fentanyl, or any of the other ingredients of FENDERMAL (listed in section 6).
- If you suffer from pain which lasts only for a short period (e.g. after a surgical procedure) or if the pain is mild and can be managed with less potent painkillers.
- If you have difficulty breathing.
- If you have a slow heartbeat and a disturbance in your heart rhythm.
- If you are pregnant, planning to become pregnant or breastfeeding your baby (see “Pregnancy, breastfeeding and fertility”).
- FENDERMAL transdermal patches may not be used on children less than 12 years of age.
- If you have severe or uncontrolled asthma.
- If your central nervous system is severely impaired, e.g., by brain injury.

Certain medicines can cause undesired effects when used together with FENDERMAL. Such medicines have the potential to affect your breathing, blood pressure, and may lead to coma. These include medicines used to treat allergies, medicines used to treat muscle pain (muscle relaxants), medicines used for the treatment of sleeplessness as well as alcoholic beverages and other medicines as listed in the section “Other medicines and FENDERMAL”.

Warnings and precautions:

FENDERMAL can have life-threatening side effects in people who are not already regularly using prescribed opioid medicines (strong painkillers like morphine), even at the lowest dose.

FENDERMAL is a medicine that could be life-threatening to children, even if the patches have been used. Bear in mind that a sticky patch (unused or used) could be tempting to a child and if it sticks to a child’s skin or they put it in their mouth, the result may be fatal.

FENDERMAL should not be used to treat short-term pain or pain after an operation, as it could cause life-threatening side effects.

Before starting to use FENDERMAL you should inform your doctor immediately if you suffer from any of the following:

- Asthma, breathing difficulties or any lung disease. If you experience difficulty breathing, remove the FENDERMAL patch immediately and get medical assistance.
- Low blood pressure.
- Problems with your liver.
- Kidney problems.
- If you have had a head injury, brain tumour, headache, visual disturbances, changes in your state of consciousness or loss of consciousness or coma.
- Slow irregular heartbeat.
- Myasthenia gravis; if you suffer from a disease causing weakness of the muscles and fatigue (tiredness).
- If you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs. Abuse or intentional misuse of FENDERMAL may result in overdose and/or death.
- If you are taking or have recently taken certain medicines for depression called Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Noradrenaline Re-uptake Inhibitors (SNRIs) or Monoamine Oxidase Inhibitors (MAOIs), as they may increase the risk of a condition called serotonin syndrome. (See section 4 for the signs and symptoms of serotonin syndrome. Also see section 'Other medicines and FENDERMAL'.)

FENDERMAL may make you unusually drowsy, as well as making your breathing slower or shallow. Very rarely these breathing problems can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like FENDERMAL or morphine) before. If you, or your partner or carer, notice that the person wearing the patch is unusually drowsy, with slow or shallow breathing:

- Take the patch off
- Call a doctor, or go to your nearest hospital straight away
- Keep the person moving and talking as much as possible

Increased body temperature may cause too much medicine to pass through the skin. Therefore:

- Inform your doctor if you develop a fever during treatment.

- Avoid exposing the patch on the skin to direct heat such as electric blankets, hot-water bottles, solarium (sunroom) or hot baths.
- You may stay outside in the sun, but you must protect the patch with a piece of clothing during hot summer days.
- Remove the patch before you take a sauna. Using a sauna is only possible when replacing a transdermal patch. A new patch should be applied to cool dry skin.
- Avoid excessive/strenuous exercise.

Decreasing relief of pain (tolerance), physical or psychological dependence may develop if you use FENDERMAL for a longer period.

If you are an elderly patient or if you suffer from an illness causing ongoing muscle loss (e.g. myasthenia gravis, cancer, AIDS, heart failure or advanced chronic obstructive pulmonary disease (COPD)) your doctor will monitor you more carefully, because it may be necessary to prescribe a lower dose.

FENDERMAL may cause constipation. Talk to your doctor or pharmacist for advice on how to help prevent constipation. If you develop severe (spasmodic) pain and swelling in the stomach, are unable to pass a bowel motion and feel sick or are being sick, talk to your doctor straight away.

Patch sticking to another person:

The patch should be used only on the skin of the person for whom it has been prescribed. There have been reports of patches accidentally sticking to a family member while in close physical contact or sharing the same bed as the person wearing the patch. A patch accidently sticking to another person (particularly a child) can cause the medicine in the patch to go through the skin of the other person and cause serious side effects such as breathing difficulties, with slow or shallow breathing which may be fatal. In case the patch sticks to the skin of another person, take the patch off right away and get medical attention.

The patches should not be divided, cut into smaller parts or damaged in any way as this affects the quality and safety of such patches.

Children and adolescents:

FENDERMAL is contraindicated in children under 12 years of age.

Other medicines and FENDERMAL:

Always tell your health care provider if you are taking any other medicine (This includes complementary or traditional medicines).

Please tell your doctor if you are using the following medication:

- Barbiturates (used for treating sleep disorders and epilepsy).
- Buprenorphine, nalbuphine or pentazocine (other strong painkillers).
- Some painkillers for nerve pain (gabapentin and pregabalin).

It is not recommended to use the following medicines together with FENDERMAL:

Medicines that affect brain function for example:

- Medicines used for treating anxiety (anxiolytics) and to help you calm down (tranquillizers).
- Medicines used for treating depression called Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Noradrenaline Re-uptake Inhibitors (SNRIs) (such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine or duloxetine).
- Medicines used for treating psychological disorders (neuroleptics).
- Anaesthetics (medicines that bring about a reversible loss of consciousness, used in surgery), if you think you are going to receive anaesthesia, tell the doctor or dentist that you are using FENDERMAL.
- Medicines used for treating sleep disorders (hypnotics, sedatives).
- Medicines used for treating allergies or travel sickness (antihistamines/ anti-emetics).
- Other strong-acting painkillers (opioids).
- Alcohol.

You should not take the medicines listed below at the same time as using FENDERMAL, unless you are closely monitored by your doctor. These medicines may increase the effects and side effects of FENDERMAL:

This applies, for example, to:

- Ritonavir (used to treat AIDS).
- Ketoconazole, itraconazole, fluconazole, voriconazole (used to treat fungal diseases).
- Diltiazem, amiodarone, verapamil (used to treat heart disease).
- Cimetidine (used to treat gastrointestinal diseases).
- Erythromycin, clarithromycin (antibiotics used to treat infections).
- Medicines for relaxing your muscles.
- Medicines used for treating high blood pressure.
- Medicines used for treating diarrhoea (such as loperamide, diphenoxylate, atropine), as they may cause severe constipation.
- Some medicines used to treat angina (chest pain).
- Some medicines used to treat cancer of the blood (such as idelalisib).

The following medicines may make FENDERMAL less effective:

- Medicines to treat tuberculosis (such as rifampicin).
- Carbamazepine, phenytoin and phenobarbital (normally used for epilepsy).

Please tell your doctor if you are taking MAO – inhibitors (monoamine oxidase inhibitors) (e.g. moclobemide for depression or selegiline for Parkinson's disease) or have taken them within the last 14 days. If these medicines are taken together with FENDERMAL this may enhance their toxicity.

FENDERMAL with food, drink and alcohol:

You should not consume alcohol during FENDERMAL treatment. Alcohol may increase the risk of severe side effects and may cause breathing problems, a drop in blood pressure, sleepiness and coma.

Pregnancy, breastfeeding and fertility:

FENDERMAL should not be used during pregnancy or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- Do not use FENDERMAL during labour and delivery (including caesarean section), because FENDERMAL may cause breathing problems in the newborn child.
- If you become pregnant during treatment with FENDERMAL transdermal patch, consult your doctor.
- FENDERMAL passes into the breast milk and may cause undesirable effects to your baby. Discard any breast milk produced during treatment or within 72 hours after the removal of the last patch.

Driving and using machines:

FENDERMAL has a major influence on the ability to drive and use machines. Do not drive or operate dangerous machines while using FENDERMAL, unless your doctor has approved it.

3. How to use FENDERMAL

Do not share medicines prescribed for you with any other person.

Always use FENDERMAL exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will decide which dose of FENDERMAL is most suitable for you, depending on the severity of your pain, your general condition and the type of pain treatment that you have received so far. The usual starting dose is 25 µg/h.

According to your reaction the dose of the patch or the number of patches may need to be adjusted. The effect is reached within 24 hours after the first patch has been applied and its effects lessen gradually after the patch is removed. Do not discontinue treatment without consulting your doctor.

Your first patch will start to work slowly; this may take as long as one day.

Your doctor may give you extra painkillers until your FENDERMAL transdermal patch starts working completely. After this, FENDERMAL should help to relieve pain continuously and you should be able to stop taking these extra painkillers. However sometimes you may still need extra painkillers.

How to apply FENDERMAL:

1. Find a flat part of your upper body (trunk) or upper arm, where the skin is without hair, cuts, spots or other skin blemishes. The area must not have been treated with radiotherapy. Carefully check correct adhesion of the patch and if necessary, additionally fix the patch in place.
2. If the skin is hairy, cut the hair as close to the skin as possible, with scissors or clippers. Do not shave, as shaving irritates the skin. If the skin needs washing, wash with water. Do not use soap, oil, lotions, alcohol or other cleansers that may irritate the skin. The skin must be completely dry before applying the patch.
3. Apply the patch immediately after opening the package. When the release liner has been removed, apply the patch by pressing it firmly onto the skin with the palm of the hand for approximately 30 seconds to make sure that the patch sticks well to the skin. Make sure that the patch sticks properly at the edges.
4. FENDERMAL is usually used for 72 hours (3 days).
5. Do not expose the patch application site to heat from external sources (see Warnings and Precautions).
6. As FENDERMAL is protected by an outer waterproof backing film, you can also wear it while showering.

How to change FENDERMAL:

- Remove the patch after the period your doctor has told you. In most cases this is after 72 hours (3 days), in some patients after 48 hours (2 days). The patch does not come off by itself. If traces of the transdermal patch remain on the skin after its removal, you can clean them off using plenty of soap and water. Do not use alcohol or any other solvent.
- Fold the used patch in half with the sticky sides together. Put used patches back in the outer package and discard safely or whenever possible give it to your pharmacist.
- Apply a new patch as described above, but on another part of the skin. At least 7 days should elapse before the same area is used again.

If you use more FENDERMAL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you have applied more patches than prescribed, remove the patches and contact your doctor or hospital immediately.

The most common sign of an overdose is reduced ability to breathe. Symptoms are that the person breathes abnormally slowly or weakly. If this should occur remove the patches and contact a doctor immediately.
An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

If you forget to use FENDERMAL:
Do not under any circumstances use a double dose to make up for missed doses. You should change your patch at the same time of day every three days (every 72 hours) unless directed otherwise by your doctor. If you forget to change your patch, change it as soon as you remember. If you are very late changing your patch, you should contact your doctor because you might need some extra painkillers.

If you stop using FENDERMAL:
If you wish to interrupt or stop the treatment, you should always talk to your doctor about the reasons for discontinuation and your continued treatment.

Prolonged use of FENDERMAL can cause physical dependence. If you do stop using the patches you may feel unwell.

As the risk of withdrawal symptoms, such as restlessness, difficulty sleeping, irritability, agitation, nausea, vomiting, diarrhoea, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, loss of appetite, shaking, sweating or shivering, is greater when the treatment is stopped suddenly, do not stop treatment with FENDERMAL. Treatment with FENDERMAL should be stopped gradually; your doctor will give you proper instructions on how to do this.

4. Possible side effects

FENDERMAL can have side effects. Not all side effects reported for FENDERMAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using

FENDERMAL, please consult your healthcare provider for advice.

Stop using FENDERMAL and seek medical help immediately if you have any of these signs of an allergic reaction:

- Hives, difficulty breathing, swelling of your face, lips, tongue, or throat, severe irritation, reddening or blistering of your skin.

If any of the following happens, stop taking FENDERMAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Feeling unusually drowsy, breathing that is more slow or shallow than expected. Follow the advice above and keep the person who was wearing the patch moving and talking as much as possible. Very rarely these breathing difficulties can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like FENDERMAL or morphine) before.
- Fits (seizures).
- Reduced consciousness or loss of consciousness.

These are all very serious side effects. If you have them, you may have had a serious reaction to FENDERMAL. You may need urgent medical attention or hospitalisation.

Consult your doctor if any of the following side effects continue or are bothersome and occur frequently:

- Allergic reaction
- Loss of appetite
- Difficulties in sleeping
- Hallucinations (seeing or hearing things that are not there)
- Depression
- Feeling anxious or confused
- Sleepiness, nervousness, weight loss
- Headache
- Feeling dizzy
- Pins and needles (paraesthesia)

- Muscle tremors
- Spinning sensation (vertigo)
- Heartbeat feels fast or uneven (palpitations, tachycardia)
- High blood pressure
- Difficulties in breathing, shortness of breath
- Nausea (the feeling of wanting to vomit or feeling sick in your stomach), vomiting, constipation (difficulty passing stool), dry mouth, heartburn (a burning sensation in your chest that makes you feel uncomfortable and uneasy)
- Diarrhoea (passing of loose or watery stools)
- Stomach pain
- Increased sweating, itching (itching will usually disappear within one day after the patch has been removed)
- Skin rash, skin reddening
- Muscle spasms
- Difficulties in passing urine
- Swollen hands, ankles or feet (peripheral oedema)
- Feeling very tired, weak or generally unwell
- Feeling cold

Less frequent side effects that may occur include the following:

- An exaggerated feeling of well-being (feeling “high”), memory loss
- Feeling agitated or disoriented
- Speech disorders, excessive anxiety or fear
- Convulsions (fits)
- Being uncertain about your surroundings, becoming unconscious
- Decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- Fall in blood pressure
- Dilation of the blood vessels (you may notice reddening of the skin)
- Slow heart rate
- Blue colour to the skin caused by low oxygen in the blood (cyanosis)
- Breathing problems, including asthma

- Being unable to breath
- Stopping breathing from time to time (apnoea)
- Severe spasmodic pain owing to the lack of movement of the intestines (ileus)
- Difficulty in swallowing (dysphagia)
- Skin condition with itching, redness and a burning feeling (eczema) or other skin disorders including dermatitis
- Skin reactions at the attachment site
- Muscle twitching
- Disturbances in vision
- Blurred vision
- Constricted pupils (miosis)
- Difficulty getting and keeping an erection (impotence) or problems having sex
- Flu-like illness
- Feeling of body temperature change
- Fever
- Abdominal pain, including inflamed and irritated pancreas

Side effects that have been reported with frequency unknown:

- Lack of male sex hormones (androgen deficiency)
- Delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- Loss of coordination
- Reduced vision in one eye (lazy eye)
- Irregular heartbeat (dysrhythmia)
- Abnormally slow breathing rate
- Hiccups
- Pain when passing wind
- Passing less urine than normal
- Pain in the bladder
- Tolerance (a condition that occurs when the body gets used to the medicine so that either more medicine is needed, or different medicine is needed)

- You can become dependent on FENDERMAL

FENDERMAL with antidepressants:

The risk of side effects increases if you are taking medicines such as certain antidepressants. FENDERMAL may interact with these medicines, and you may experience changes to mental status such as feeling agitated, seeing, feeling, hearing, or smelling things that are not there (hallucinations) and other effects such as changing blood pressure, fast heartbeat, high body temperature, overactive reflexes, lack of coordination, muscle stiffness, nausea, vomiting and diarrhoea.

If you have been using FENDERMAL for some time, it might happen that FENDERMAL will become less effective for you so that a dose adjustment will be necessary (tolerance may develop). Physical and psychological dependence may develop as well and you might experience withdrawal symptoms, if you do suddenly stop using the patches. Withdrawal symptoms may be nausea, vomiting, diarrhoea, anxiety and shivering. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FENDERMAL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store FENDERMAL

- Store in sealed sachet at or below 25 °C.
- Do not remove from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN BEFORE AND AFTER USE.**
- **Do not store in a bathroom.**
- Do not use after the expiry date printed on the label or carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FENDERMAL contains:

Fendermal 25 µg/h: Each 10,5 cm^2 transdermal patch contains 4,2 mg fentanyl delivering 25 µg fentanyl/h.

Fendermal 50 µg/h: Each 21 cm^2 transdermal patch contains 8,4 mg fentanyl delivering 50 µg fentanyl/h.

Fendermal 75 µg/h: Each 31,5 cm^2 transdermal patch contains 12,6 mg fentanyl delivering 75 µg fentanyl/h.

Fendermal 100 µg/h: Each 42 cm^2 transdermal patch contains 16,8 mg fentanyl delivering 100 µg fentanyl/h.

Inactive ingredients:

- Acrylic-vinylacetate copolymer (Durotak® 87-4287)
- Polyethylen-terephthalat foil
- Polyethylen-terephthalat foil, siliconized

What FENDERMAL looks like and contents of the pack:

FENDERMAL 25 µg/h: Matt, homogenous, rectangular transdermal medicine delivery system on release liner. Imprint on backing foil: “fentanyl 25 µg/h”.

FENDERMAL 50 µg/h: Matt, homogenous, rectangular transdermal medicine delivery system on release liner. Imprint on backing foil: “fentanyl 50 µg/h”.

FENDERMAL 75 µg/h: Matt, homogenous, rectangular transdermal medicine delivery system on release liner. Imprint on backing foil: “fentanyl 75 µg/h”.

FENDERMAL 100 µg/h: Matt, homogenous, rectangular transdermal medicine delivery system on release liner. Imprint on backing foil: “fentanyl 100 µg/h”.

The FENDERMAL transdermal patches are packed in sachets (sachet foil paper/PE/AL/PE) and finally in cardboard cartons. The package leaflet is inserted into the carton.

FENDERMAL is available in pack sizes of 5 transdermal patches.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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FENDERMAL 25 µg/h: 44/2.9/0757

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FENDERMAL 75 µg/h: 44/2.9/0759

FENDERMAL 100 µg/h: 44/2.9/0760

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07