

FENTANYL-HEXAL[®] MAT TRANSDERMAL PATCH

Fentanyl Base (25 mcg/h, 50 mcg/h)

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What Fentanyl-HEXAL[®] MAT is used for

Fentanyl-HEXAL[®] MAT is used to relieve moderate to severe long-lasting pain. It is not used for pain that only lasts for a short time.

How Fentanyl-HEXAL[®] MAT works

Fentanyl-HEXAL[®] MAT is a strong opioid (narcotic) painkiller. It comes in the form of adhesive patches to be applied to the skin. It contains the active ingredient Fentanyl which belongs to a group of medicines known as opioid analgesics. It releases a continuous amount of fentanyl that is absorbed through the skin in contact with it, and relieves pain by blocking the nerves that recognise pain messages from the body.

Before you use Fentanyl-HEXAL[®] MAT

- *When you must not use it*

Fentanyl is a strong opioid and should not be used unless you have previously been prescribed other opioids.

Do not use Fentanyl-HEXAL[®] MAT if:

- You are allergic to fentanyl or any other ingredients of this medicine (listed in Product Description).
- You suffer from pain which lasts only for a short period, such as sudden pain or pain after having an operation.
- You have breathing difficulties, with slow or shallow breathing.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Fentanyl-HEXAL[®] MAT.

- *Before you start to use it*

Talk to your doctor or pharmacist before using this medicine if any of the following apply to you:

- You have ever had problems with your lungs or breathing.
- You have ever had problems with your heart, liver, kidneys, or low blood pressure.
- You have ever had a brain tumour.
- You have ever had persistent headaches or a head injury.
- You are elderly - you may be more sensitive to the effects of this medicine.
- You have a condition called 'myasthenia gravis' in which muscles become weak and easily tired.
- You (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs or have a mental illness.

Fentanyl-HEXAL[®] MAT 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. Fentanyl-HEXAL[®] MAT can have life-threatening side effects in people who are not already regularly using prescribed opioid medicines.

Fentanyl-HEXAL[®] MAT 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. Keep unused and used patches out of children's reach.

Children and adolescents

Fentanyl-HEXAL[®] MAT should only be used in children above 2 years of age who are already using opioid medication.

Pregnancy and lactation

Do not use Fentanyl-HEXAL[®] MAT if you are pregnant or think you might be pregnant, unless you have discussed this with your doctor and the benefits of treatment outweigh the potential harm to your baby.

Fentanyl-HEXAL[®] MAT should not be used during childbirth as the medication can affect the breathing of newborn child. Prolonged

use of Fentanyl-HEXAL[®] MAT during pregnancy can cause withdrawal symptoms in the newborn baby that could be life-threatening if not recognised and treated.

Do not use Fentanyl-HEXAL[®] MAT if you are breastfeeding. You should not breastfeed for 3 days after removing Fentanyl-HEXAL[®] MAT patch. This is because the medicine may pass into breast milk.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. In particular, tell your doctor or pharmacist if you are taking:

- Other medicines for pain, such as other opioid painkillers (e.g. buprenorphine, nalbuphine or pentazocine) and painkillers for nerve pain (gabapentin and pregabalin).
- Medicines used to help you sleep or to reduce anxiety (e.g. benzodiazepine).
- Medicines to help you calm down (tranquillisers) and medicines for mental conditions.
- Medicines used for surgery (anaesthetics) and muscle relaxants.
- Some medicines used to treat depression (e.g. selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) or nefazodone).
- Some medicines used to treat depression or Parkinson's disease (e.g. monoamine oxidase inhibitors (MAOIs)). You should not take Fentanyl-HEXAL[®] MAT within 14 days of stopping these medicines.
- Some antihistamines that makes you drowsy.
- Some antibiotics used to treat infection (e.g. erythromycin or clarithromycin).
- Medicines used to treat fungal infection (e.g. itraconazole, ketoconazole, fluconazole or voriconazole).
- Medicines used to treat HIV infection (e.g. ritonavir).
- Some medicines used to treat irregular heartbeat, chest pain or high blood pressure (e.g. amiodarone, diltiazem, verapamil or nicardipine).
- Medicines to treat tuberculosis (e.g. rifampicin).

- Some medicines used to treat epilepsy (e.g. carbamazepine, phenobarbital or phenytoin).
- Some medicines used to relieve severe nausea and vomiting (e.g. phenothiazines).
- Some medicines used to treat heartburn or ulcers (e.g. cimetidine).
- Medicines used to treat certain blood cancer (e.g. idelalisib).
- Medicines used to treat migraines (e.g. triptans).

Taking Fentanyl-HEXAL[®] MAT with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine. Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Concomitant use of Fentanyl-HEXAL[®] MAT with antidepressants

Fentanyl-HEXAL[®] MAT may interact with certain antidepressants 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 changes in blood pressure, fast heartbeat, high body temperature, overactive reflexes, loss of coordination, muscle stiffness, nausea, vomiting and diarrhoea (these could be signs of Serotonin syndrome, a rare but potentially life-threatening condition). If used together, your doctor may want to closely monitor your condition in particular when starting treatment or when the dose of your medicine is changed.

Do not drink alcohol while using Fentanyl-HEXAL[®] MAT unless you have talked to your doctor first.

How to use Fentanyl-HEXAL[®] MAT

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Fentanyl-HEXAL[®] MAT, when and how long you need to take it, when to contact your doctor, and when you need to stop it.

- How much to use

Your doctor will decide which strength of Fentanyl-HEXAL[®] MAT is most suitable for you, taking into account the severity of your pain, your general condition and type of pain

treatment that you have received so far. The lowest effective strength should be used.

Using and changing the patches

- Each patch lasts for three days. Change the patch at the same time of day every 3 days (72 hours), unless your doctor has told you differently.
- Always remove the old patch before applying a new one. This is important to avoid overdose.
- If you are using more than one patch, change all your patches at the same time.
- Make a note of the day, date and time you apply a patch, to remind you when you need to change your patch.

Where to apply the patch

Fentanyl-HEXAL[®] MAT should be applied to non-irritated and non-irradiated skin on a flat surface of the upper body or upper arms.

Do not apply the patch on:

- The same place twice in a row.
- Areas that you move a lot (joints).
- Skin that is irritated or with cuts, or very hairy.

In children, always apply the patch to the upper back to make it difficult for your child to reach it or take it off.

Step 1: Preparing the skin

- Hair at the application site (a non-hairy area is preferable) should be clipped (not shaved) prior to application.
- If the application site needs to be cleaned before applying the patch, this should be done with clear water. Soaps, oils, lotions, or any other agent that might irritate the skin or alter its characteristics should not be used.
- Make sure your skin is completely dry before the patch is applied. Do not stick a patch on straight after a hot bath or shower.
- Patches should be inspected prior to use.

Do not use the patch if it has been divided, cut or looks damaged.

Step 2: Open the sachet

- Fentanyl-HEXAL[®] MAT should be applied immediately upon removal from the sealed package. The patches may occasionally show crystallization (white structures at the edges and/or in the matrix surface). This has no influence on the application or efficacy of the patches.
- To remove the patch from the protective sachet, locate the pre-cut notch along the

edge of the seal. Tear off the edge of the sachet completely.

- Further, open the sachet along both sides, folding the sachet open like a book. The release liner for the patch is slit.

Step 3: Peel and press

- Peel away the first part of the liner from the centre of the patch. Avoid touching the adhesive side of the patch.
- Press the sticky part of the patch onto the skin. Remove the other part of the liner.
- Press the whole patch onto the skin by applying light pressure with the palm of your hand for about 30 seconds.
- Make certain that the edges of the patch are adhering properly. Then wash hands with clean water.

Step 4: Disposing of the patch

- Wear the patch continuously for 3 days (72 hours). After 3 days (72 hours), remove the patch by tearing it off and apply a new patch to a different skin area. Your skin can get sore or itchy if you keep putting the patches in the same place.
- Fold the used patch in half with the sticky side sticks to itself. Dispose the used patch as instructed by your pharmacist.

Because the medicine in Fentanyl-HEXAL[®] MAT is gradually released from the patch and slowly absorbed through the skin, it may take some time for your first patch to have its maximum effect. Your doctor may prescribe additional medicines to control the pain until the patch become effective.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

Continue using Fentanyl-HEXAL[®] MAT for as long as your doctor tells you.

- If you forget to use it

Change your patch as soon as you remember and make note of the day and time. Be sure to remove your used patch before applying a new patch. Change the patch again after 3 days (72 hours) as usual.

If you are very late changing your patch, you should talk to your doctor because you might need some extra painkillers, but do not apply an extra patch.

- If you use too much (overdose)

If you have stuck on too many patches, take the patches off and contact a doctor or go to the nearest hospital straight away.

Signs of overdose include trouble breathing or shallow breathing, tiredness, extreme sleepiness, being unable to think clearly, walk or talk normally and feeling faint, dizzy or confused. An overdose may also cause damage to the white matter of the brain (known as toxic leukoencephalopathy).

While you are using it

- Things you must do

- Always follow the instructions given to you by your doctor or pharmacist.
- If you are having surgery, including dental surgery, tell the doctor or dentist that you are using Fentanyl-HEXAL® MAT.
- Tell your doctor immediately if you become pregnant while using this medicine.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are using Fentanyl-HEXAL® MAT.
- If you get a fever while using this medicine, tell your doctor immediately - this may increase the amount of medicine that passes through your skin.
- Tell your doctor or pharmacist immediately if you notice any side effects worsen or any other discomforts.

Tell your doctor if:

- You feel your pain is no longer relieved by the patch.
- You feel an increase in pain.
- There is a change in how you feel the pain (for example, you feel pain in another part of your body).
- You feel pain when something touches your body that you wouldn't expect to hurt you.

Do not change the dose yourself. Your doctor may decide to change your dose or treatment.

While using the patch, tell your doctor if you have breathing problems while sleeping. Opioids like Fentanyl-HEXAL® MAT can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxaemia (low oxygen level in the blood). Tell your doctor if you, your partner or carer notice you have any of the following:

- Breathing pauses during sleep.
- Night awakening due to shortness of breath.
- Difficulties staying asleep.

- Excessive drowsiness during the day. Your doctor may decide to change your dose.

- Things you must not do

- Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor says so.
- Do not cut the patch or apply a damaged patch as this may alter the release of the drug from the patch.
- While you are wearing the patch, do not expose it to direct heat such as heating pads, electric blankets, hot water bottles, heated water beds, heat or tanning lamps. Do not sunbathe, have long hot baths or saunas. 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 suddenly stop using this medicine. If you want to stop using this medicine, discuss this with your doctor first. Your doctor will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum.
- If you stop using the patches, do not start again without asking your doctor first. You might need a different patch strength when you restart.

If you have any further questions on the use of Fentanyl-HEXAL® MAT, ask your doctor or pharmacist.

- Things to be careful of

Damaged patch

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

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 patch wearer. A patch accidentally 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 immediately and seek medical attention.

Long-term use and tolerance

Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using Fentanyl-HEXAL® MAT. This is known as hyperalgesia. Increasing the dose of your patches may help to further reduce your pain for a while, but it may also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dose or to gradually decrease your use of Fentanyl-HEXAL® MAT.

Dependence and addiction

Repeated use of Fentanyl-HEXAL® MAT can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Fentanyl-HEXAL® MAT if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs.
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness.

If you notice any of the following signs whilst using Fentanyl-HEXAL® MAT, it could be a sign that you have become dependent or addicted:

- You need to use the medicine for longer than advised by your doctor.
- You need to use more than the recommended dose.
- You are using the medicine for reasons other than prescribed.
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once using the medicine again.

If you notice any of these signs, discuss with your doctor the best treatment pathway for

you, including when it is appropriate to stop and how to stop safely.

Serotonin syndrome

Fentanyl-HEXAL® MAT may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency

Long-term use of Fentanyl-HEXAL® MAT may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility

Long-term use of Fentanyl-HEXAL® MAT may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Fentanyl-HEXAL® MAT contains soya-bean oil. In very rare cases, soya-bean oil may cause allergic reactions.

Driving and using machines

Fentanyl-HEXAL® MAT can affect your ability to drive and use machines or tools as it may make you sleepy or dizzy. Do not drive while taking this medicine until you know how it affects you.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you or your partner, or carer, notice any of the following about the person wearing the patch, take the patch off and call a doctor, or go to your nearest hospital, straight away. You may need urgent medical treatment:

- Feeling unusually drowsy, breathing that is more slow or shallow than expected. Very rarely these breathing difficulties can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers before. Follow the advice above and keep the

person who was wearing the patch moving and talking as much as possible.

- Sudden swelling of the face or throat, severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction.
- Fits (seizures) or loss of consciousness.

The following side effects have also been reported:

Very common

- Nausea, vomiting, constipation
- Feeling sleepy
- Feeling dizzy
- Headache

Common

- Allergic reaction
- Loss of appetite
- Difficulty sleeping
- Depression
- Feeling anxious or confused
- Seeing, feeling, hearing or smelling things that are not there
- Muscle tremors or spasms
- Tingling or numbness of the hands or feet
- Spinning sensation
- Fast or irregular heartbeat
- High blood pressure
- Shortness of breath
- Diarrhoea
- Dry mouth
- Stomach pain or indigestion
- Excessive sweating
- Itching, skin rash or redness of the skin
- Being unable to pass urine or empty bladder completely
- Unusual tiredness or weakness
- Feeling cold
- Swollen hands, ankles or feet

Uncommon

- Feeling agitated or disoriented
- Feeling extremely happy
- Loss of memory
- Blurred vision
- Slow heartbeat or low blood pressure
- Blue colour to the skin caused by low oxygen in the blood
- Loss of contractions of the gut
- Difficulty swallowing
- Itchy skin rash, allergic reaction or other skin disorders where the patch is placed
- Flu-like illness
- Feeling of body temperature change
- Fever
- Muscle twitching
- Difficulty getting and keeping an erection or problems having sex

Rare

- Constricted pupils
- Stopping breathing from time to time while sleeping

The following side effects have also been reported with unknown frequency:

- 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).
- You can become dependent on Fentanyl-HEXAL® MAT.

You may notice rashes, redness or slight itching of the skin at the site of the patch. This is usually mild and disappears after you have removed the patch. If it does not, or if the patch irritates your skin badly, tell your doctor.

Repeated use of the patches can make the medicine become less effective (you get used to it or you may become more sensitive to pain), or you can become dependent on it.

If you switch from a different painkiller to Fentanyl-HEXAL® MAT or if you suddenly stop using Fentanyl-HEXAL® MAT, you may notice withdrawal effects such as nausea, vomiting, diarrhoea, anxiety and shivering. Tell your doctor if you notice any of these symptoms. There have been reports of newborn infants experiencing withdrawal effects after their mothers have used this medicine for a long time during pregnancy.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed in this leaflet may also occur in some patients. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Fentanyl-HEXAL® MAT

Storage

Store in the original package.

Do not store above 30°C.

Keep this medicine out of reach and sight of children.

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

- Disposal

A used or unused patch accidentally sticking to another person, especially a child, may be fatal. Used patches should be folded firmly in half so that the sticky side of the patch sticks to itself. Then they should be safely discarded by putting them back into the original sachet and stored out of sight and reach of other people, especially children, until safely disposed. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Fentanyl-HEXAL® MAT 25 µg/h:

Milky-white rectangular transdermal patch with rounded corners on transparent release liner, and “fentanyl 25 µg/h” imprinted on the backing foil.

Fentanyl-HEXAL® MAT 50 µg/h:

Milky-white rectangular transdermal patch with rounded corners on transparent release liner, and “fentanyl 50 µg/h” imprinted on the backing foil.

- Ingredients

- Active ingredient

Fentanyl-HEXAL® MAT 25 µg/h:

One transdermal patch (10.5 cm² absorption area) contains 5.78 mg Fentanyl (equivalent to 25 µg/hour agent release).

Fentanyl-HEXAL® MAT 50 µg/h:

One transdermal patch (21 cm² absorption area) contains 11.56 mg Fentanyl (equivalent to 50 µg/hour agent release).

- Inactive ingredients

Release liner: Polyethylene terephthalate foil, siliconized

Self-adhesive matrix layer: Ester of kolophonium resin (hydrogenated), Poly-(2-ethylhexyl-acrylate, vinyl acetate), Soya-bean oil, refined

Backing film: Polyethylene terephthalate foil, Printing ink

- Packing

The transdermal patches are individually packed in sachets and are available in packs containing 5, 10 and 20 transdermal patches.

- MAL Number

Fentanyl-HEXAL® MAT 25 µg/h

MAL09072774AZ

Fentanyl-HEXAL® MAT 50 µg/h

MAL09072775AZ

Manufacturer

HEXAL® AG

Industriestraße 25, D-83607 Holzkirchen, Germany.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.

No. 5 & 9, Jalan Udang Harimau 2,

Medan Niaga Kepong,

51200 Kuala Lumpur, Malaysia.

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