

This medicine requires a doctor's prescription

## Fentadol 12, Fentadol 25, Fentadol 50, Fentadol 75, Fentadol 100

### Transdermal patches

Each Fentadol 12 patch contains 2.1 mg fentanyl and releases 12.5 mcg/hour.

Each Fentadol 25 patch contains 4.2 mg fentanyl and releases 25 mcg/hour.

Each Fentadol 50 patch contains 8.4 mg fentanyl and releases 50 mcg/hour.

Each Fentadol 75 patch contains 12.6 mg fentanyl and releases 75 mcg/hour.

Each Fentadol 100 patch contains 16.8 mg fentanyl and releases 100 mcg/hour.

Inactive ingredients / see section 6 of this leaflet.

- The patches contain a strong painkiller (opioid).
- Ensure that the old patch is removed before applying a new patch.
- Do not cut the patches.
- Do not expose the patches to a heat source (such as hot water bottles).
- If you develop a fever tell your doctor immediately.
- Follow the usage and dosage instructions carefully and change the patch every 3 days (72 hours).
- If your breathing becomes shallow and weak, remove the patch and seek medical attention immediately.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may want to read it again.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

**Opioid medicines may cause addiction, especially with prolonged use, and they have a potential for abuse and overdose. The reaction to overdose can be slower breathing, and even death.**

**Make sure you know the name of your medication, how much and how often to take it, the duration of treatment, and its potential risks and side effects.**

**Further information regarding the risk of dependence and addiction can be found at:**

[https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Risk/DocLib/Opioids\\_en.pdf](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Risk/DocLib/Opioids_en.pdf)

**Taking this medicine with benzodiazepines, other central nervous system depressants (including drugs) or alcohol, may cause a heavy sleepy feeling, breathing difficulties (respiratory depression), coma, and death.**

In addition to this leaflet, the medicines Fentadol 12, 25, 50, 75, 100 also have a patient information sheet. The information sheet contains important safety information that you need to know before you start and during treatment with Fentadol 12, 25, 50, 75, 100 and you should follow it. Carefully read the patient information sheet and patient leaflet before using these medicines. Keep the information sheet in case you need to read it again.

### 1. What is the medicine intended for?

The medicine is intended for relief of strong chronic pain requiring treatment with opioids. Fentadol is indicated for patients who are already using opioid treatment.

**Therapeutic group:** opioid analgesic.

### 2. Before using the medicine

#### Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for the list of inactive ingredients - see section 6).
- You have pain which lasts only for a short period (acute pain), such as sudden pain or pain after surgery.
- You have difficulty breathing, including slow or shallow breathing (respiratory depression).
- You are taking medicines belonging to the monoamine oxidase inhibitor group (MAOIs) (for instance for treatment of depression), or if you have taken such a medicine within the last two weeks. See also 'Interactions with other medicines' below.
- Do not use this medicine if you are breastfeeding - see 'Pregnancy and breastfeeding', below.
- Do not use in children under 2 years of age - see 'Use in Children', below.

If you are unsure whether any of the above conditions apply to you, consult your doctor.

#### Special warnings regarding the use of this medicine

- Fentadol patches can have life-threatening side effects in people who are not already using prescribed opioid medicines regularly.
- Fentadol patches, including used patches, could be life-threatening to children. Bear in mind that a patch (new or used) sticks to the child's skin and if a patch (new or used) sticks to the child's skin or the child puts it in their mouth, the result may be fatal.
- Even a used patch still contains some medicine and can harm children and even be life-threatening.
- Store the medicine in a safe and secure place, where other people will have no access to it - see section 5 for more information.

#### Patch sticking to another person:

The patch should be used only on the skin of the patient for whom it was prescribed. There have been reports of patches accidentally sticking to another person (e.g., a family member) who was in close physical contact or shared the same bed as the patient wearing the patch. A patch accidentally sticking to another person (especially a child) can cause serious side effects (as a result of absorption of the active ingredient in their body), such as difficulty breathing with slow and shallow breathing, which may be fatal. If the patch sticks to the skin of another person, remove the patch immediately and seek medical attention.

#### Before (and during) treatment with Fentadol tell your doctor if the following conditions apply to you.

##### Your doctor may monitor your condition more closely:

- You suffer or have suffered in the past from lung or breathing problems.
- You suffer or have suffered in the past from heart, liver or kidney problems or from low blood pressure or low blood volume.
- You have ever had a brain tumor.
- You have ever suffered from persistent headaches or a head injury.
- You suffer from increased intracranial pressure, coma, or impaired consciousness.
- You are elderly, very thin or infirm, since you may be more sensitive to the effects of the medicine.
- You have myasthenia gravis (a condition in which the muscles become weak and tend to tire easily).
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ('addiction').
- You smoke.
- You suffer or have suffered in the past from mood problems (depression, anxiety, personality disorder), or have suffered in the past from other mental problems that were treated by a psychiatrist.
- You suffer from problems in the digestive system (such as intestinal obstruction, chronic constipation).

If you are unsure whether any of these conditions apply to you, consult your doctor.

#### During the treatment with Fentadol patches, tell your doctor if you have breathing problems while sleeping.

Opioids like Fentadol can cause breathing problems when sleeping, such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxemia (low oxygen level in the blood). Tell your doctor if you, or someone in your surroundings, notice the following symptoms: breathing pauses during sleep, waking up because of shortness of breath, difficulty staying asleep, increased daytime drowsiness. In this case, your doctor may recommend changing your dosage.

#### During treatment with Fentadol patches, tell your doctor if you notice a change in your pain, for instance: pain relief is no longer obtained, an increase in pain, a change in how you feel the pain (pain in another part of your body), you feel pain on touch (that is not expected to hurt). Do not change the dose yourself. Your doctor may change your dose or your treatment.

#### Side effects with Fentadol requiring special attention

Using Fentadol may cause unusual sleepiness and breathing problems, such as slow, shallower breathing. Very rarely, these breathing problems may be life-threatening and even fatal, especially in people who have not used strong opioid pain-killers (like fentanyl or morphine) in the past. If the patient using the Fentadol patch becomes unusually sleepy and their breathing becomes slow and shallow (or if someone in their surroundings notices this), act as follows:

- Remove the patch.
- Proceed immediately to a doctor or a hospital to receive immediate medical attention.
- Keep the person moving and talking as much as possible.

These side effects can continue also for some time after removal of the patch.

If you develop a fever while using Fentadol, tell your doctor immediately. This situation may cause absorption of larger amounts of the active ingredient via the skin into your body, to the point of a life-threatening overdose. Your doctor may adjust your medicine dosage as necessary.

The medicine may cause constipation. Consult your doctor or pharmacist on how to prevent constipation or relieve constipation.

Long-term use of the patches may make the medicine less effective (you get used to it, or you may become more sensitive to pain), or you may become dependent on it. Do not change the dosage yourself. Increasing the dosage may help reduce the pain for a while, but it may also be harmful. If you feel that the medicine is becoming less effective, refer to your doctor. The doctor will decide whether it is better to increase your dose or to gradually decrease the use of the patches. In addition, if you are concerned that you are developing dependence on the medicine, consult your doctor.

See section 4 for the complete list of side effects.

#### Additional warnings:

- Fentadol patches contain fentanyl, an opioid substance, and have the potential for abuse.
- During use, do not expose the patch to a direct heat source such as heating pads, electric blankets, hot-water bottles, heated water beds, heat or tanning lamps. Do not sunbathe, have long hot baths, or stay in saunas or Jacuzzis baths. These situations may cause the release of greater than desirable quantities of the active ingredient and its absorption into the body.
- Consult your doctor whether you can engage in sports activity while using the patch.
- Do not bandage the patch application site with an elastic bandage or a tight bandage.

#### Withdrawal symptoms when stopping treatment with the patches:

Do not stop using the patches suddenly since there may be withdrawal symptoms, such as restlessness, sleeping difficulties, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increase in blood pressure, nausea, vomiting, diarrhoea, loss of appetite, shaking, chills, sweating. If you want to stop using the medicine, consult your doctor first; so that they will guide you how to do it. Your doctor will usually recommend that you gradually decrease the dosage in order to reduce the withdrawal symptoms to a minimum. See also section 3 under 'If you stop using the medicine'.

**Make sure to use the Fentadol patches appropriately and to dispose of them properly (see section 5).**

If a child or any other person accidentally swallows the patch, refer to a doctor immediately or proceed to a hospital emergency room.

Periodically check (by looking or touching) the area where the patch has been applied, to ensure that it is properly affixed, is not loose, and has not fallen off. If the patch is not attached properly, attach it to the skin with an adhesive bandage (around the patch).

Do not remove the patch and try to apply it in another place!

#### Use in Children:

- This medicine is usually not intended for babies and children, unless instructed by a specialist to use it, and it is not intended for use in children under the age of 2 years.
- Observe the child very closely for 48 hours after application of the first patch and also after each increase in dosage.

#### Tests and follow up:

During long-term treatment, you need to undergo periodic evaluations to assess the ongoing need for the medicine.

#### Drug interactions:

If you are taking or have recently taken any other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.

Also tell your doctor or pharmacist that you are using Fentadol whenever you purchase another medicine. Your doctor will know which medicines are safe to use together with Fentadol. You may need to be closely monitored when taking Fentadol concomitantly with other medicines or if you stop taking them, as they may affect the strength of the patch your doctor will prescribe for you. Especially inform your doctor or pharmacist if you are taking the following medicines (note that the list below is a list of the active ingredients in these medicines. If you are not sure whether you are using any of these medicines, please consult your doctor or pharmacist):

- Other painkillers, such as other opioid painkillers (such as buprenorphine, nalbuphine or pentazocine) and certain painkillers for nerve pain (gabapentin and pregabalin).
- Sleep inducing medicines (such as temazepam, zaleplon, zolpidem, brotizolam).
- Medicines for calming/tranquillizers (such as alprazolam, clonazepam, diazepam, hydroxyzine, lorazepam) and medicines for treating mental problems (antipsychotics such as aripiprazole, haloperidol, olanzapine, risperidone, or phenothiazines).
- Muscle relaxants (such as cyclobenzaprine, diazepam).
- Anesthetics and medicines for general anesthesia.
- Certain medicines from the SSRIs or SNRIs group for the treatment of depression (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, and venlafaxine). See 'Fentadol and antidepressants' below.

Medicines of the monoamine oxidase inhibitor group (MAOIs) used for instance for treatment of depression or Parkinson's disease (such as isocarboxazid, phenelzine, selegiline, tranlylpropramine). Do not use Fentadol if you are currently taking, or have taken within the last two weeks, medicines from the MAOIs group. See 'Fentadol and antidepressants' below.

Some anti-infectives, especially ones that cause sleepiness (such as chloramphenicol, clemastine, cyproheptadine, diphenhydramine, hydroxyzine).

Some antibiotics for treatment of infections (such as erythromycin, clarithromycin).

Medicines for treatment of fungal infection (such as itraconazole, ketoconazole, fluconazole, voriconazole).

Medicines for treatment of HIV/AIDS infection (such as ritonavir).

Medicines for treatment of an irregular heartbeat (such as amiodarone, diltiazem, verapamil).

Medicines for treatment of tuberculosis (such as rifampicin).

Some medicines used to treat epilepsy (such as carbamazepine, phenobarbital, phenytoin).

Some medicines for treatment of nausea or motion sickness (such as phenothiazines).

Some medicines for treatment of heartburn or ulcers (such as cimetidine).

Some medicines for treatment of chest pain (angina pectoris) or high blood pressure (such as nicardipine).

Some medicines for treatment of blood cancer (such as idelalisib).

#### Fentadol and antidepressants:

The risk of side effects increases if you are taking certain antidepressants (from the SSRIs, SNRIs, or MAOIs group) or other serotonergic medicines. These medicines may create a drug interaction with Fentadol and cause you to experience symptoms such as changes in your mental condition such as agitation, seeing, feeling, hearing, or smelling things that are not there (hallucinations), coma; changes in blood pressure, tachycardia (rapid heartbeat), fever, overactive reflexes, lack of coordination, muscle stiffness; digestive system symptoms such as nausea, vomiting, diarrhoea. These symptoms could be signs of serotonin syndrome that could be life-threatening. Nevertheless, if these medicines are taken concomitantly, your doctor may want to closely monitor such side effects, in particular at the start of treatment or at dosage changes. Contact your doctor whenever you experience such symptoms.

#### Concomitant use with central nervous system depressants, including alcohol and some opioid/narcotic medicines

##### Using Fentadol concomitantly with sedatives (medicines that cause sedation, calming or induce sleep), such as benzodiazepines or similar medicines, increases the risk of drowsiness (including profound drowsiness), low blood pressure, breathing difficulties (respiratory depression) and coma, and might be life-threatening and fatal. Therefore, concomitant use should be considered only if no other treatment options are available. If your doctor has decided to prescribe Fentadol for you together with sedatives, the doctor may limit the dosage and you duration of the concomitant treatment. Tell your doctor about any sedative medicines you are taking, and follow your doctor's dosage recommendations strictly.

It is advisable to ask friends and relatives to look out for the above-mentioned symptoms. Refer to your doctor if you feel these symptoms.

#### Use of the medicine and alcohol consumption:

Do not drink alcohol during the treatment period with this medicine.

#### Surgery:

If you are about to undergo a medical procedure and receive anaesthetics, tell your doctor/dentist in advance that you are using Fentadol.

#### Pregnancy and breastfeeding:

If you are pregnant, think you are pregnant, are planning a pregnancy or if you are breastfeeding, consult your doctor before using this medicine.

Do not use the patches during pregnancy, unless your doctor expressly instructs you to do so.

Do not use the patches during childbirth. The medicine may affect the newborn baby's breathing.

Prolonged use of Fentadol patches during pregnancy can cause withdrawal symptoms in the newborn baby that could be life-threatening if not recognized and treated in time. Symptoms may include high-pitched crying, jitteriness, fits/seizures, feeding difficulties, diarrhoea. Refer to your doctor immediately if any of these symptoms appear in your baby.

Do not breastfeed if you are using Fentadol patches, since the medicine passes into the breastmilk and may cause sedation/severe drowsiness, respiratory depression in the breastfeeding baby. Do not breastfeed for at least 3 days (72 hours) after removing the patch.

#### Driving and use of machinery:

The use of this medicine can impair your ability to drive and operate machinery or tools as you may feel sleepy or dizzy. If you feel these effects, do not drive or operate machinery or tools. Do not drive or use machinery while using this medicine until you know how it affects you. Consult your doctor if you are not sure whether driving is safe for you while using this medicine.

#### 3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

##### The standard dosage is usually:

**The dosage will be determined by your doctor only, taking into consideration the intensity of the pain, your general condition, your age and the pain treatment you are receiving, including other opioid medicines you have used. Do not change the dosage without consulting your doctor.**

Each patch is intended for 3 days (72 hours) only. Replace the patch every 72 hours (at the same time of day), unless instructed otherwise by your doctor.

Due to the slow absorption of the medicine into the skin, the effect may not be felt immediately with the application of the first patch. Sometimes, the maximum effect is felt only after 24 hours from application of the first patch. Therefore, you may need additional painkillers on the first day of treatment.

##### Do not exceed the recommended dose.

If your pain returns, refer to your doctor, who can prescribe additional painkillers and change the dosage of the patches. The doctor may instruct you to use a number of patches simultaneously.

Your doctor may prescribe you additional painkillers for relief in case of breakthrough pain.

Follow your doctor's instructions precisely.

Stopping prolonged treatment with Fentadol patches suddenly can cause the appearance of withdrawal symptoms (see section 3 under 'If you stop using the medicine'). Therefore, do not stop treatment on your own initiative, without being instructed to do so by your doctor. If your doctor decides that you should stop the treatment with Fentadol patches, follow your doctor's instructions closely.

Withdrawal symptoms may also occur when switching from Fentadol patches to other painkillers and vice versa.

##### Attention:

Do not swallow! This medicine is intended for external use only.

Do not put the patch in your mouth, do not chew and/or swallow the patch.

Do not cut the patch or separate its parts.

Do not use the patch if it is cut, damaged or has become redness, burns or to skin that has undergone radiation therapy.

Do not stop using unless explicitly instructed to do so by the doctor. The doctor will instruct you how to stop using the patches gradually.

Each patch is intended for a single use.

##### How to use the patch:

###### Choosing the site for application

Fentadol is intended for use on the upper body or upper arm, on clean, dry skin without hair (or with little hair), in an area without cuts, scars, small sores, redness, burns or on skin that has undergone radiation therapy. **In young children** (and in patients with limited mental/cognitive capabilities) - carefully select an application site (see below) to prevent them from possibly removing the patch or putting it in their mouth. Carefully check that the patch sticks well (if necessary, use other means to ensure this). As far as possible, check that the patch is not loose and that it actually remains affixed to the skin.

###### Children

In young children, apply the patch to the upper part of the back, to ensure that they cannot remove it on their own. The patch will be applied, removed and discarded by medical staff, a doctor or an adult attendant, and never by the child himself.

In the following cases, closely supervise and monitor children for the first 48 hours:

- After applying a patch for the first time.
- After applying a patch with a higher dosage than the previous one.

###### Applying the patch

If the skin is hairy, cut the hair with scissors. Do not shave, so as not to irritate the skin. Rinse the skin (if necessary) with water only. 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. Apply the patch immediately after opening the patch sachet. To remove the patch from the sachet, fold along the red line and tear open the sachet at the notch (Figure 1). Open the sachet in the direction of the arrow, pulling slowly and constantly. Gently tear off the edge of the sachet completely, and carefully take the patch out. Carefully peel off half of the protective patch cover, using the diagonal perforated line in the center of the patch, **without touching the sticky surface** (Figure 2). Place the patch on the selected skin area and press it firmly onto the skin, while peeling away the other half of the protective cover. **Avoid touching the sticky surface.** Press for 30 seconds with the palm of your hand, make sure it sticks well to the skin (Figure 3). Make sure the edges stick well. Afterwards, wash your hands with clean water (do not use soap or other detergents).

- Do not expose the area with the patch to an external heat source (see 'Special warnings').

- Since the transdermal patch has a waterproof backing, you can shower with the patch.

- Do not rub or soap the area with the patch.



Figure 1



Figure 2



Figure 3

###### Changing the patch

Change the patch after 3 days (72 hours), or as per the doctor's instructions. If traces remain on the skin after removing the patch, wash them off with plenty of soap and water. Do not use alcohol or any other liquid.

Fold the used patch in half, with the sticky side inward. Discard immediately in a safe manner.

Apply a new patch as described above, but on another area of the skin. A patch can only be applied on the same area after at least 7 days have elapsed.

Do not keep patches at home after treatment with this medicine has ended. If you have extra patches that you do not need, remove them from the aluminum sachet, remove the protective cover, fold the patch in half (with the sticky side facing inward) and discard immediately in a safe manner. If the patch becomes loose or falls off on its own, discard it in a safe manner and apply a new patch as soon as you notice.

The new patch should be applied on a different area of the skin to avoid skin irritation or other problems. **Inform your doctor if the patch falls off.**

###### If the patch accidentally sticks to another person (see also section 2 above)

Only apply a patch on the skin of the person for whom the medicine was prescribed.

Make sure that the patch does not fall off or accidentally stick to a child or to your partner, especially while in close physical contact or sharing the same bed.

If a patch accidentally sticks to another person or child, remove it immediately and proceed to a hospital emergency room and bring the package of the medicine.

If a child or any other person accidentally swallows the patch, refer to a doctor immediately or proceed to a hospital emergency room.

###### If your pain gets worse:

If your pain suddenly gets worse, you should check whether your pain is still sticking well or whether it has fallen off. See also 'If the patch falls off below.'

If your pain gets worse over time during the treatment period with the patches, your doctor may prescribe you a higher dose of patches and/or an additional painkiller.

If increasing the dose does not help, your doctor may decide to stop the use of the patches. See also 'If you stop using the medicine'.

###### If you have accidentally used a higher dosage

If you accidentally used more patches than recommended by your doctor or a wrong strength, remove the patch and proceed immediately to a doctor or hospital emergency room and bring the medicine package with you. Signs of overdose include breathing difficulties, shallow breathing, respiratory depression (the most serious reaction); tiredness, extreme sleepiness, inability to think clearly, walk or talk normally; feeling faint, dizzy or confused. If the patient suffers from breathing difficulties, remove the patch and proceed immediately to a doctor or hospital. Keep the person moving and talking as much as possible. See also section 2 under 'Patch sticking to another person'.

###### If you forget to change the Fentadol patch:

Change the patch as soon as you remember and write down the date and time. Change the patch again after 3 days (72 hours) as usual.

If you are very late with changing the patch, contact your doctor, since you may need additional painkillers. Do not use more patches than instructed by the doctor.

###### If the patch falls off:

If a patch falls off before the time it needs to be changed, apply a new patch straight away and write down the date and time. Apply the patch to another area of skin (on the upper part of the arm or on the upper part of your body), and in the case of a child - on the upper back.

Leave the new patch on for another 3 days (72 hours). Inform your doctor, and in any case act according to his instructions.

If your patch keeps falling off, consult a doctor, pharmacist or nurse.

Even if the treatment as recommended by your doctor. Adhere if your health improves, do not stop the treatment with the medicine without consulting your doctor.

###### If you stop using the medicine

Do not stop using Fentadol patches suddenly. If you want to stop using the medicine, first consult your doctor who will guide you how to do it. Your doctor will usually recommend that you gradually decrease the dosage in order to reduce the withdrawal symptoms to a minimum.

Withdrawal symptoms may include restlessness, sleeping difficulties, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increase in blood pressure, nausea, vomiting, diarrhoea, loss of appetite, shaking, chills, sweating, increased heart and/or breathing rate; weakness, yawning, muscle pain, abdominal cramps, tearing, runny nose, dilated pupils, hyperactivity (also of the muscles).

If you stopped using Fentadol patches, do not start using them again without consulting your doctor. You might need a different patch strength when you start using them again.

###### Do not take medicines in the dark! Check the label and the dose each time you use a medicine. Wear glasses if you use them.

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

#### 4. Side Effects

As with any medicine, the use of Fentadol may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

##### If you or someone in your surroundings notice one or more of the following symptoms in a person wearing the patch, remove the patch and proceed to a doctor or hospital immediately; urgent medical treatment may be required. The symptoms:

- Feeling unusually drowsy, breathing that is slower or shallower than usual (respiratory depression). Follow the above instructions and also keep the person who was wearing the patch moving and talking as much as possible. Very rarely, these breathing difficulties can be life-threatening and even fatal, especially in people who have not used strong opioid painkillers (such as fentanyl or morphine) in the past. These side effects are uncommon (may affect up to 1 in 100 people).
- Sudden swelling of the face or throat; severe irritation, reddening or blistering of the skin. These symptoms may be a sign of a severe allergic reaction (including anaphylactic shock, anaphylactoid reaction). The frequency of this side effect is unknown.
- Fits/seizures. These side effects are uncommon (may affect up to 1 in 100 people).
- Reduced level of consciousness or loss of consciousness. These side effects are uncommon (may affect up to 1 in 100 people).

See also section 2, under 'Side effects with Fentadol requiring special attention'.

##### Additional side effects:

Very common side effects - appear in more than 1 user out of 10

- nausea, vomiting, constipation
- drowsiness/sleepiness
- dizziness
- headache

Common side effects - appear in 1-10 users out of 100

- allergic reaction
- loss of appetite
- sleeping difficulties
- depression
- feeling of anxiousness or confusion
- seeing, feeling, hearing, or smelling things that are not there (hallucinations)
- muscle tremors or spasms
- unusual feelings in the skin, such as crawling or tingling
- spinning sensation (vertigo)
- heartbeat feels fast or irregular (palpitations, tachycardia)
- high blood pressure
- shortness of breath
- diarrhoea
- dry mouth
- abdominal pain (including in upper abdomen) or digestion difficulties
- excessive sweating
- itching, rash or redness of the skin
- being unable to pass urine or empty bladder completely (urinary retention)
- feeling very tired, weak or generally

appearing on the package/aluminum sachet. The expiry date refers to the last day of that month.

- Store below 30°C. Be sure that the patches are stored in the original aluminum sachet.

## 6. Additional information

- In addition to the active ingredient, this medicine also contains:

Acrylic vinyl acetate copolymer, polyethylene terephthalate foil siliconized, polyethylene terephthalate foil, printing ink.

- **What the medicine looks like and the contents of the package:**

A rectangular or square, uniform transdermal patch. Each patch is provided in an aluminum foil sachet. Each pack contains 5 patches.

Fentadol 12: fentanyl 12 µg/h is printed on the patch.

Fentadol 25: fentanyl 25 µg/h is printed on the patch.

Fentadol 50: fentanyl 50 µg/h is printed on the patch.

Fentadol 75: fentanyl 75 µg/h is printed on the patch.

Fentadol 100: fentanyl 100 µg/h is printed on the patch.

- License Holder and Importer's name and address: Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel.

- Revised in February 2023 according to MOH guidelines.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Fentadol 12: 154-83-34317

Fentadol 25: 154-84-34314

Fentadol 50: 154-85-34318

Fentadol 75: 154-86-34319

Fentadol 100: 154-87-34320

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