Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine requires a doctor's prescription

Fenta 12, Fenta 25, Fenta 50, Fenta 75, Fenta 100

Transdermal Patches

Active ingredient:

Each patch of Fenta 12 contains 2.063 mg Fentanyl and releases 12.5 mcg/hr.
Each patch of Fenta 25 contains 4.125 mg Fentanyl and releases 25 mcg/hr.
Each patch of Fenta 50 contains 8.25 mg Fentanyl and releases 50 mcg/hr.
Each patch of Fenta 75 contains 12.375 mg Fentanyl and releases 75 mcg/hr.
Each patch of Fenta 100 contains 16.5 mg Fentanyl and releases 100 mcg/hr.
For the list of the additional ingredients, see section 6.

- **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 dosage usage 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 the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

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

Medicines of the opioids group may cause addiction, especially with prolonged use, and they have a potential for misuse and overdose. A reaction to an overdose may be manifested by slow breathing and may even cause death.
Make sure you know the name of the medicine, the dosage that you take, how often you take it, the duration of treatment, potential side effects and risks.
Additional information regarding the risk of dependence and addiction can be found at the following link:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

Taking this medicine along with medicines from the benzodiazepines group, other medicines which depress the central nervous system (including drugs) or alcohol may cause a feeling of profound drowsiness, breathing difficulties (respiratory depression), coma and death.

1. What is the medicine intended for?

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

Therapeutic Group: Opioid painkiller

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (fentanyl) or to any of the other ingredients the patches contain (for the list of the other 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 took such a medicine within the last two weeks. See also 'Drug interactions' section below.
- Do not use this medicine if you are breastfeeding – see the section "Pregnancy and Breastfeeding" below.
- Do not use in children under 2 years of age – see the section "Use in Children" below.

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

Special warnings regarding the use of this medicine:

- Fenta patches can have life-threatening side effects in people who are not already using prescribed opioid medicines regularly.
- Fenta patches, including used patches, could be life-threatening to children. Bear in mindthat a patch (new or used) could be tempting to a child and if a patch (new or used) sticks to the child's skin or the child puts it in his 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 relative) who was in close physical contact, or sharing the same bed as the patient wearing the patch. A patch accidently sticking to another person (especially a child) can cause serious side effects (as a result of absorption of the active ingredient in his body), such as difficulty breathing with slow or 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 Fenta tell your doctor if the following conditions are relevant to you. Your doctor may monitor your condition more closely.

- You suffer or have suffered in the past from lung problems or breathing difficulties.
- You suffer or have suffered in the past from heart, liver or kidney problems or from low blood pressure or low blood volume.
- You ever had a brain tumor at some point.
- You 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 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 are relevant to you, consult your doctor.

During the treatment with Fenta patches, tell your doctor if you have breathing problems while sleeping. Opioids like Fenta can cause breathing problems when sleeping such as sleep apnea (breathing pauses during sleep) and sleep-related hypoxemia (low oxygen level in the blood). Tell your doctor if you, or someone in your surroundings, notices the following symptoms: breathing pauses during sleep, waking up because of shortness of breath, difficulties staying asleep, increased daytime drowsiness. In this case, the doctor may recommend changing the dosage.
During the treatment with Fenta patches, tell your doctor if you notice a change in the 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 the treatment.

Side effects with Fenta requiring special attention

- The use of Fenta, may cause you unusual **sleepiness** and breathing problems, such as slower and shallower breathing. Very rarely, these **breathing problems** 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. If the patient using the Fenta patch becomes unusually sleepy and his breathing becomes slow and shallow (or if someone in his 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 Fenta, 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. The doctor may adjust the 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 cause the medicine to be less effective for you (this situation may occur either because of getting used to it, or developing hypersensitivity to pain), or you may develop a dependency on the medicine. Do not change the dosage yourself. True, 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 the doctor. The doctor will decide whether it is better to increase the 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 the doctor.

See section 4 for the complete list of side effects.

Additional warnings:

- Fenta 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 Jacuzzi baths. These situations may cause the release of greater than desirable quantities of the active ingredient and its absorption into the body.
- Consult the doctor whether you can carry out 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, diarrhea, loss of appetite, shaking, shivering, sweating. If you want to stop using the medicine, consult with your doctor first; so that he will guide you how to do it. He will usually recommend you gradually decrease the dosage in order to reduce the withdrawal symptoms to a minimum. See also in section 3 "If you stop using the medicine".

- **Make sure to use the Fenta patches appropriately and to dispose them properly (see section 5).**
- If a child or any other person has accidentally swallowed the patch, proceed immediately to a doctor or a hospital emergency room.
- Periodically check (by sight or touch) the site where the patch has been applied, to verify that it is attached properly, 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 it). 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.
- Observe the child very closely for 48 hours after application of the first patch and also after each increase in dosage.

Drug interactions:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Also tell the doctor or pharmacist that you are using Fenta each time you purchase another medicine. The doctor will know which medicines are safe to use together with Fenta. You may need to be closely monitored when taking Fenta 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 the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Other painkillers, such as other opioid painkillers (including 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/tranquilizers (such as alprazolam, clonazepam, diazepam, hydroxyzine, or 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 SNRIs or SSRIs group for the treatment of depression (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, and venlafaxine), nefazodone. *See "Fenta 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, or tranylcypromine). Do not use Fenta if you are currently taking, or have taken within the last two weeks, medicines from the MAOIs group. *See "Fenta and antidepressants" below.*
- Some antihistamines, especially ones that cause sleepiness (such as chlorpheniramine, 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).

Fenta 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 Fenta and cause you to experience symptoms such as changes in your mental condition e.g. 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, diarrhea. These symptoms could be signs of Serotonin syndrome that could be life-threatening. Nevertheless, if these medicines are taken concomitantly, the doctor may want to closely monitor such side effects, in particular at the start of treatment or when the dose is changed. In any case that you experience these side effects, refer to your doctor.

Concomitant use with central nervous system depressants, including alcohol and some opioid/narcotic medicines
Using Fenta 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 the doctor has decided to prescribe Fenta for you together with sedatives, the doctor may limit the dosage and duration of the concomitant treatment. Inform the doctor of all the sedatives you are taking and strictly follow the doctor's dose recommendations.

Recommended to ask friends and relatives to pay attention to the above-mentioned symptoms. Refer to the doctor if you feel these symptoms.

Use of the medicine and alcohol consumption:
Do not drink alcohol during the treatment period with this medicine.

Surgeries:
If you are to undergo a medical procedure and receive anesthesia, tell your doctor/dentist in advance that you are using Fenta.

Pregnancy and breastfeeding:
If you are pregnant, think you are pregnant, are planning a pregnancy or if you are breastfeeding, consult the doctor before using the medicine.
- Do not use the patches during pregnancy, unless your doctor expressly instructed to do so.
- Do not use the patches during childbirth. The medicine may affect the newborn baby's breathing.
- Prolonged use of Fenta 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, diarrhea. Refer to the doctor immediately if any of these symptoms appear in the baby.

- Do not breastfeed if you are using Fenta 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 the doctor if you are not sure whether driving is safe for you while using this medicine.

Tests and follow-up:
During long-term treatment, you need to undergo periodic evaluations to assess the ongoing need for the medicine.

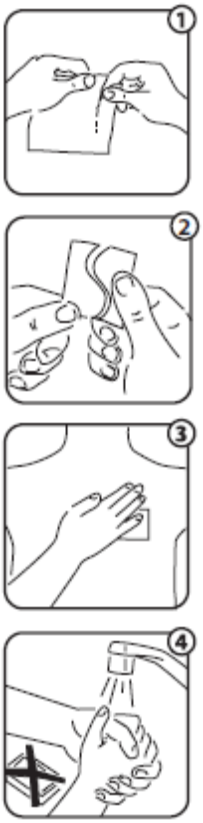
3. How to use this medicine?
Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The dosage, manner and length of treatment will be determined by the doctor only.
The standard dosage is usually:
The dosage will be determined by the 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 used. Do not change the dosage without consulting the 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 the 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 dosage.
If your pain returns, refer to the 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.
The doctor may prescribe for you additional painkillers for relief in case of breakthrough pain.
Follow the doctor’s instructions precisely.
Stopping prolonged treatment with Fenta patches suddenly, can cause the appearance of withdrawal symptoms (see in section “If you stop taking the medicine'”). Therefore, do not stop treatment on your own initiative, without being instructed so by the doctor. If your doctor decides to stop the treatment with Fenta patches, follow his instructions precisely.
Withdrawal symptoms may also occur when switching from Fenta 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 seems damaged.
Do not apply the patch to skin that has wounds, redness, burns or to skin that has undergone radiation.

Do not stop using Fenta 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 one-time use.

Manner of use:
Apply the Fenta patch immediately upon its removal from the aluminum sachet according to the following instructions:
Apply the patch to a clean hairless area of skin on the upper part of the arm or on the upper part of the body (chest or back). Choose a place without scars, cuts or irritation. Do not apply on joints (since they are in constant movement). In patients who are mentally/cognitively impaired and in children, the patch should preferably be applied to the upper back in order to reduce the risk that they will remove the patch and put it in their mouth.
Cut off excess hair from the skin with scissors only (do not shave so as not to injure the skin). Wash the skin (if necessary) in cold water only (without soap!). Dry the skin well and gently. Do not use soap, lotions, oils, creams, talc or alcohol before applying the patch to the skin. Do not apply the patch immediately after a hot shower or a hot bath. Wait until the skin dries and cools down completely.
Before applying a new patch, remove the previous patch. Open the aluminum sachet only right before applying the patch.
Recommended to keep the original sachet so you can dispose in it the used patch.
Make sure that the patch will be covered by loose and not tight-fitting clothing, and also not under a tight or elastic bandage.
<u>Directions for use (see illustrations):</u>

1. Gently tear the edge of the aluminum sachet and remove the patch. Be careful not to damage the patch when opening the sachet.
2. Fold the patch along the “S” mark, until the protective cover is raised. Remove half of the protective cover, stick the patch onto the skin (without touching the sticky part) and remove the second half of the protective cover.
3. Press the patch to the skin for 30 seconds using your palm. Make sure that the whole patch closely adheres to the skin (particularly the patch edges).
4. After completing the application wash your hands with water only (without soap).
5. Note the date and time of the patch application on the designated place on the package (this will help you know when the 3 days of treatment have passed).
6. Leave the patch adhered to the skin for 3 days (72 hours). While the patch is adhered to the skin, you may bathe (shower or bath) and



even swim with the patch. Do not scrub or soap the patch and the application site.
7. After 3 days (72 hours), remove the patch by peeling it off the skin.
8. Fold the used patch in half, with the sticky side inward, and dispose of it immediately in a safe way. See section 5.
9. Apply the next patch to another place on the skin. Do not apply a new patch to the same area as the previous patch. You can apply the patch to the same area again, only after a few days.

If your pain gets worse

- If your pain suddenly gets worse, you should check whether your patch 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'.

Do not keep remaining patches at home after the treatment has ended. Consult the pharmacist how to dispose of the patches. See also section 5.
If the patch fell off by itself, dispose of it and apply a new patch as soon as you notice. Apply the new patch to a different skin site. Write down the date and time. Inform the doctor that the patch fell off. The new patch should be replaced after 3 days (72 hours) or as directed by your doctor.

If you have accidentally used a higher dosage: if you accidentally used more patches than recommended by the doctor or a wrong strength, remove the patch and proceed immediately to a doctor or hospital emergency room and bring the package of the medicine. Signs of overdose include breathing difficulties or 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 “Patch sticking to another person”.

If you forgot to change the Fenta 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 side 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 the doctor, and either way, act according to his instructions.
- If your patch keeps falling off, consult a doctor, pharmacist or nurse.

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

If you stop using the medicine:

- Do not stop using the Fenta patches suddenly. If you want to stop using the medicine, first consult the 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, diarrhea, loss of appetite, shaking, shivering, sweating, increased heart and/or

breathing rate; weakness, yawning, muscle pains, abdominal cramps, tearing, runny nose, dilated pupils, hyperactivity (also of the muscles).
- If you stopped using Fenta patches, do not start using them again without consulting the doctor first. You might need a different patch strength when you start using them again.

Do not take or use medicines in the dark! Check the label and the dose each time you use a medicine. Wear glasses if you need 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 Fenta 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 more slow or shallow 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, anaphylactic 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 subsection “Side effects with Fenta requiring special attention” in section 2.

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 tingling or crawling; spinning sensation (vertigo); heartbeat feels fast or irregular (palpitations, tachycardia); high blood pressure; shortness of breath; diarrhea; 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 feel unwell; feeling cold; swollen hands, feet or ankles (peripheral edema).

Uncommon side effects (appear in 1-10 users out of 1,000):
Feeling of agitation or disorientation; feeling of extreme happiness (euphoria); decrease in feeling or sensitivity (especially in the skin); loss of memory, blurred vision; slow heartbeat (bradycardia), low blood pressure; blue color to the skin caused by low oxygen level in the blood (cyanosis); absence of contractions of the gut (intestinal blockage); itchy skin rash (eczema), skin inflammation, allergic reaction or other skin problems where the patch is applied; flulike illness; feeling of body temperature change; fever; muscle twitching; difficulty getting and keeping an erection (impotence) or problems having sexual intercourse; withdrawal symptoms, difficulty or severe difficulty breathing.

Rare side effects (appear in 1-10 users out of 10,000):
Constricted pupils; stopping breathing from time to time (apnea); partial intestinal obstruction, hypoventilation (too little air entering the lungs).
Side effects of unknown frequency (effects whose frequency has not yet been determined):
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 disturbances, nightmares); very slow breathing rate.

Additional remarks:

- You may notice a rash, redness or slight itching of the skin at the patch application site. These effects are usually mild and disappear after removing the patch. If not, or if the patch causes severe skin irritation, refer to the doctor.
- Repeated use of the patches may cause the medicine to become less effective (due to getting used to the medicine/tolerance or development of hypersensitivity to pain); in addition reusing the patches may cause development of dependency on the medicine.
- If your medicine is switched from a different painkiller to Fenta patches, or if you suddenly stop using Fenta patches, you may experience withdrawal symptoms such as nausea, vomiting, diarrhea, anxiety or shivering, shaking. Tell your doctor if you feel these symptoms. See also "*If you stop using the medicine*" in section 3.
- There have also been reports of newborn babies experiencing withdrawal symptoms when their mothers used Fenta patches for a long time during pregnancy. See also section 2 – "Pregnancy and breastfeeding".

If a side effect appears, if any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

Side Effects in Children:
The side effects are similar to those of adults.
The most common side effects (appear in more than 1 user out of 10), reported in clinical trials in children (up to age 18):
Headache, nausea or vomiting, constipation, diarrhea, itching.

Parents need to inform the attending doctor about any side effect, and on any other medicine given to the child.

5. How to store the medicine?

Avoid poisoning! This medicine in particular (used and/or new patches) and any other medicine must be stored in a closed place out of the reach and sight of children and/or babies, to avoid poisoning, which might cause life-threatening harm.
Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Patches after their expiry date or that are no longer needed should be returned to the pharmacy.
- Storage conditions: store below 25°C in the original sachet.
- Fenta patches should be kept in a safe and secure place to which other people have no access. Serious harm that might be fatal could be caused to people using this medicine accidentally or intentionally, if it is not prescribed for them.
- How to dispose of used patches or patches you have no more need for them: a new or used patch that accidentally stuck to a person who is not the patient, especially a child, can be fatal (even a used patch still contains some of the medicine). Fold the used patch in half so that the

sticky side of the patch is inside and return it to the original sachet. Store the sachet out of reach and sight of other people, especially children, until they are safely disposed of. Ask the pharmacist how to dispose of medicines you are no longer using.

6. Additional information

In addition to the active ingredient, the patches also contain the following inactive ingredient:

Polyacrylate adhesive layer (Polybutyltitanate & Duro-Tak)
Backing layer: Polypropylene foil
Release liner: Polyethylene terephthalate foil siliconized
Blue printing ink

What does the medicine look like and what does the package contain?

In each package there are 5 transparent transdermal patches. Each patch is packed in a separate aluminum sachet.

Fenta 12: square patches with a size of 3.75 cm^2. On the back of the patch “fentanyl 12 µg/h“ is imprinted in blue ink
Fenta 25: square patches with a size of 7.5 cm^2. On the back of the patch “fentanyl 25 µg/h“ is imprinted in blue ink
Fenta 50: square patches with a size of 15 cm^2. On the back of the patch “fentanyl 50 µg/h“ is imprinted in blue ink
Fenta 75: square patches with a size of 22.5 cm^2. On the back of the patch “fentanyl 75 µg/h“ is imprinted in blue ink
Fenta 100: square patches with a size of 30 cm^2. On the back of the patch “fentanyl 100 µg/h“ is imprinted in blue ink

Manufacturer: tesa Labtec, GmbH, Langenfeld, Germany.
Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Fenta 12: 1373931638, Fenta 25: 1363731287, Fenta 50: 1363831288, Fenta 75: 1363931289, Fenta 100: 1364031290.

Revised in December 2022 in accordance with the Ministry of Health guidelines.

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