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## Duragesic Patch

Pronunciation: FEN-ta-nil

Generic Name: [Fentanyl](#)

Brand Name: Duragesic

Duragesic Patch should be used only for long-term or chronic pain requiring continuous, around-the-clock narcotic pain relief that is not helped by other less powerful pain medicines or less frequent dosing. Do not use Duragesic Patch if you have not already been taking other prescription narcotic pain medicines (eg, morphine, codeine) on a regular schedule. Do not use Duragesic Patch for short-term pain, mild pain, pain that occurs after surgery, or pain that does not require medicine on a regular schedule. Because serious, sometimes life-threatening, breathing problems can occur (especially in patients who have not been given narcotic medicines in the past), seek immediate medical attention in the unlikely event that very slow, shallow breathing occurs.

Tell your doctor if you are also taking ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone, amiodarone, amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, or verapamil. Tell your doctor if you eat grapefruit or drink grapefruit juice. The risk of Duragesic Patch's side effects may be increased.

Do not give Duragesic Patch to children younger than 2 years old or children who have not previously received narcotic pain medicines.

When used for long periods of time or at high doses, some people develop a need to continue taking Duragesic Patch. This is known as DEPENDENCE or addiction. Do not use more of Duragesic Patch than prescribed by your doctor. Tell your doctor if you or a family member has a history of mental or mood problems (eg, depression) or addiction to alcohol or other substances.

Do not apply the patch to skin that is broken or damaged. Do not cut the patch. Using a cut or damaged patch may lead to a rapid release of medicine and serious, even fatal, side effects. Do not expose the patch to direct sources of heat, such as heating pads, electric blankets, heat lamps, saunas, hot tubs, or heated waterbeds. Avoid sunbathing; long, hot baths; or other sources of heat to the body. Tell your doctor if you develop a fever. The heat may cause more medicine to be released into your skin and could cause serious, even fatal, side effects.

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**Rx** Availability  
Prescription only

**C** Pregnancy Category  
Risk cannot be ruled out

**2** CSA Schedule  
High potential for abuse



This document is intended to supplement, not substitute the expertise and judgement of your physician, pharmacist or other healthcare professional. It should not be construed to indicate that the use of the drug is safe, appropriate or effective for you. Consult your healthcare professional before taking this drug.

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## Duragesic Patch is used for:

Managing moderate to severe chronic pain in patients who need continuous, around-the-clock narcotic (opioid) pain relief and whose pain cannot be managed by less powerful pain medicines.

Duragesic Patch is a narcotic (opioid) analgesic. It works by dulling the pain center in the brain.

## Do NOT use Duragesic Patch if:

- you are allergic to any ingredient in Duragesic Patch, to any other fentanyl-related medicine (eg, sufentanil), or to adhesives like those used on bandages
- you have not already been taking other prescription narcotic pain medicines (eg, morphine, codeine) on a regular schedule
- you have mild or short-term pain, including pain from injuries and surgery, that can be managed by less powerful medicines
- you do not need to take pain medicine on a regular basis
- you have trouble breathing, asthma, or bowel problems (paralytic ileus)
- you drink alcohol, or you are taking sodium oxybate (GHB) or any other sedative that causes drowsiness and decreases breathing rate
- you are taking or have taken a monoamine oxidase inhibitor (MAOI) (eg, phenelzine) within the past 14 days

Contact your doctor or health care provider right away if any of these apply to you.

## Before using Duragesic Patch:

Some medical conditions may interact with Duragesic Patch. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you or a family member has a history of mental or mood problems (eg, depression), alcohol or substance abuse, narcotic dependence, or suicidal thoughts or actions
- if you have asthma or other breathing problems (eg, chronic obstructive pulmonary disease [COPD]), heart problems (eg, slow or abnormal heartbeat, cor pulmonale), liver or kidney problems, pancreatitis, stomach pain, bowel problems (eg, constipation, inflammatory bowel disease), severe bloody diarrhea (eg, pseudomembranous colitis), prostate problems, fever, thyroid problems, urinary problems or blockage, or you have had recent surgery
- if you have severe drowsiness, recent head or brain injury, brain tumor, increased pressure in the brain, or a history of fainting or loss of consciousness
- if you drink alcohol or you are in poor health

Some MEDICINES MAY INTERACT with Duragesic Patch. Tell your health care provider if you are taking any other medicines, especially any of the following:

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- Alcohol, amiodarone, aprepitant, azole antifungals (eg, ketoconazole, voriconazole), barbiturate anesthetics (eg, thiopental), benzodiazepines (eg, alprazolam), calcium channel blockers (eg, diltiazem, verapamil), cimetidine, HIV protease inhibitors (eg, ritonavir), macrolides (eg, clarithromycin), MAOIs (eg, phenelzine), nefazodone, or sodium oxybate (GHB) because side effects, such as difficult or shallow breathing, seizures, and severe disorientation, may occur
- Naltrexone and rifamycins (eg, rifampin) because it may decrease Duragesic Patch's effectiveness
- Barbiturate anesthetics (eg, thiopental), benzodiazepines (eg, alprazolam), sibutramine, selective serotonin reuptake inhibitors (SSRIs) (eg, fluoxetine), or sodium oxybate (GHB) because the risk of their side effects may be increased by Duragesic Patch

This may not be a complete list of all interactions that may occur. Ask your health care provider if Duragesic Patch may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

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## How to use Duragesic Patch:

Use Duragesic Patch as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Duragesic Patch comes with an extra patient information sheet called a Medication Guide. Read it carefully. Read it again each time you get Duragesic Patch refilled.
- Apply Duragesic Patch right away after removing it from the sealed package. Do not use a patch if the package is not sealed. Do not apply a patch that has been cut or damaged in any way.
- The patch should be applied to a dry, smooth, undamaged, nonirradiated section of skin on your chest or back. In young children or patients with mental impairment, place the patch on their upper back to decrease the chance that they will remove the patch and put it in their mouths.
- Before applying the patch, clip (do not shave) any hair at the application site, clean the area with clear water only, and then dry the area. Do not use soaps, oils, lotions, or any other liquid that could irritate or otherwise affect the skin.
- Press the patch firmly in place with the palm of your hand for 30 seconds. Make sure the contact is complete, especially around the edges. Wash your hands after applying the patch.
- If the patch does not stick, you may tape only the edges with first-aid tape or cover the patch with a special type of clear adhesive film dressing (eg, Bioclusive, Tegaderm). Do not cover the patch with any other bandage or tape. Ask your doctor if you are unsure of what type of dressing you can use.
- A patch may be worn continuously for 72 hours. If pain relief for more than 72 hours is needed, apply a new patch to a different skin area after removing the old patch. Do not wear more than 1 patch at a time unless your doctor tells you otherwise.
- If the patch falls off before 72 hours have passed, apply a new patch to a different skin site.
- After removing the used patch, fold it in half with the sticky sides together. Discard the patch out of the reach of children and away from pets. You should also dispose of any

unused patches remaining from a prescription as soon as they are no longer needed. Ask your doctor or pharmacist how to dispose of Duragesic Patch properly.

- Check with your doctor before you eat grapefruit or drink grapefruit juice while you are using Duragesic Patch.
- If you forget to change your patch on the day it is due, change the patch as soon as you remember. Do NOT double your dose to catch up.

Ask your health care provider any questions you may have about how to use Duragesic Patch.

## Important safety information:

- Duragesic Patch may cause drowsiness, dizziness, or lightheadedness. These effects may be worse if you take it with alcohol or certain medicines. Use Duragesic Patch with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it.
- Do not drink alcohol or use medicines that may cause drowsiness (eg, sleep aids, muscle relaxers) while you are using Duragesic Patch; it may add to their effects. Ask your pharmacist if you have questions about which medicines may cause drowsiness.
- Duragesic Patch may cause dizziness, lightheadedness, or fainting; alcohol, hot weather, exercise, or fever may increase these effects. To prevent them, sit up or stand slowly, especially in the morning. Sit or lie down at the first sign of any of these effects.
- Duragesic Patch is to be applied to the skin only. Duragesic Patch may cause choking or severe and sometimes life-threatening problems if it is placed in the mouth, chewed, or swallowed. If you may have taken it by mouth, contact your [poison control center](#) or emergency room right away.
- Do NOT use more than the recommended dose or for longer than prescribed without checking with your doctor. Do not change the patch more often than directed by your doctor.
- Do not expose the patch on your skin to direct sources of heat, such as heating pads, electric blankets, heat or tanning lamps, saunas, hot tubs, or heated waterbeds. Avoid sunbathing; long, hot baths; or other sources of heat to the body. Tell your doctor if you develop a fever. The heat may cause more medicine to be released into your skin.
- The patch contains a strong narcotic pain medicine (similar to morphine, hydromorphone, methadone, oxycodone, and oxymorphone) in the form of a gel. If the gel leaks from the patch at any time, do not touch the gel. If you have unintended contact with the gel, immediately wash the affected area with large amounts of water only. If you have concerns, speak with your pharmacist or doctor for further instructions.
- If the patch comes off your skin and accidentally sticks to the skin of another person, remove the patch from their skin immediately, wash the exposed area of skin with water, and call you doctor, emergency room, or local [poison control center](#) right away.
- Tell your doctor or dentist that you take Duragesic Patch before you receive any medical or dental care, emergency care, or surgery.
- Skin burns may occur if this patch is worn during a magnetic resonance imaging (MRI) scan. If you will be having an MRI, tell your doctor that you use Duragesic Patch. You will need to remove the patch before having the MRI.
- Duragesic Patch may cause constipation. Talk with your doctor about taking a stool softener or fiber laxative to prevent or treat constipation.
- Use Duragesic Patch with caution in the ELDERLY; they may be more sensitive to its effects, especially the possibility of decreased breathing and drowsiness.
- Duragesic Patch should not be used in CHILDREN younger than 2 years old; safety and effectiveness in these children have not been confirmed.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using Duragesic Patch while you are pregnant. Duragesic Patch is found in breast milk. Do not breast-feed while taking Duragesic Patch.

When used for long periods of time or at high doses, Duragesic Patch may not work as well and may require higher doses to obtain the same effect as when originally taken. This is known as TOLERANCE. Talk with your doctor if Duragesic Patch stops working well. Do not take more than prescribed.

Some people who use Duragesic Patch for a long time may develop a need to continue taking it.

People who take high doses are also at risk. This is known as DEPENDENCE or addiction. If you suddenly stop taking Duragesic Patch, you may experience WITHDRAWAL symptoms including anxiety; diarrhea; fever, runny nose, or sneezing; goose bumps and abnormal skin sensations; nausea; vomiting; pain; rigid muscles; rapid heartbeat; hallucinations (seeing, hearing, or feeling things that are not really there); shivering or tremors; sweating; and trouble sleeping. Stop using Duragesic Patch gradually as instructed by your health care provider.

## Possible side effects of Duragesic Patch:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Constipation; diarrhea; dizziness; drowsiness; dry mouth; exaggerated sense of well-being; headache; indigestion; loss of appetite; nausea; nervousness or anxiety; mild redness, swelling, or discomfort at the skin application site; sleeplessness; stomach pain or discomfort; sweating; vomiting.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); chest pain; confusion; coughing up blood; difficulty urinating; difficulty talking, thinking, or walking; difficult, shallow, or slow breathing; excessive dizziness or drowsiness; fainting; fast, slow, or irregular heartbeat; fatigue; fever; flu-like symptoms (eg, headache, muscle aches, tiredness); hallucinations; mood or mental changes (eg, anxiety, agitation, depression); memory loss; muscle rigidity; numbness or tingling; persistent sore throat; seizures; shortness of breath; tremor; vision problems; weakness.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the [Guide to Reporting Problems to FDA](#).

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## If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local [poison control center](#), or emergency room immediately. Symptoms may include bluish skin; cold and clammy skin; difficult, shallow, or slow breathing; drowsiness leading to unresponsiveness; excessive sweating; nausea and vomiting; seizures.

Proper storage of Duragesic Patch:

Store Duragesic Patch below 77 degrees F (25 degrees C) in its original sealed pouch. Brief storage at temperatures between 59 and 86 degrees F (15 and 30 degrees C) is permitted. Store away from heat and light. Keep Duragesic Patch out of the reach of children and away from pets.

## General information:

- If you have any questions about Duragesic Patch, please talk with your doctor, pharmacist, or other health care provider.
- Duragesic Patch is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your pharmacist about how to dispose of unused medicine.

This information is a summary only. It does not contain all information about Duragesic Patch. If you have questions about the medicine you are taking or would like more information, check with your doctor, pharmacist, or other health care provider.

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