

Medication Guide

**DURAGESIC® (Dur-ah-GEE-zik)
(fentanyl) Transdermal System, CII**

DURAGESIC® is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain, in people who are already regularly using opioid pain medicine.

Important information about DURAGESIC®:

- Get emergency help right away if you use too much DURAGESIC® (overdose). DURAGESIC® overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your DURAGESIC®. They could die from using it. Store DURAGESIC® away from children and in a safe place to prevent stealing or abuse. Selling or giving away DURAGESIC® is against the law.

Do not use DURAGESIC® if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before applying DURAGESIC®, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you:

- have a fever
- **are pregnant or planning to become pregnant.** DURAGESIC® may harm your unborn baby.
- **are breastfeeding.** DURAGESIC® passes into breast milk and may harm your baby.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When using DURAGESIC®:

- Do not change your dose. Apply DURAGESIC® exactly as prescribed by your healthcare provider.
- See the detailed Instructions for Use for information about how to apply and dispose of the DURAGESIC® patch.
- Do not wear more than 1 patch at the same time unless your healthcare provider tells you to.
- **Call your healthcare provider if the dose you are using does not control your pain.**
- **Do not stop using DURAGESIC® without talking to your healthcare provider.**

While using DURAGESIC® Do Not:

- Take hot baths or sunbathe, use hot tubs, saunas, heating pads, electric blankets, heated waterbeds, or tanning lamps, or engage in exercise that increases your body temperature. These can cause an overdose that can lead to death.
- Drive or operate heavy machinery, until you know how DURAGESIC® affects you. DURAGESIC® can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of DURAGESIC® are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, itching, redness, or rash where the patch is applied. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

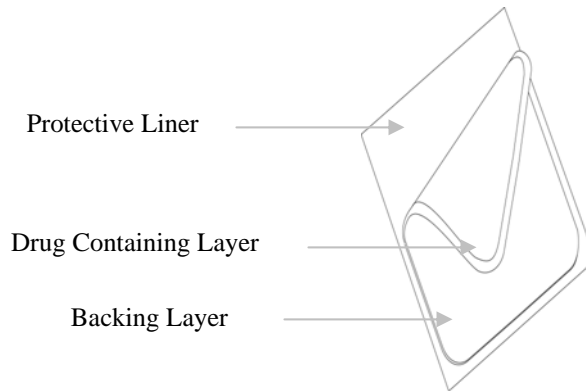
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of DURAGESIC®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Alza Corporation, Vacaville, CA 95688; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, www.Duragesic.com or call 1-800-526-7736

**DURAGESIC® (Dur-ah-GEE-zik)
(Fentanyl Transdermal System) CII**

Instructions for Applying a DURAGESIC® patch



Before Applying DURAGESIC®

- **Each DURAGESIC® patch is sealed in its own protective pouch. Do not remove a DURAGESIC® patch from the pouch until you are ready to use it.**
- **Do not use a DURAGESIC® patch if the pouch seal is broken or the patch is cut, damaged or changed in any way.**
- **DURAGESIC® patches are available in 5 different doses and patch sizes. Make sure you have the right dose patch or patches that have been prescribed for you.**

Applying a DURAGESIC® Patch

1. Skin Areas Where the DURAGESIC® Patch May Be

Applied:

For adults:

- Put the patch on the chest, back, flank (sides of the waist), or upper arm in a place where there is no hair (see Figures 1-4).

For children (and adults with mental impairment):

- **Put the patch on the upper back (see Figure 2).** This will lower the chances that the child will remove the patch and put it in their mouth.

For adults and children

- Do not put a DURAGESIC® patch on skin that is very oily, burned, broken out, cut, irritated, or damaged in any way.
- Avoid sensitive areas or those that move around a lot. If there is hair, **do not shave (shaving irritates the skin)**. Instead, clip hair as close to the skin as possible (see Figure 5).
- **Talk to your doctor if you have questions about skin application sites.**

2. Prepare to Apply a DURAGESIC® Patch:

- Choose the time of day that is best for you to apply DURAGESIC®. Change it at about the same time of day (3 days or 72 hours after you apply the patch) or as directed by your doctor.
- Do not wear more than one DURAGESIC® patch at a time unless your doctor tells you to do so. Before putting on a new DURAGESIC® patch, remove the patch you have been wearing.
- Clean the skin area with clear water **only**. **Pat skin completely dry.** Do not use anything on the skin such as soaps, lotions, oils, or alcohol before the patch is applied.

3. Open the Pouch: Fold and tear at slit, or cut at slit taking

Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6

care so as not to cut the patch, and remove the DURAGESIC[®] patch. Each DURAGESIC[®] patch is sealed in its own protective pouch. Do not remove the DURAGESIC[®] patch from the pouch until you are ready to use it (see Figure 6).



- 4. Peel:** Peel off both parts of the protective liner from the patch. Each DURAGESIC[®] patch has a clear plastic backing that can be peeled off in two pieces. This covers the sticky side of the patch. Carefully peel this backing off. Throw the clear plastic backing away. **Touch the sticky side of the DURAGESIC[®] patch as little as possible** (see Figure 7).

Figure 7



5. **Press:** Press the patch onto the chosen skin site **with the palm of your hand and hold there for at least 30 seconds** (see Figure 8). Make sure it sticks well, especially at the edges.

Figure 8



- DURAGESIC[®] may not stick to all patients. You need to check the patches often to make sure that they are sticking well to the skin.
- If the patch falls off right away after applying, throw it away and put a new one on at a different skin site (see Disposing a DURAGESIC[®] Patch).
- If you have a problem with the patch not sticking
 - Apply first aid tape only to the edges of the patch.
 - If you continue to have problems with the patch sticking, you may cover the patch with Bioclusive[™] or Tegaderm[™]. These are special see-through adhesive dressings. **Never cover a DURAGESIC[®] patch with any other bandage or tape.** Remove the backing from the Bioclusive[™] or Tegaderm[™] dressing and place it carefully over the DURAGESIC[®] patch, smoothing it over the patch and your skin.
- **If your patch falls off later, but before 3 days (72 hours) of use, discard it properly (see Disposing a DURAGESIC[®] patch) and put a new one on at a different skin site. Be sure to let your doctor know that this has happened, and do not replace the new patch until 3 days (72 hours) after you put it on (or as directed by your doctor).**

6. Wash your hands when you have finished applying a

DURAGESIC[®] patch.

7. Remove a DURAGESIC[®] patch after wearing it for 3 days (72 hours) (see “Disposing a DURAGESIC[®] Patch”). Choose a **different** place on the skin to apply a new DURAGESIC[®] patch and repeat Steps 2 through 6.

Do not apply the new patch to the same place as the last one.

Water and DURAGESIC[®]

- You can bathe, swim or shower while you are wearing a DURAGESIC[®] patch. If the patch falls off before 3 days (72 hours) after application, discard it properly (see Disposing a DURAGESIC[®] Patch) and put a new one on at a different skin site. Be sure to let your doctor know that this has happened, and do not replace the new patch until 3 days (72 hours) after you put it on (or as directed by your doctor).

Disposing a DURAGESIC[®] Patch

- Fold the used DURAGESIC[®] patch in half so that the sticky side sticks to itself (Figure 9). **Flush the used DURAGESIC[®] down the toilet right away** (Figure 10). **A used DURAGESIC[®] patch CAN be VERY dangerous for or even lead to death in babies, children, pets, and adults who have not been prescribed DURAGESIC[®].**
- Throw away any DURAGESIC[®] patches that are left over from your prescription as soon as they are no longer needed. Remove the leftover patches from their protective pouch and remove the protective liner. **Fold the patches in half with the sticky sides together, and flush the patches down the toilet.** Do not flush the pouch or the protective liner down the toilet. These items can be thrown away in a trashcan.

Figure 9



Figure 10



Bioclusive[™] is a trademark of Ethicon, Inc.

Tegaderm[™] is a trademark of 3M

Rx Only

Manufactured by:
ALZA Corporation
Vacaville, CA 95688

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

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