

## Medication Guide

**DURAGESIC<sup>®</sup>**  
(FENTANYL  
TRANSDERMAL  
SYSTEM) 

(Dur-ah-GEE-zik)

### IMPORTANT:

- Keep DURAGESIC<sup>®</sup> in a safe place away from children and pets. Accidental use by a child or pet is a medical emergency and may result in death. If a child or pet accidentally uses DURAGESIC<sup>®</sup>, get emergency help right away.
- Make sure you read the separate “Instructions for Applying a DURAGESIC<sup>®</sup> Patch.” Always use a DURAGESIC<sup>®</sup> Patch the right way. DURAGESIC<sup>®</sup> can cause serious breathing problems and death, especially if it is used the wrong way.
- DURAGESIC<sup>®</sup> is a federally controlled substance (C-II) because it can be abused. Keep DURAGESIC<sup>®</sup> in a safe place to prevent theft. Selling or giving away DURAGESIC<sup>®</sup> may harm others, and is against the law.
- Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines or street drugs.

**Read the Medication Guide that comes with DURAGESIC<sup>®</sup> before you start using it and each time you get a new prescription.** There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Make sure you read and understand all the instructions for using DURAGESIC<sup>®</sup>. Do not use DURAGESIC<sup>®</sup> unless you understand everything. Talk to your healthcare provider if you have questions.

### What is the most important information I should know about DURAGESIC<sup>®</sup>?

DURAGESIC<sup>®</sup> is a skin patch that contains fentanyl. Fentanyl is a very strong opioid narcotic pain medicine that can cause serious and life-threatening breathing problems. Serious and life-threatening breathing problems can happen because of an overdose or if the dose you are using is too high for you. Call your doctor right away or get emergency medical help if you:

- have trouble breathing, or have slow or shallow breathing
- have a slow heartbeat
- have severe sleepiness
- have cold, clammy skin
- feel faint, dizzy, confused, or cannot think, walk, or talk normally

- have a seizure
- have hallucinations

**DURAGESIC<sup>®</sup> is only for adults and children over the age of two with persistent, moderate to severe chronic pain and who:**

- are already using another strong opioid narcotic pain medicine around-the-clock, and have been using the medicine regularly for a week or longer. This is called being opioid-tolerant
- have pain that cannot be controlled with other medicines

### Do not use DURAGESIC<sup>®</sup>:

- **if you are not already using another opioid narcotic medicine and are not opioid tolerant**
- if you need opioid pain medicines for only a short time

- for pain from surgery, medical or dental procedures
- if your pain can be taken care of by occasional use of other pain medicines
- in children who are less than 2 years of age
- if you have asthma symptoms or have severe asthma

**A DURAGESIC® patch must be used only on the skin of the person for whom it was prescribed.** If the patch comes off and accidentally sticks to the skin of another person, take the patch off of that person right away, wash the area with water, and get medical care for them right away.

**DURAGESIC® patch is not safe for everyone. Tell your doctor about all of your medical conditions.**

**Tell your doctor if you are planning to become pregnant, are pregnant, or breastfeeding.** DURAGESIC® may cause serious harm to a baby.

**Tell your doctor about all the medicines you take. Some medicines may cause serious or life-threatening side effects when used with DURAGESIC®.** Your doctor will tell you if it is safe to take other medicines while you are using DURAGESIC®.

Know the medicines you take. Keep a list of your medicines to show to your doctor and pharmacist.

**How should I use DURAGESIC®?**  
**Read the separate “Instructions for Applying a DURAGESIC® Patch.**

- **You must always use DURAGESIC® patches** the right way:
  - **Do not** use a DURAGESIC® patch if the seal is broken, or the patch is cut, damaged, or changed in any way.
  - **Do not** use heat sources such as heating pads, electric blankets, heat lamps, tanning lamps, saunas, hot tubs, or heated waterbeds while wearing a DURAGESIC® patch.
  - **Do not** take hot baths or sunbathe while wearing a DURAGESIC® patch.

- **If you have problems with the DURAGESIC® patch not sticking:**
  1. Apply first aid tape only to the edges of the patch.
  2. If problems with the patch not sticking persist, 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.**
- **If your DURAGESIC® patch falls off before 3 days or 72 hours, fold the sticky side together and flush down a toilet. Put a new one on at a different skin site.**
- **Do not change your dose unless your doctor tells you to.** Your doctor may change your dose after seeing how the medicine affects you. Do not use DURAGESIC® more often than prescribed. Call your doctor if your pain is not well controlled while using DURAGESIC®.
- **Do not stop using DURAGESIC® suddenly.** Stopping DURAGESIC® suddenly can make you sick with withdrawal symptoms (for example, nausea, vomiting, diarrhea, anxiety, and shivering). Your body can develop a physical dependence on DURAGESIC®. If your doctor decides you no longer need DURAGESIC®, ask how to slowly reduce this medicine so you don’t have withdrawal symptoms. Do not stop taking DURAGESIC® without talking to your doctor.
- **Do not wear more than one DURAGESIC® patch at a time,** unless your doctor tells you to do so.
- **Call your doctor right away if**
  - **You get a fever higher than 102°F**
  - Your body temperature increases from exercise
 A fever or increase in body temperature may cause too much of the medicine in DURAGESIC® to pass into your body.

- **If you use more DURAGESIC<sup>®</sup> than your doctor has prescribed, get emergency medical help right away.**
- **Do not drink any alcohol while using DURAGESIC<sup>®</sup>.** Alcohol can increase your chances of having serious side effects.
- **Do not drive, operate heavy machinery, or do other possibly dangerous activities** until you know how DURAGESIC<sup>®</sup> affects you. DURAGESIC<sup>®</sup> can make you sleepy. Ask your doctor to tell you when it is okay to do these activities.
- When you remove your DURAGESIC<sup>®</sup> patch, fold the sticky sides of a used DURAGESIC<sup>®</sup> patch together and flush it down the toilet. **Do not put used DURAGESIC<sup>®</sup> patches in a trash can.**

### **What are the possible side effects of DURAGESIC<sup>®</sup>?**

#### **Serious side effects include:**

- **Life-threatening breathing problems.** See “What is the most important information I should know about DURAGESIC<sup>®</sup>?”
- **Low blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down.

**The common side effects with DURAGESIC<sup>®</sup>** are nausea, vomiting, constipation, dry mouth, sleepiness, confusion, weakness, sweating, and pain and redness where the patch was applied.

Constipation is a very common side effect of all opioid medicines. Talk to your doctor about the use of laxatives and stool softeners to prevent or treat constipation while taking DURAGESIC<sup>®</sup>.

Talk to your healthcare provider about any side effect that concerns you.

These are not all the possible side effects of DURAGESIC<sup>®</sup>. For a complete list, ask your doctor or pharmacist.

[Call your doctor for medical advice about side effects.](#)  
[You may report side effects to FDA at 1-800-FDA-1088.](#)

### **How should I store DURAGESIC<sup>®</sup>?**

- Store DURAGESIC<sup>®</sup> below 77° F (25° C).
- Keep a DURAGESIC<sup>®</sup> patch in its protective pouch until you are ready to use it.
- **Keep DURAGESIC<sup>®</sup> in a safe place out of the reach of children and pets.**
- Dispose of DURAGESIC<sup>®</sup> patches you no longer need. Open the unused packages, fold the sticky sides of the patches together, and flush them down the toilet.

### **General information about the safe and effective use of DURAGESIC<sup>®</sup>**

- Do not use DURAGESIC<sup>®</sup> for a condition for which it was not prescribed.
- **Do not give DURAGESIC<sup>®</sup> to other people, even if they have the same symptoms you have. DURAGESIC<sup>®</sup> can harm other people and even cause death. Sharing DURAGESIC<sup>®</sup> is against the law.**
- This Medication Guide summarizes the most important information about DURAGESIC<sup>®</sup>. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DURAGESIC<sup>®</sup> that is written for doctors.

For questions about DURAGESIC<sup>®</sup>, call the Ortho-McNeil Janssen Scientific Affairs Customer Communications Center at 1-800-526-7736. If this is a medical emergency, please call 911.

### **What are the ingredients of DURAGESIC<sup>®</sup>?**

#### **Active Ingredient: fentanyl**

Inactive ingredients: alcohol\*, ethylene-vinyl acetate copolymer membrane, hydroxyethyl cellulose, polyester film backing, silicone adhesive.

\*Less than 0.2 mL of alcohol is released from the patch during use.

**This Medication Guide has been approved by the  
United States Food and Drug Administration.**

Bioclusive™ is a trademark of Ethicon, Inc.  
Tegaderm™ is a trademark of 3M

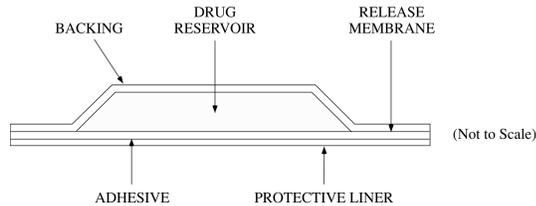
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ALZA Corporation  
Mountain View, CA 94043

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**DURAGESIC® (Dur-ah-GEE-zik)  
(fentanyl transdermal system) CII**

**Instructions for Applying a DURAGESIC® patch**



**Before Applying DURAGESIC®**

- **DURAGESIC® is a patch with a medicine gel sealed inside. The patch is designed to keep the medicine gel from getting on your hands or body. If the gel from the patch accidentally gets on your skin, wash the area with large amounts of water only. Do not use soap, alcohol, lotions, oils, or other products to remove the medicine gel because they may increase the medicine's ability to go through the skin.**
- **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 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.

Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



- 3. Tear open** the pouch along the dotted line, starting at the slit, and remove a DURAGESIC<sup>®</sup> patch. Each DURAGESIC<sup>®</sup> patch is sealed in its own protective pouch. Do not remove the DURAGESIC<sup>®</sup> patch from the pouch until you are ready to use it (see Figure 6).

Figure 6



- 4. Peel:** Peel the liner from the back of the patch and throw away. **Touch the sticky side of a DURAGESIC<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>™</sup> or Tegaderm<sup>™</sup>. These are special see-through adhesive dressings. **Never cover a DURAGESIC<sup>®</sup> patch with any other bandage or tape.** Remove the backing from the Bioclusive<sup>™</sup> or Tegaderm<sup>™</sup> dressing and place it carefully over the DURAGESIC<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> patch.

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

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

### **Water and DURAGESIC<sup>®</sup>**

- You can bathe, swim or shower while you are wearing a DURAGESIC<sup>®</sup> patch. If the patch falls off before 3 days (72 hours) after application, discard it properly (see Disposing a DURAGESIC<sup>®</sup> 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<sup>®</sup> Patch**

- Fold the used DURAGESIC<sup>®</sup> patch in half so that the sticky side sticks to itself (Figure 9). **Flush the used DURAGESIC<sup>®</sup> down the toilet right away** (Figure 10). **A used DURAGESIC<sup>®</sup> patch CAN be VERY dangerous for or even lead to death in babies, children, pets, and adults who have not been prescribed DURAGESIC<sup>®</sup>.**
- Throw away any DURAGESIC<sup>®</sup> 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<sup>™</sup> is a trademark of Ethicon, Inc.

Tegaderm™ is a trademark of 3M

Rx Only

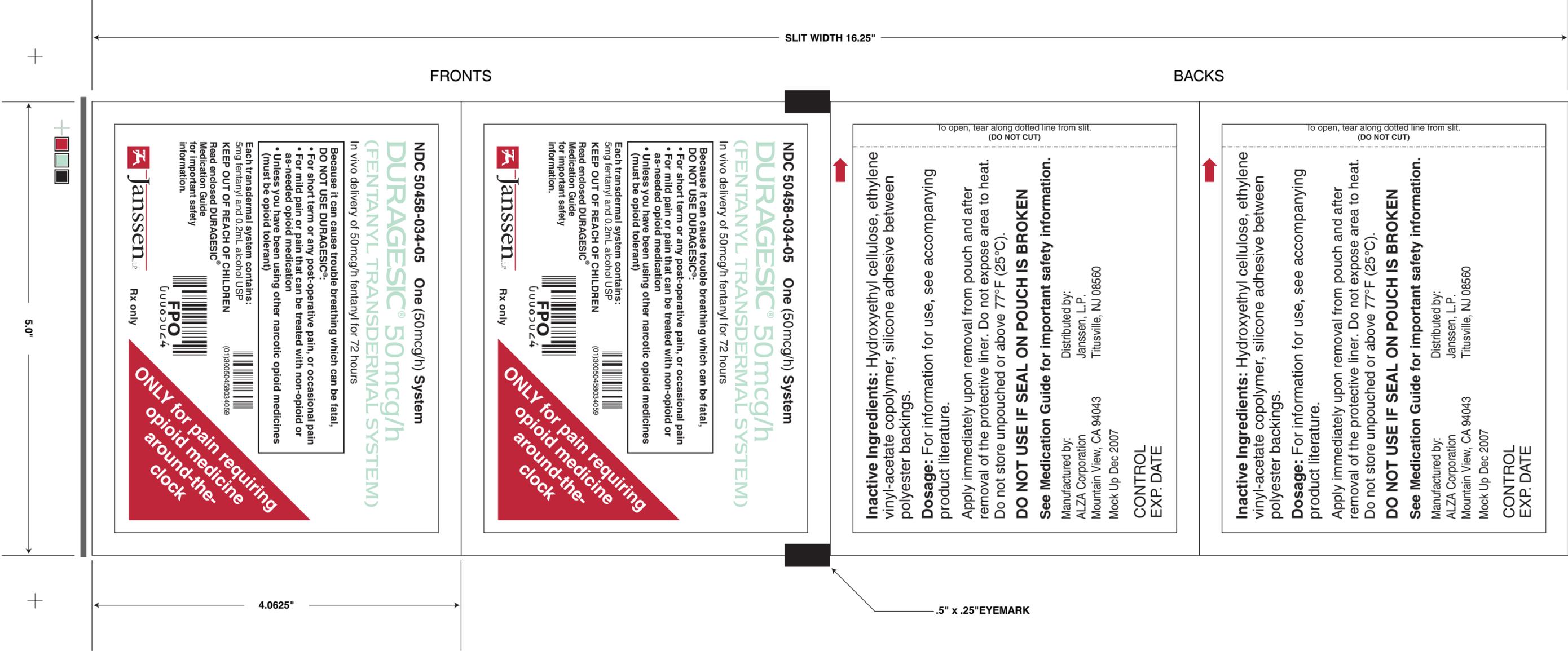
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ALZA Corporation  
Mountain View, CA 94043

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Titusville, NJ 08560



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**GPSG** Global Pharmaceutical Supply Group

PRODUCT NAME Duragesic pouch 50mcg/h COMPONENT TYPE Pouch

COMP. NUMBER Duragesic pouch 50mcg/h MU ARTWORK VERSION 3

SOFTWARE USED Illustrator VERS. CS UPGRADE

MODIFIED DATE 12/11/07 DESIGNER Candace Rechsteiner

Date/Comment: TITLE BLOCK PROOFED  NO  YES

02/21/06: V1: KD created MU using pouch file 00085024 and made requested text changes  
 12/7/07: V2: KT made revs per PDF markup and replaced slug.  
 12/11/07: V3: CR Made ONLY all caps in red triangle. Added 'safety' to Read enclosed statement.

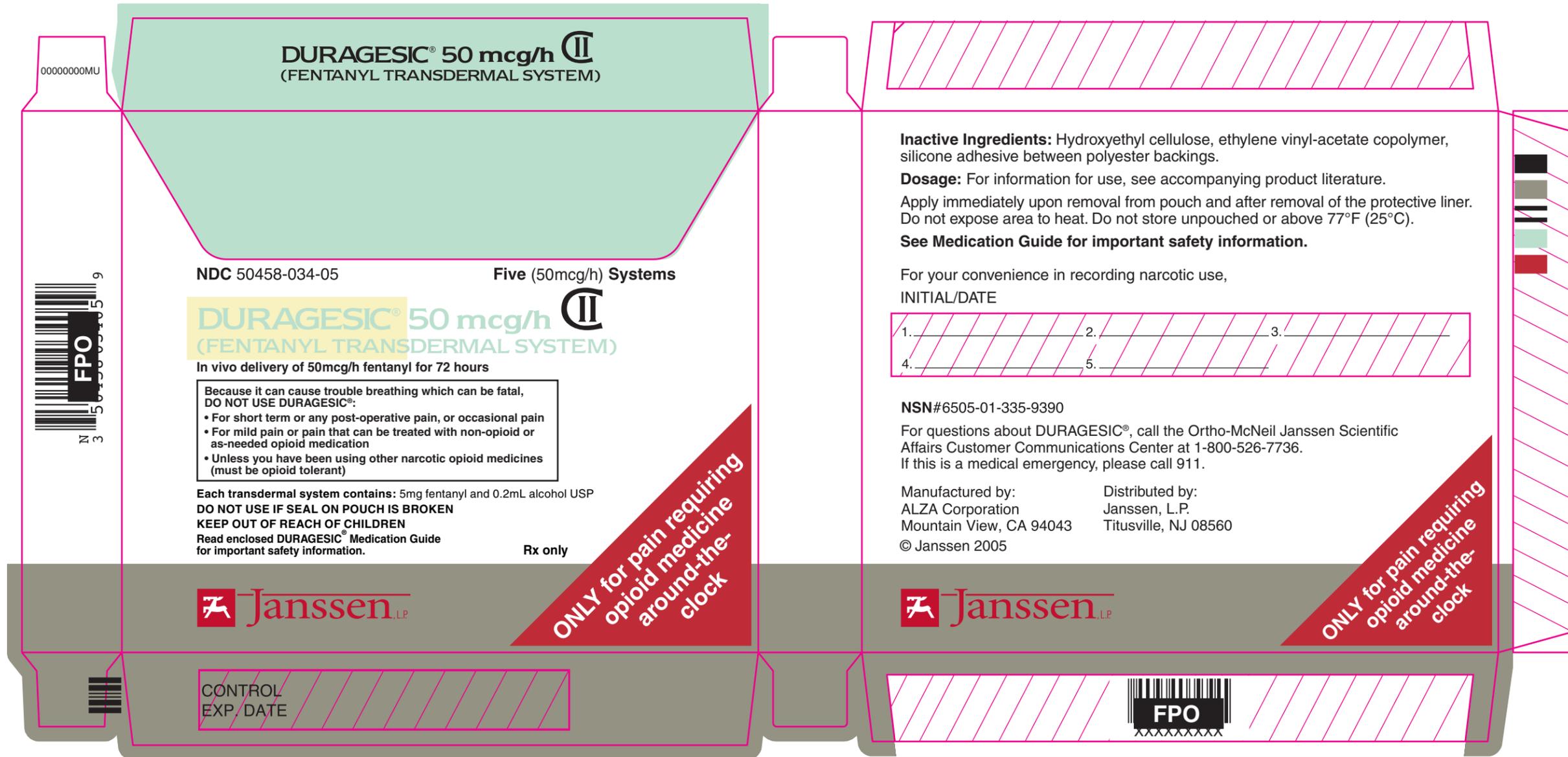
**COLORS USED IN FILE**



DIMENSIONS NA

DWG # NA OUTPUT % 100%

SPEC # NA ePM Order # Number



**GPSG** Global Pharmaceutical Supply Group

PRODUCT NAME	Duragesic 50 MU	COMPONENT TYPE	Carton	COLORS USED IN FILE					
COMP. NUMBER	Duragesic 50 carton MU	ARTWORK VERSION	_6_	 BLACK	 PMS 187	 PMS 344	 PMS 416	 Security Ink	 Non Varnish Indication
SOFTWARE USED	Illustrator	VERS.	_CS_	DIMENSIONS 5-3/8" x 7/8" x 4-9/16"					
MODIFIED DATE	12/11/07	DESIGNER	Candace Rechsteiner	DWG # NA		OUTPUT % 100%			
Date/Comment:	TITLE BLOCK PROOFED <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES			SPEC # NA ePM Order # NA					
02/21/07: V1: KD created mockup using 10083300 carton artwork and added requested lines of text 02/22/07: V2: KD made minor revisions per SB 02/27/07: V3: CR made changes per SB. (Pharmacist line in bold on back) 02/28/07: V4: KD made "medication guide" initial caps 12/07/07: V5: KT made revs per PDF with comments, placed new die from 10083301, updated slug. 12/11/07: V6: CR made revs to copy 'ONLY' all caps in red triangle. IS to IF in broken pouch line. Added safety to 'Read enclosed line'. made 'you' your to back line 'For your convenience'. 12/12/07: V7: CR changed paragraph..'For questions about DURAGESIC.....' per TG.									