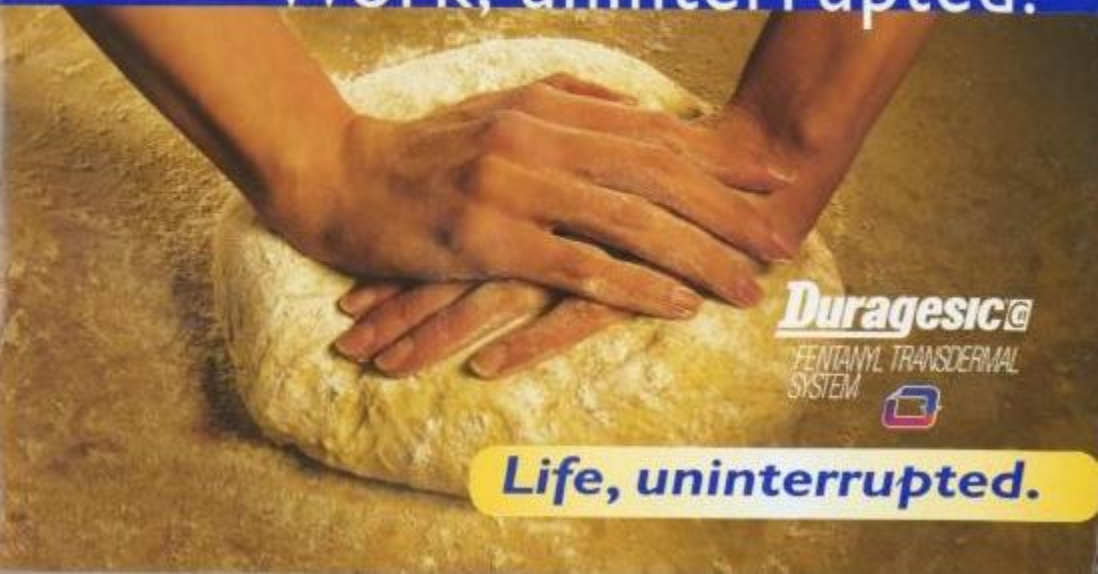
1,360 LOAVES...AND COUNTING

Work, uninterrupted.



Long-lasting efficacy

Up to 72 hours of uninterrupted pain relief per patch

- Provides fewer peaks and troughs
- Consistent drug delivery over 3 days

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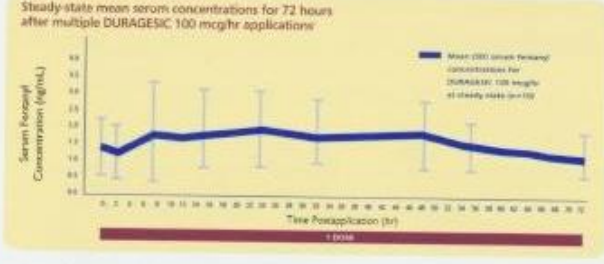

As with other drug-level measurements, serum fentanyl concentrations may be useful clinically although they do not reflect patient sensitivity to fentanyl and should not be used by physicians as a sole indicator of effectiveness or toxicity.

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Long-lasting efficacy

Demonstrated effectiveness in chronic back pain with additional patient benefits

86% of patients experienced overall benefit in a clinical study* based on[1]:

- Pain control
- Disability in ADLs
- Quality of sleep

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- All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.[2]
- Significantly reduced nighttime awakenings.[2]
- Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.[2]

* Study participants had chronic low back pain inadequately controlled by short-acting opioids. Participants underwent a 9- to 12-day titration phase with transdermal fentanyl once titration was completed, patients were maintained on transdermal fentanyl for 1 month. Sixty-eight patients were originally enrolled in this study. A total of 18 patients left the study due to nausea and vomiting (10 patients), transportation hardships (4 patients), noncompliance with study protocol (3 patients), and drowsiness (1 patient). No significant change in quality of sleep was observed based on the summed analog VSH Scale.

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Long-term effects:
12-month open-label study

Significant improvement in physical functioning summary score

*p<0.05.

Study involved 532 patients who had chronic nonmalignant pain for at least 6 weeks preceding the trial that required continuous treatment with a potent opioid; patients must have achieved moderate pain control with a stable daily dose for at least 1 week preceding the trial. Patients received appropriate doses of DURAGESIC for up to 12 months. Mental health summary score was not significant at 12 months. Twenty-five percent of patients discontinued due to adverse events, including nausea (7%), vomiting (5%), somnolence (4%), dizziness (2%), increased sweating (2%), and anorexia (2%). There were 9 deaths during the trial; only one was possibly related to therapy (severe bronchopneumonia).[1]

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Significant improvement in social functioning

*p<0.05.

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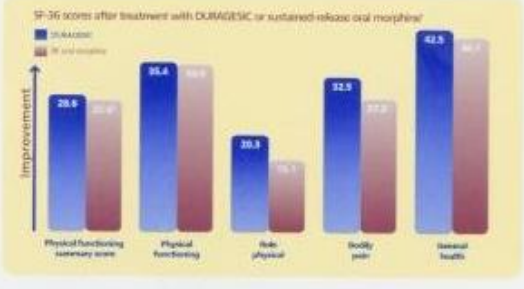
Improved patient outcomes:
Open-label, crossover comparison study

Significant improvement in physical functioning summary score



*p<0.05.

Study involved 256 patients who had chronic nonmalignant pain requiring potent opioids for 6 weeks preceding trial; patients must have achieved moderate pain control with a stable dose of oral opioid for 7 days preceding the trial. Patients were given appropriate doses of DURAGESIC or sustained-release morphine over 4 weeks, followed by a crossover period in which patients were given the equivalent dose of the other therapy for 4 weeks. Within the total patient population, 11% of patients using DURAGESIC and 4% of patients using sustained-release oral morphine withdrew due to adverse events. Among patients who were fentanyl- and morphine-naive, 11% using DURAGESIC and 9.8% using sustained-release oral morphine withdrew due to adverse events.*

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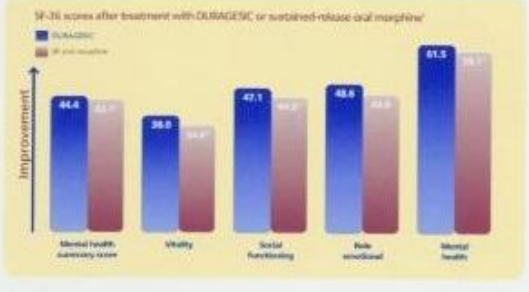
Significant improvement in social functioning



*p<0.05.

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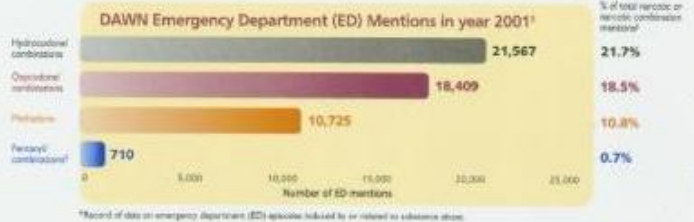
Proven clinical experience

Low reported rate of mentions in DAWN data*

Source: Drug Abuse Warning Network (DAWN) database



*Record of data on emergency department (ED) episodes induced by or related to substance abuse.

- Data do not distinguish between IV, transdermal, transmucosal, or illicit fentanyl analogs
- DAWN only captures drug abuse events that result in ED admission
- No data on severity of adverse events or hospital admissions

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Favorable side-effect profile

Adverse experiences in patients with cancer (N=153)‡

Adverse experience	Incidence	Discontinued
Nausea	23%	6%
Vomiting	22%	3%
Somnolence	17%	2%
Constipation	**14%**	**0%**
Diaphoresis	14%	0%

Many patients were receiving other regimens, including chemotherapy and radiation.

Minimizes the potential for local GI side effects by avoiding GI absorption.

† Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine. DURAGESIC therefore has the potential for abuse. Tolerance and physical and psychological dependence may develop upon repeated administration of opioids. Iatrogenic addiction following opioid administration is relatively rare. Physicians should not let concerns of physical dependence deter them from using adequate amounts of opioids in the management of severe pain when such use is indicated.

‡ A total of 99,317 ED mentions was recorded.

§ Please see full Prescribing Information for a more extensive list of adverse events.

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What to tell patients about applying the patch

1.

Prepare: Choose a site to apply the patch on the chest, back, or any flat part of the body where there is no hair, taking care to avoid sensitive areas or areas of excessive movement. If there is hair, **do not shave (shaving irritates the skin)**. Instead, clip hair as close to the skin as possible. Clean the application site with clear water **only. Pat skin completely dry**. Do not apply anything to the skin (lotions, oils, etc) before the patch is applied.

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2.

Peel: Peel the liner from the back of the patch. Minimize contact with the sticky side.

3.

Press: Press the patch onto the skin **with the palm of your hand and hold there for a minimum of 30 seconds**, making sure it sticks well, particularly at the edges.

Note: If the patch does not stick well or loosens after application, tape down the edges with first aid tape.

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Indication

DURAGESIC® (fentanyl transdermal system) CII is indicated for patients in chronic pain who require continuous opioid analgesia and whose pain cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics, or p.r.n. dosing with short-acting opioids.

BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC IS CONTRAINDICATED:

- In the management of acute or postoperative pain, including use in outpatient surgeries
- In the management of mild or intermittent pain responsive to p.r.n. or non-opioid therapy
- In doses exceeding 25 mcg/hr at the initiation of opioid therapy

(See CONTRAINDICATIONS section of full Prescribing Information for further information.)

SAFETY OF DURAGESIC HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 2 YEARS OF AGE. DURAGESIC SHOULD BE ADMINISTERED TO CHILDREN ONLY IF THEY ARE OPIOID-TOLERANT AND AGE 2 YEARS OR OLDER. (SEE PRECAUTIONS—PEDIATRIC USE SECTION OF FULL PRESCRIBING INFORMATION FOR FURTHER INFORMATION.)

DURAGESIC is indicated for treatment of chronic pain (such as that of malignancy) that:

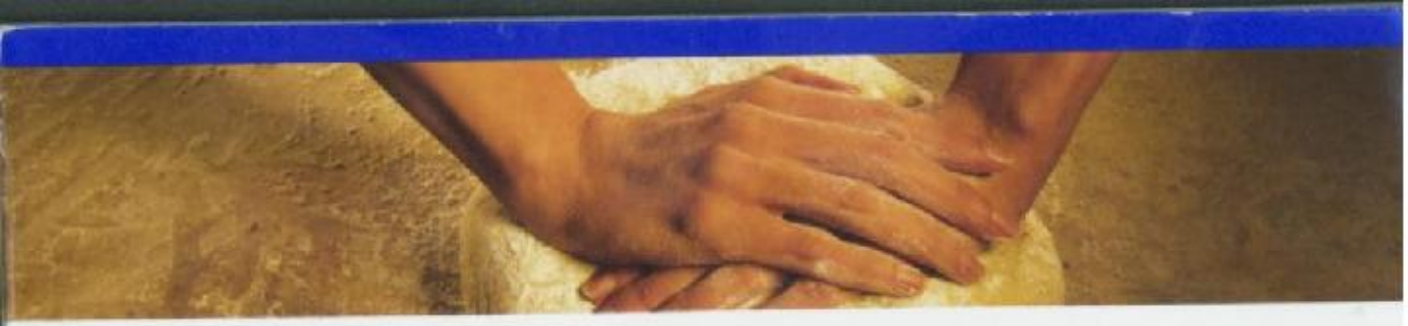
- Cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics, or p.r.n. dosing with short-acting opioids and
- Requires continuous opioid administration

The 50, 75, and 100 mcg/hr dosages should ONLY be used in patients already on and tolerant to opioid therapy.

In children, apply DURAGESIC to the upper back to reduce the risk of removal by the child.

Please see full Prescribing Information, including Boxed Warning.

NOTE: Since elderly, cachectic, or debilitated patients may have altered pharmacokinetics due to poor fat stores, muscle wasting, or altered clearance, they should not be started on DURAGESIC doses higher than 25 mcg/hr unless they are taking more than 135 mg/day of oral morphine or equivalent dose of another opioid.



Chronic pain relief that supports functionality

- Uninterrupted pain relief for up to 72 hours with fewer peaks and troughs
- Helps patients think less about their pain
- Improvements in physical and social functioning

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For more information about DURAGESIC, call Janssen Medical Services at 1-800-JANSSEN (1-800-526-7736) 9 AM to 5 PM, Eastern Time, Monday through Friday.

For additional physician and patient information about the use of DURAGESIC and chronic pain, please visit:

www.duragesic.com

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