Duragesic (fentanyl) - Drug Summary

Janssen Pharmaceuticals, Inc.

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Duragesic (fentanyl)

BOXED WARNING

Exposes patients and other users to the risk of opioid addiction/abuse/misuse, which may lead to overdose and death; assess risk prior to therapy and monitor all patients regularly for development of these behaviors or conditions. Serious, life-threatening, or fatal respiratory depression may occur; monitor especially during initiation or following a dose increase. Contraindicated for use as a prn analgesic, in nonopioid tolerant patients, in acute pain, and in postoperative pain. Deaths due to fatal overdose have occurred from accidental exposure; strict adherence to handling/disposal instructions is of utmost importance to prevent accidental exposure. Prolonged use during pregnancy may result in neonatal opioid withdrawal syndrome. Concomitant use with all CYP3A4 inhibitors and discontinuation of a concomitantly administered CYP3A4 inducer may increase plasma concentrations and potentially cause fatal respiratory depression; monitor patients during concomitant therapy. Exposure of application site and surrounding area to direct external heat sources may increase absorption and result in fatal overdose and death; patients who develop fever or increased core body temperature due to strenuous exertion are at increased risk and may require dose adjustment.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Severe Pain (Daily, Around-the-Clock Management)

Opioid-Tolerant Patients:
D/C or taper all other ER and around-the-clock opioids when beginning therapy

25-300mcg/hr reapplied q72hr; initiate dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment (refer to PI for dose conversions)

Titrate dose based on daily dose of supplemental opioid analgesics required on the 2nd or 3rd day of initial application; use the ratio of 45mg/24 hrs of oral morphine to a 12mcg/hr increase in fentanyl dose

Evaluate for further titration after no less than two 3-day applications before any further increase in dose

A small portion of patients may require systems to be applied q48h; an increase in dose should be evaluated before changing dosing interval

PEDIATRIC DOSAGE & INDICATIONS

Severe Pain (Daily, Around-the-Clock Management)

Opioid-Tolerant Patients:
≥2 Years:
D/C or taper all other ER and around-the-clock opioids when beginning therapy

25-300mcg/hr reapplied q72hr; initiate dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment (refer to PI for dose conversions)

Titrate dose based on daily dose of supplemental opioid analgesics required on the 2nd or 3rd day of initial application; use the ratio of 45mg/24 hrs of oral morphine to a 12mcg/hr increase in fentanyl dose

Evaluate for further titration after no less than two 3-day applications before any further increase in dose

A small portion of patients may require systems to be applied q48h; an increase in dose should be evaluated before changing dosing interval

DOSING CONSIDERATIONS

Renal Impairment
Mild to Moderate: Start w/ one half of the usual dosage
Severe: Avoid use

Hepatic Impairment
Mild to Moderate: Start w/ one half of the usual dosage
Severe: Avoid use

Discontinuation
Significant amounts of fentanyl continue to be absorbed from the skin for ≥24 hrs after the patch is removed
Converting to Another Opioid:
1. Remove patch and titrate the dose of the new analgesic based upon the patient's report of pain until adequate analgesia has been attained
2. Upon system removal, ≥17 hrs are required for a 50% decrease in serum fentanyl concentrations
Not Converting to Another Opioid:
Use a gradual downward titration (eg, having the dose every 6 days), in order to reduce the possibility of withdrawal symptoms; it is not known at what dose level fentanyl may be discontinued w/o producing the signs and symptoms of opioid withdrawal

Elderly
Start at lower end of the dosing range

ADMINISTRATION

Transdermal route

Application and Handling Instructions
1. Apply to intact, non-irritated, and non-irradiated skin on a flat surface such as the chest, back, flank, or upper arm; in young children and persons w/ cognitive impairment, adhesion should be monitored and the upper back is the preferred location to minimize the potential of inappropriate patch removal
2. Hair at the application site may be clipped (not shaved) prior to system application
3. If the application site must be cleansed prior to application of the patch, do so w/ clear water; do not use soaps, oils, lotions, alcohol, or any other agents that might irritate the skin or alter its characteristics. Allow the skin to dry completely prior to patch application
4. Apply immediately upon removal from the sealed package; the patch must not be altered (eg, cut) in any way prior to application. Do not use if the pouch seal is broken or if the patch is cut or damaged
5. Press the transdermal system firmly in place w/ the palm of the hand for 30 sec, making sure the contact is complete, especially around the edges
6. Each patch may be worn continuously for 72 hrs; the next patch is applied to a different skin site after removal of the previous transdermal system
7. If problems w/ adhesion of the patch occur, the edges of the patch may be taped w/ first aid tape; if adhesion problems persist, the patch may be overlayed w/ a transparent adhesive film dressing
8. If the patch falls off before 72 hrs, dispose of it by folding in 1/2 and flushing down the toilet; a new patch may be applied to a different skin site
9. Patients (or caregivers) should wash their hands immediately w/ soap and water after applying patch
10. Contact w/ unwashed or unclothed application sites can result in secondary exposure and should be avoided

Disposal Instructions
1. Patients should dispose of used patches immediately upon removal by folding the adhesive side of the patch to itself, then flushing down the toilet
2. Unused patches should be removed from their pouches, the protective liners removed, the patches folded so that the adhesive side of the patch adheres to itself, and immediately flushed down the toilet
3. Patients should dispose of any patches remaining from a prescription as soon as they are no longer needed

HOW SUPPLIED

Patch: 12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr [5^{S}]

CONTRAINDICATIONS

Opioid-intolerant patients; management of acute/intermittent pain, or in patients who require opioid analgesia for a short period; management of postoperative pain, including use after outpatient/day surgeries (eg, tonsillectomies); management of mild pain; significant respiratory compromise, especially if adequate monitoring and resuscitative equipment are not readily available; acute or severe bronchial asthma; diagnosis or suspicion of paralytic ileus; known hypersensitivity to fentanyl or any components of the transdermal system.

WARNINGS/PRECAUTIONS

Should be prescribed only by healthcare professionals knowledgeable in the use of potent opioids for the management of chronic pain. Reserve for use in patients for whom alternative treatment options (eg, nonopioid analgesics, immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Do not use as the 1st opioid. Risk of addiction is increased with personal/family history of substance abuse or mental illness. Prescribe smallest appropriate quantity. Closely monitor elderly, cachectic, or debilitated patients for respiratory depression. May decrease respiratory drive to the point of apnea in patients with chronic pulmonary disease; consider use of other nonopioid analgesic alternatives if possible. Avoid in patients who may be susceptible to the intracranial effects of CO_2 retention. May obscure clinical course of head injury and may increase intracranial pressure (ICP); monitor patients with brain tumors. May cause severe hypotension, including orthostatic hypotension and syncope, in ambulatory patients; increased risk with reduced blood volume. May produce bradycardia. Avoid use with severe hepatic/renal impairment. May cause spasm of the sphincter of Oddi; monitor patients with biliary tract disease (eg, acute pancreatitis). May cause increases in serum amylase concentration. Tolerance and physical dependence may develop during chronic therapy. May impair mental/physical abilities. Significant absorption from the skin continues for ≥24 hrs after patch removal. Avoid abrupt discontinuation; use a gradual downward dose titration. Not for use in women during and immediately prior to labor.

ADVERSE REACTIONS

Respiratory depression, N/V, constipation, diarrhea, headache, muscle spasms, malaise, palpitations, dizziness, insomnia, somnolence, fatigue, feeling cold, hyperhidrosis, anorexia.

DRUG INTERACTIONS

See Boxed Warning. Monitor respiratory depression when given with other drugs that depress respiration. Concomitant use with CNS depressants (eg, other opioids, sedatives, alcohol) may cause respiratory depression, hypotension, profound sedation, coma, or death; closely monitor and reduce dose of 1 or both agents. Coadministration with CYP3A4 inducers may lead to lack of efficacy of fentanyl or development of withdrawal; monitor for signs of opioid withdrawal and consider dose adjustments until stable drug effects are achieved. Avoid concomitant use with MAOIs or within 14 days of stopping such treatment. Mixed agonist/antagonist (eg, pentazocine, nalbuphine, butorphanol) or partial agonist (buprenorphine) analgesics may reduce analgesic effect or may precipitate withdrawal symptoms; avoid concomitant use. Monitor for signs of urinary retention or reduced GI motility with anticholinergics or other medications with anticholinergic activity.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Opioid analgesic; interacts predominantly with the opioid mu-receptor in the brain, spinal cord, and other tissues.

PHARMACOKINETICS

Absorption: T_{max}=20-72 hrs. Transdermal administration of variable doses resulted in different parameters. **Distribution:** V_d=6L/kg; found in breast milk; crosses placenta. **Metabolism:** Liver via CYP3A4; oxidative N-dealkylation to norfentanyl. **Elimination:** (IV) Urine (75%, <10% unchanged), feces (9% primarily metabolites); $T_{1/2}$=7 hrs (IV).

ASSESSMENT

Assess for degree of opioid tolerance, type and severity of pain, risks for opioid abuse, addiction, or misuse, paralytic ileus, acute/severe bronchial asthma, history of hypersensitivity to drug or any component of patch, debilitation, seizures, biliary tract disease, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, bradycardia, worsening of biliary tract disease, increased ICP, increased serum amylase levels, increased body temperature/fever, abuse, misuse, addiction, tolerance/physical dependence, opioid withdrawal syndrome in neonates born to mothers on prolonged therapy during pregnancy, and other adverse reactions.

PATIENT COUNSELING

Inform that use of patch may result in addiction, abuse, and misuse, which may lead to overdose or death; instruct not to share with others and protect from theft, misuse, and from children. Inform of the risk of life-threatening respiratory depression; advise on how to recognize respiratory depression and to seek medical attention. Instruct to avoid accidental contact when holding or caring for children. Instruct to immediately take patch off if it dislodges and accidentally sticks to the skin of another person, wash exposed area with water, and seek medical attention. Advise to never change the dose/number of patches unless instructed. Advise how to safely taper medication and not to stop abruptly. Warn of the potential for temperature-dependent increases in drug release from patch; instruct to avoid strenuous exertion that may increase body temperature and avoid exposing application site and surrounding area to direct external heat sources. Counsel that medication may impair mental and/or physical ability; instruct patients to refrain from potentially hazardous tasks until therapy is established that they have not been adversely affected. Inform of pregnancy risks and advise women of childbearing potential who become/are planning to become pregnant to consult physician prior to initiating or continuing therapy. Advise to notify physician of all medications currently being taken and avoid using other CNS depressants and alcohol. Inform that severe constipation may develop. Instruct to refer to the instructions for use for proper disposal of patch.

STORAGE

Up to 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Store in original unopened pouch.

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