



IRISH MEDICINES BOARD

Fentanyl Transdermal Patches ¹ - Recommendations for Safe and Appropriate Use

Fentanyl is a potent opioid analgesic and is a controlled drug in Ireland. Fentanyl patches are authorised for the management of malignant and non-malignant chronic intractable pain and a 25 micrograms (µg) per hour fentanyl patch equates to a daily dose of oral morphine of up to 90mg. Fentanyl patches should be used only in patients who have previously tolerated opioids because of a risk of significant respiratory depression in opioid-naïve patients. The initial dose should be based on a patient's opioid history. Information on starting doses and dose conversion can be found in the products' Summaries of Product Characteristics (SmPCs), which also include detailed information on appropriate use to minimise the risk of life-threatening adverse reactions due to accidental exposure and overdose.

Having reviewed global data, the IMB is aware of reports from other countries of life-threatening adverse reactions and death after fentanyl overdose in people who were using the patches to control malignant and non-malignant pain. Factors identified as possibly related to unintentional overdose include dosing errors (by healthcare professionals, patients, or caregivers); accidental exposure (particularly in children); and exposure of the patch to a heat source, possibly resulting in increased fentanyl absorption. Reports from other European countries provide some evidence of inappropriate prescribing of fentanyl patches, including prescribing in unlicensed indications and in opioid-naïve patients.

Advice for Healthcare Professionals

Healthcare professionals, particularly those who prescribe and dispense fentanyl patches, should fully inform patients and caregivers about directions for safe use:

- follow the prescribed dose in line with the approved product information
- follow the correct frequency of patch application
- ensure that old patches are removed before applying a new one
- patches must not be cut
- avoid touching the adhesive side of patches and wash hands after application
- follow instructions for safe storage and disposal of used or unused patches

The following safety messages are communicated in the SmPC for prescribers and in the package leaflet for patients:

- Increased body temperature, exposure of patches to external heat sources, and concomitant use of CYP3A4 inhibitors may lead to potentially dangerous rises in serum fentanyl levels.
- Concomitant use of other CNS depressants might also potentiate adverse effects of fentanyl.

Key Messages:

- **Fentanyl patches should only be used in accordance with the authorised indications and prescribing instructions.**
- **Fentanyl patches should be used only in patients who have previously tolerated opioids because of a risk of significant respiratory depression in opioid-naïve patients. The initial dose should be based on a patient's opioid history.**
- **Healthcare professionals, particularly those who prescribe and dispense fentanyl patches, should ensure that patients and caregivers are aware of the signs and symptoms of fentanyl overdose - i.e., trouble breathing or shallow breathing; tiredness; extreme sleepiness or sedation; inability to think, walk, or talk normally; and feeling faint, dizzy, or confused. Patients and caregivers should be advised to seek medical attention immediately if overdose is suspected.**
- **Patients who experience serious adverse events should have the patches removed immediately and should be monitored for up to 24 hours after patch removal.**

Healthcare Professionals are reminded to report any suspected adverse reactions or medication errors to the Irish Medicines Board using the online reporting form at www.imb.ie or using the freepost yellow card system.

¹Brand names include Durogesic DTrans, Fentanex, Matrifen, Mytanyl, Fental Matrix