

Safety Alert

Oct 2023

Fentanyl transdermal Patches - risks of Accidental use and Ingestion

EDA performs label update to include the following:

Accidental ingestion/exposure

Accidental ingestion or exposure of fentanyl, especially by children, can result in a fatal overdose of fentanyl. Accidental transfer of a fentanyl patch to the skin of non-patch wearer (particularly a child), while sharing a bed or being in close physical contact with a patch wearer, may result in an opioid overdose for the non-patch wearer. Patients should be advised that if accidental patch transfer occurs, the transferred patch must be removed immediately from the skin of the non-patch wearer. Patients and their caregivers should be given information on safe storage and disposal of unused fentanyl.

Background:

Therapeutic indications

Adults

Fentanyl is indicated for management of severe chronic pain that requires continuous long-term opioid administration.

Children

Long-term management of severe chronic pain in children from 2 years of age who are receiving opioid therapy.

References:

EMA ([Click here](#))