

6.2.4. Summary of Safety Concerns

6.2.4.1. Important Identified Risks

Risk	What is Known	Preventability
Breathing more slowly or weakly (respiratory depression)	Fentanyl can dangerously suppress breathing in any patient, leading to low body oxygen, unconsciousness, and even death. The risk of side effects is higher in patients with lung problems or breathing problems. Sometimes a lower dose of fentanyl is prescribed in these situations.	Patients who breathe more slowly or weakly while using fentanyl should discontinue treatment and immediately contact a doctor or visit a hospital.
Drug dependence and withdrawal	Physical or psychological dependence and symptoms of withdrawal may develop for repeat use of opium-like substances (opioids).	Patients who have been dependent or shown withdrawal while taking alcohol, prescription medicines, or illegal drugs should be monitored for signs of dependence or withdrawal.
Abuse, misuse, and diversion	Resistance (tolerance) may develop for repeat use of opium-like substances (opioids). Abuse or intentional misuse of fentanyl may result in overdose and/or death.	Patients who have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs should be monitored for signs of misuse, abuse, or addiction.
Accidental exposure	Accidental exposure to fentanyl patches has occurred, mainly because of confusion over product packaging, accidental transfer and improper disposal of the used product. To minimize the risk of accidental exposure to fentanyl patches, the name and strength of the drug on the patch are now printed in long-lasting ink that can be seen clearly by patients and caregivers. This change should help patients and caregivers find patches on patients' bodies and see patches that have fallen off, which children and pets could accidentally touch or eat. In addition, the SmPC and Patient Leaflet have been revised to include warnings concerning this risk. Section 4.4 (Special warnings and precautions for use) and Section 6.6 (Special Precautions for Disposal) of the core patch SmPC and corresponding changes to the Patient Leaflet have all been amended to warn patients and caregivers concerning potential accidental transfer of patches and the importance of proper disposal of used patches.	Patients should dispose of used and unused patches properly. Used patches should be folded inward so that the sticky sides meet. Unused patches should be returned to the hospital or pharmacy.
Medication error	Medication errors can result from mistakes by physicians, pharmacists, patients or caregivers. In order to avoid medication errors, the SmPCs and package leaflets should be read carefully before this medicine is used and kept for future reference. Any questions should be referred to the prescribing physician or the pharmacist. If the patient experiences any side effects, contact the patient's doctor or pharmacist.	Use these patches only as instructed by your health care provider. The outer packaging of each patch should be consulted to verify the dose of the patch before it is applied to the skin.
Overdose	Overdose can result from prescribing errors by physicians, dispensing errors by pharmacists,	Patients should use these patches only as instructed by

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