5.1  Addiction, Abuse, and Misuse

Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing tramadol hydrochloride extended-release tablets, and monitor all patients regularly for the development of these behaviors and conditions.

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TRAMADOL HYDROCHLORIDE

5.4  Contraindications

Contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus and strictures, and in patients who are receiving a full opioid agonist analgesic, including tramadol hydrochloride extended-release tablets. In these patients, use tramadol hydrochloride extended-release tablets may cause spasm of the sphincter of Oddi. Opioids may cause increases in gastrointestinal tract tone, which may be additive to the spasm of the sphincter of Oddi.

5.6  Warnings and Precautions

Cases of serotonin syndrome, a potentially life-threatening condition, have been reported with the use of tramadol, including tramadol hydrochloride extended-release tablets. The risk of serotonin syndrome may be greater with concomitant use of an SSRI or SNRI and tramadol hydrochloride extended-release tablets. The risk may be greater with concomitant use of a CYP2D6 inhibitor and tramadol hydrochloride extended-release tablets.

5.7  Drug Interactions

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of tramadol hydrochloride extended-release tablets, the risk is generally lowest during the initial dose titration of opioid analgesics and may be additive to the use of other CNS depressants.

Table: 102 (26)
Tramadol hydrochloride extended-release tablets are for oral use only. The abuse of tramadol hydrochloride extended-release tablets poses risks of severe misuse and abuse, which can lead to overdose and death.

The potential abuse and misuse of tramadol hydrochloride extended-release tablets can lead to overdose and death, especially in patients with a history of substance use disorder. The risk of abuse and misuse of tramadol hydrochloride extended-release tablets is increased by increasing the total daily dose, the number of tablets per dose, and the duration of treatment. Adverse reactions may occur in patients who abuse or misuse tramadol hydrochloride extended-release tablets. Although these reactions may occur in patients who do not have a history of substance use disorder, they are more likely to occur in such patients.

Tramadol hydrochloride extended-release tablets can be abused or misused in ways not intended by the manufacturer. It is important to take tramadol hydrochloride extended-release tablets as prescribed by your healthcare provider. Do not take more of tramadol hydrochloride extended-release tablets than prescribed, take other people’s tramadol hydrochloride extended-release tablets, or take tramadol hydrochloride extended-release tablets in a way that is not prescribed by your healthcare provider.

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