

Supplemental Approvals

Generic Name (Trade Name—Company)

January 31, 2011

Uses/Notes

Treatment of breakthrough pain in adult patients 18 years of age or older with cancer who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medication

Fentanyl

(Abstral—ProStrakan)

Sublingual tablets approved in six strengths

A new formulation of fentanyl, sublingual immediate-release tablets, has been [FDA](#) approved in six different strengths: 100, 200, 300, 400, 600, and 800 µg; the 100-µg strength is recommended to be taken as the initial dose. Because serious adverse reactions, including death, have been reported with other immediate-release fentanyl transmucosal products, this product is available only through a Risk Evaluation and Mitigation Strategy program, which requires pharmacies, distributors, health care providers, and patients to enroll.

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<http://www.aphanet.org/sublingual-tablets-approved-six-strengths>

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