

News Article downloaded from - <http://www.bioportfolio.com> on Friday, November 27, 2009
Read [Meda Launches Onsolis\(TM\) \(Fentanyl Buccal Soluble Film\) for the Treatment of Breakthrough Cancer Pain in Opioid Tolerant Patients](http://www.bioportfolio.com/news/Meda-Launches-Onsolis(TM)-(Fentanyl-Buccal.html)) on BioPortfolio.com
([http://www.bioportfolio.com/news/Meda-Launches-Onsolis\(TM\)-\(Fentanyl-Buccal.html\)](http://www.bioportfolio.com/news/Meda-Launches-Onsolis(TM)-(Fentanyl-Buccal.html)))

Meda Launches Onsolis(TM) (Fentanyl Buccal Soluble Film) for the Treatment of Breakthrough Cancer Pain in Opioid Tolerant Patients

Tuesday 13th of October 2009 8:00

-- Training prescribers, pharmacists, and patients about proper dosing and administration.

Under the FOCUS Program, only prescribers, pharmacies, and patients registered with the program are able to prescribe, dispense, and receive Onsolis. This program provides educational materials, patient counseling and managed distribution of the drug. Healthcare practitioners who wish to enroll in the FOCUS Program may call 1-877-466-7654 (1-877-4ONSOLIS) or visit www.OnsolisFocus.com.

Clinical Study

The efficacy of Onsolis was investigated in a clinical trial in opioid tolerant adult patients experiencing breakthrough cancer pain. Breakthrough cancer pain was defined as a transient flare of moderate-to-severe pain occurring in patients with cancer experiencing persistent cancer pain otherwise controlled with maintenance doses of opioid medications including at least 60 mg morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for one week or longer. All patients were on stable doses of either long-acting oral opioids or transdermal fentanyl for their persistent cancer pain.

A double-blind, placebo-controlled, crossover study was performed in patients with cancer to evaluate the effectiveness of Onsolis for the treatment of breakthrough cancer pain. Open-label titration identified a successful dose of Onsolis, within the range of 200 to 1200 mcg. A "successful" dose was defined as a dose in which a patient obtained adequate analgesia with tolerable side effects. In the double-blind portion of the study, patients who identified a successful dose were randomized to a sequence of nine treatments; six with the successful dose of Onsolis and three with placebo. Of the patients who entered the study, 54 percent achieved a successful dose during the titration phase and 4 percent withdrew for lack of effective pain relief. The final titrated dose of Onsolis for breakthrough cancer pain was not predicted from the daily maintenance dose of opioid used to manage the persistent cancer pain and, therefore, the dose was determined by titration starting at 200 mcg. The primary outcome measure, the mean sum of pain intensity differences at 30 minutes (SPID30) for Onsolis-treated episodes was statistically significantly higher than for placebo-treated

episodes.

About Onsolis

Onsolis is a small, dissolvable, polymer film, formulated with the opioid fentanyl for application to the buccal mucosa (inner lining of the cheek) that is designed to deliver a dose of drug across the oral mucous membranes. Fentanyl belongs to the group of medicines called narcotic analgesics, which are used to relieve pain. Onsolis was evaluated in over 300 patients; over 90,000 doses were administered in clinical trials. Onsolis adheres to the buccal mucosa in 5 seconds, starts to dissolve in 15 to 30 minutes and delivers fentanyl across the mucosa. In clinical trials, following buccal application of Onsolis in healthy volunteers, the absolute bioavailability of fentanyl was 71%.

About Breakthrough Pain in Cancer

Breakthrough Pain (BTP) in cancer is a transitory, severe, or excruciating pain flare-up that "breaks through" the relief provided by around-the-clock analgesics. Unlike persistent cancer pain, BTP is generally rapid in onset (within three minutes) and lasts up to two hours. A large multicenter survey conducted by pain specialists in twenty-four countries found that 65% of 1,095 cancer patients had BTP. It is estimated that over a half-million people in the U.S. with cancer suffer from breakthrough pain, however, only about twenty thousand receive a treatment approved for the condition.

IMPORTANT SAFETY INFORMATION

Onsolis (fentanyl buccal soluble film) is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, *who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*. Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

Onsolis is contraindicated in opioid non-tolerant patients; in the treatment of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room; and in patients with intolerance or hypersensitivity to fentanyl, Onsolis, or its components. Life-threatening respiratory depression could occur in patients not taking chronic opiates.

Onsolis contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics.

Clinically significant respiratory and CNS depression can occur; patients should be monitored accordingly. Onsolis films contain medicine in an amount that can be fatal to a child. Keep out of the reach of children and dispose of unneeded films properly. Use with other CNS depressants or CYP3A4 inhibitors may increase

depressant effects including hypoventilation (which may lead to potentially fatal respiratory depression), hypotension, and profound sedation; dosage adjustments may be warranted. Onsolis may impair ability for the performance of potentially dangerous tasks (e.g., driving a car or operating machinery). Onsolis should be titrated cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to hypoventilation. Onsolis should be administered with extreme caution in patients susceptible to intracranial effects of CO₂ retention.

Substantial differences exist in the pharmacokinetic profile of Onsolis compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of Onsolis for any other fentanyl product may result in fatal overdose.

The most common adverse reactions (frequency greater than or equal to 10%) seen in Onsolis clinical trials were: nausea, vomiting, dizziness, dehydration, dyspnea, and somnolence.

Safety and efficacy below age 18 years have not been established. Onsolis should be administered with caution to patients with renal or hepatic impairment.

Please see full prescribing information available at www.Onsolis.com.

For more information, contact Anders Larnholt, VP Corporate Development & Investor Relations at anders.larnholt@meda.se or +46 709 458 878.

MEDA AB (publ) is a leading international specialty pharma company. Meda's products are sold in 120 countries worldwide and the company is represented by its own organizations in more than 40 countries. The Meda share is listed under Large Cap on the Nasdaq OMX Nordic Stock Exchange in Stockholm. Find out more, visit www.meda.se.

SOURCE Meda Pharmaceuticals Inc.

Via PR Newswire - PRNewswire.co.uk

Nothing in this document should be used in place of personal medical advice from your own qualified medical practitioner. See BioPortfolio.com [User Agreement](#)

Send comments and feedback to:

Peter Barfoot Managing Director, BioPortfolio Ltd.

UK Tel: (+44) 1300 321501

USA Voicemail and Fax: (+1) 415 680 2472

[Peter Barfoot peter.barfoot@bioportfolio.com](mailto:peter.barfoot@bioportfolio.com)

All rights reserved. All other trademarks recognized.

BioPortfolio Limited is registered in England & Wales at Stafford House, 10 Prince of Wales Road,
Dorchester, Dorset, DT1 1PW, UK. No.3312883 VAT No. GB 744 6483 10

Copyright 1997-2009 - BioPortfolio Limited.

