Abstral® ▼ 100 micrograms, 200 micrograms, 300 micrograms, 400 micrograms, 600 micrograms and 800 micrograms Sublingual Tablets (fentanyl)

Abbreviated Prescribing Information Please refer to Summary of Product Characteristics before prescribing. **Presentation** Sublingual tablets containing 100µg, 200µg, 300µg, 400µg, 600µg and 800µg of fentanyl. **Indication** Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. **Dosage and Administration** Only for use in patients who are considered tolerant to their opioid therapy for persistent cancer pain (i.e. using 60 mg oral morphine per day or 25 micrograms transdermal fentanyl per hour or equivalent). Administer directly under the tongue and allow to dissolve without chewing, sucking or swallowing. *Adults:* Initially 100µg, titrating upwards as necessary. Patients must be monitored closely by a health professional during the titration process. Once an appropriate dose has been established patients should be maintained on this dose and should limit consumption to a maximum of four doses per day. *Elderly and patients with renal and hepatic impairment:* Special care needed in titrating elderly patients and patients with kidney or liver dysfunction; observe for signs of fentanyl toxicity. *Children and adolescents:* Must not be used in patients less than 18 years of age. **Contraindications** Hypersensitivity to any of the ingredients; opioid-naïve patients; severe respiratory depression or severe obstructive lung conditions. **Warnings and Precautions** Instruct patients and carers to keep tablets out the sight and reach of children. Ensure patients and carers follow instructions for use and know what action to take in case of overdose. Before starting Abstral, ensure long-acting opioid treatment for persistent pain is stable. Dependence may develop upon repeated administration of opioids. Risk of clinically significant respiratory depression. Particular caution needed during dose titration in patients with COPD or other conditions predisposing to respiratory depression. Administer with extreme caution in patients who may be particularly susceptible to the intracranial effects of hypercapnia. Opioids may mask the clinical course in patients with head injuries. Use with caution in patients with bradyarrhythmias, hypovolaemia, hypotension, mouth wounds or mucositis. Monitor carefully use in elderly, cachectic and debilitated patients. Possible symptoms of withdrawal on cessation are anxiety, tremor, sweating, paleness, nausea and vomiting. **Interactions** Fentanyl is metabolised by CYP3A4. Use with caution if given concomitantly with CYP3A4 inhibitors such as macrolide antibiotics, azole antifungal agents, protease inhibitors or grapefruit juice. Concomitant use of other CNS depressants, such as other morphine derivatives, general anaesthetics, skeletal muscle relaxants, sedative antidepressants, sedative H1 antihistamines, barbiturates, anxiolytics, hypnotics, antipsychotics, clonidine and related substances may produce increased CNS depressant effects. Respiratory depression, hypotension and sedation may occur. Concomitant use of alcohol or partial opioid agonists/antagonists (e.g. buprenorphine, pentazocine) is not recommended. Not recommended for use in patients who have received MAO inhibitors within 14 days. **Pregnancy** Safety in pregnancy not established. Use only when necessary. Long-term treatment may cause withdrawal symptoms in newborn infant. Do not use during labour and delivery since fentanyl crosses the placenta and may cause respiratory depression in foetus or infant. **Lactation** Fentanyl is excreted into breast milk and should only be used if the benefits clearly outweigh the potential risks for both mother and child. **Driving, etc** Fentanyl may impair mental or physical ability. Advise patients not to drive or operate machinery if they become dizzy, drowsy or experience blurred or double vision. **Undesirable Effects** Typical opioid side-effects are to be expected. The most serious adverse reactions are respiratory depression, hypotension and shock. The most commonly reported adverse reactions include nausea, vomiting, constipation, headache, somnolence/fatigue and dizziness. See SPC for details of these and other undesirable effects. **Overdose** Immediate management includes removal of any remaining tablets from the mouth, physical and verbal stimulation and an assessment of the level of consciousness. A patent airway should be established and maintained, and assisted ventilation initiated if appropriate. Adequate body temperature and parenteral fluid intake should be maintained. Consider the use of opioid antagonists. **Pack Size and UK Price** Abstral 100-400µg 10 tablets: £49.99, Abstral 100-800µg 30 tablets: £149.70. **Marketing Authorisation Numbers**: **UK** PL 16508/0030-35; **ROI** PA1049/6/2-7. **Legal category** CD POM. Further information is available from the **Marketing Authorisation Holder** ProStrakan Ltd, Galashiels, TD1 1QH, UK or in **ROI** from Fannin Ltd, South County Business Park, Leopardstown, Dublin 18. ® Registered Trade Mark. **Date of PI Preparation** Oct 2009.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk or www.imb.ie. Adverse events should also be reported to the following: UK ProStrakan Ltd. on +44 (0)1896 664000; Rep. of Ireland: Fannin Ltd on +353 (0) 1 2907000.