ABBREVIATED PRESCRIBING INFORMATION:
Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Buccal tablets containing 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg fentanyl (as citrate). **Indications:** Treatment of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain. **Dosage and Administration:** *Method:* Patient should remove the tablet from the blister and immediately place the entire tablet within the buccal cavity (near a molar between the cheek and gum) and retain for a period sufficient to allow disintegration of the tablet which usually takes approximately 14-25 minutes. Alternatively, the tablet could be placed sublingually. The tablet should not be sucked, chewed or swallowed. Treatment should be supervised by a physician experienced in the management of opioid therapy in cancer patients and who is aware of the potential abuse of fentanyl. Effentora should be individually titrated to an "effective" dose that provides adequate analgesia and minimises adverse reactions. Once an effective dose has been established, the patient should continue to take this dose as a single tablet. Patients should wait at least 4 hours before treating another BTP episode with Effentora during maintenance therapy. *Hepatic and renal impairment:* Effentora should be administered with caution to patients with moderate to severe hepatic or renal impairment. Please see section 4.4 of SmPC for more information. *Xerostomia:* Patients experiencing xerostomia are advised to drink water to moisten the buccal cavity prior to administration of Effentora. If this recommendation does not result in an adequate disintegration, then a switch of therapy may be advised. *Elderly:* in clinical studies patients older than 65 years tended to titrate to a lower effective dose than younger patients. *Paediatric population:* The safety and efficacy of Effentora in children aged 0 to 18 years have not been established. No data is available. **Contraindications:** Hypersensitivity to the active substance or any of the excipients listed in section 6.1 of the SmPC. Patients not on maintenance opioid therapy. Severe respiratory depression or severe obstructive lung conditions. Treatment of acute pain other than breakthrough pain. **Warnings and Precautions:** Patients and their carers must be instructed to keep all Effentora tablets out of the sight and reach of children. To minimise the risks of opioid-related undesirable effects it is imperative that patients be monitored closely during the titration process and that the maintenance opioid therapy has been stabilised before Effentora therapy begins. As with all opioids, there is a risk of clinically significant respiratory depression. Improper use in patients without maintenance opioid therapy and/or improper dosing have resulted in fatal outcome with Effentora as well as with other fentanyl products. Effentora should only be used for conditions specified in section 4.1. of the SmPC. Dosage increase should be done with caution particularly in patients with chronic obstructive pulmonary disease or other medical conditions predisposing them to respiratory depression. Extreme caution should be exercised in patients who may be particularly susceptible to the intracranial effects of CO2 retention, such as those with evidence of increased intracranial pressure or impaired consciousness. Effentora should be used with caution in patients with pre-existing bradyarrhythmias, with hepatic or renal impairment. Careful consideration should be given to patients with hypovolaemia and hypotension. **Interactions:** Fentanyl is metabolised mainly via the cytochrome P450 3A4 isoenzyme system (CYP3A4). Coadministration with agents that induce 3A4 activity may reduce the efficacy of Effentora. Concomitant use of Effentora with strong CYP3A4 inhibitors (e.g., ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, and nelfinavir) or moderate CYP3A4 inhibitors (e.g., amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, and verapamil) may result in serious reactions including fatal respiratory depression and patients should be carefully monitored for an extended period of time. The concomitant use of other central nervous system depressants may produce additive depressant effects (please refer to the SmPC for full list). Effentora should not be used in patients who have received monoamine oxidase inhibitors (MAOIs) within 14 days. The concomitant use of partial opioid agonists/antagonists (e.g. buprenorphine, nalbuphine, pentazocine) is not recommended. **Fertility, pregnancy and lactation:** Effentora should not be used in pregnancy unless clearly necessary. Effentora should not be used during labour and delivery (including caesarean section). If Effentora is administered, an antidote for the child should be readily available. Fentanyl passes into breast milk and may cause sedation and respiratory depression in the breast-fed child. Fentanyl should not be used by breastfeeding women and breastfeeding should not be resumed within 48 hours of administration. There is no human data on fertility available. In animal studies, male fertility was impaired (see section 5.3 of the SmPC). **Effects on ability to drive and use machines:** Opioid analgesics can impair the ability to drive or operate machinery. If affected patients should be advised not to engage in these tasks. **Undesirable effects:** Please see the SmPC for complete list of adverse effects. The most serious adverse reactions are respiratory depression, circulatory depression, hypotension and shock and all patients should be closely monitored for these. Very common effects (>10%) – nausea, vomiting, headache, dizziness. Application site reactions including bleeding, pain, ulcer, irritation, paraesthesia, anaesthesia, erythema, oedema, swelling and vesicles. Common (>1% - 10%) – weight decreased, tachycardia, anaemia, neutropenia, dysgeusia, somnolence, lethargy, tremor, sedation, hypoaesthesia, migraine, dyspnoea, pharyngolaryngeal pain, constipation, stomatitis, dry mouth, diarrhoea, abdominal pain, gastro-oesaphageal reflux disease, stomach discomfort, dyspepsia, toothache, pruritus, hyperhydrosis, rash, myalgia, back pain, anorexia, oral candidiasis, fall, hypotension, hypertension, peripheral oedema, fatigue, asthenia, drug withdrawal syndrome, chills, depression, anxiety, confusional state, insomnia. **Marketing Authorisation Numbers:** EU/1/08/441/001-010. **Marketing Authorisation Holder:** Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, The Netherlands. **Legal Category:** Medicinal product subject to restricted medical prescription. **Full prescribing information available from:** Teva Pharmaceuticals Ireland, Floor 1, Wing A, Building 1, Finnabair Business & Technology Park, Dundalk, Co. Louth, Telephone: 1800 201 700. **Date of preparation:** March 2013. IE/EFF/13/0006

EFFENTORA fentanyl buccal tablet

Provided by: Teva (Ireland) Floor 1, Wing A, Building 1, Finnabair Business & Technology Park, Dundalk, Co. Louth Tel: 051 32 1740 Fax: 042 935 1516; Medical Information: +44 207 540 7117

TVIRL/EFF/12/0003(1)
Date of preparation: April 2014

EFFENTORA fentanyl buccal tablet

Breakthrough Pain Episode

Finding the right dose for your patient...

A As soon as the pain starts take...

B **If the pain stops** within 30 minutes, this is the correct dose. **Stop here** and treat all future episodes of pain with this dose, waiting at least 4 hours before treating the next pain episode.

C If the **pain does not stop** after 30 minutes, take...

D **Wait at least 4 hours after step C before treating the next pain episode of breakthrough pain**

Pull the slider out to show the episode number indicated and begin treating the next episode at step A.

Pull slider to this episode

Note: This titration tool should only be used with direct supervision by a healthcare professional experienced in the management of opioid therapy in cancer patients.

Effentora® – Information for Patients and Healthcare Professionals

Effentora® is a breakthrough pain relieving medicine known as an opioid containing the active ingredient Fentanyl. Patients are prescribed Effentora® to help manage their breakthrough cancer pain when it occurs. Breakthrough cancer pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.[1] Before commencing treatment with Effentora®, a patient must be stabilised on opioid maintenance therapy for their background persistent pain.

Effentora® is a buccal tablet that should be placed in the mouth, between the gum and cheek, where it dissolves and is absorbed through the lining of the mouth into the blood system. This allows quick absorption of the medicine to help relieve the breakthrough pain. Alternatively, if preferred, the tablet may be placed under the tongue.

- Effentora® should be individually titrated to an effective dose. The goal of titration is to find the optimal dose at which patients generally need only one tablet of Effentora® per episode of BTcP.
- The effective dose of Effentora® is that which provides satisfactory relief within 30 minutes with tolerable side effects.
- The effective dose of Effentora® for BTcP is not predictable from the daily maintenance dose of around the clock opioid for persistent cancer pain.
- Patients should start treatment at 100µg Effentora® and titrate upwards as appropriate.
- Effentora® should be taken when the breakthrough cancer pain starts.
- Effentora® may be taken before or after meals. A patient should not consume any food or drink when a tablet is in the mouth.
- In case of dry mouth, a patient can drink some water to moisten the mouth before using Effentora®.
- It is recommended that the patient change the site of tablet application for each episode of breakthrough pain that you treat with Effentora®.
- If a patient wears dentures, it may be necessary to remove the dentures before taking Effentora® to ensure that the medicine is adequately absorbed from the tablet.
- Good oral hygiene is recommended when using Effentora®.
- Effentora® should not be used to treat any other short-term pain.
- Ask your pharmacist how to dispose of any unopened Effentora® tablets remaining, as soon as they are no longer required.

The pain-relieving medicine in Effentora® is very strong and could have very serious consequences if taken accidentally by a child or anyone for whom it has not been prescribed. Keep Effentora® in a safe and secure place, away from the reach and sight of children. If anyone accidentally takes Effentora, call for emergency medical help immediately.

EFFENTORA fentanyl buccal tablet

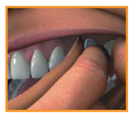
How to use Effentora®

To get the most benefit from Effentora® it is important that you use this medication correctly:

1. PEEL IT

- Effentora® tablets come individually sealed in a blister package. Only open a blister when a tablet is ready to use. The tablet must be used immediately once removed from the blister.
- Separate one of the blister units from the blister card by tearing apart at the perforations.
- Bend the blister unit along the line printed on the backing foil where indicated.
- Peel the backing foil back to expose the tablet.
- Do NOT attempt to push the tablet through the blister, because this can damage the tablet.

2. PLACE IT



- When the tablet is removed from the blister unit, the patient should immediately place the tablet near a molar tooth between the cheek and gum.
- Do not attempt to crush or split the tablet.
- Alternatively, if preferred, the tablet may be placed under the tongue.
- Do not bite, suck, chew, or swallow the tablet, as this will result in less pain relief than when taken as directed.

3. FEEL IT

- The tablet should be allowed to dissolve between the cheek and gum. This takes approximately 14 to 25 minutes.
- The patient may feel a gentle bubbling sensation as the tablet dissolves.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed with a glass of water.

1. Effentora must not be prescribed in pain other than breakthrough cancer pain.
2. Effentora must not be prescribed in patients with short term pain only.
3. Effentora must not be prescribed in patients without around-the-clock opioid pain medication.
4. Effentora must not be prescribed in patients below 18 years of age.

If you have any further questions on Effentora®, please ask your Teva representative.

5	4	3	2	1
4 x 200 µg tablet 	3 x 200 µg tablet 	2 x 200 µg tablet 	1 x 200 µg tablet 	1 x 100 µg tablet 
800 µg	600 µg	400 µg	200 µg	100 µg
Maximum dose reached	1 x 200 µg tablet 	1 x 200 µg tablet 	1 x 200 µg tablet 	1 x 100 µg tablet 
	5	4	3	2

PULL