

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: EFFENTORA 100/200/400/600/800
Registration Nos.: EFFENTORA 100: 48/2.9/0054 EFFENTORA 200: 48/2.9/0055 EFFENTORA 400: 48/2.9/0056 EFFENTORA 600: 48/2.9/0057 EFFENTORA 800: 48/2.9/0058	Dosage form & strength: Each effervescent buccal tablet contains 100, 200, 400, 600 and 800 micrograms of fentanyl (as citrate) respectively

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S6

EFFENTORA™ 100, (100 micrograms) buccal tablets

EFFENTORA™ 200, (200 micrograms) buccal tablets

EFFENTORA™ 400, (400 micrograms) buccal tablets

EFFENTORA™ 600, (600 micrograms) buccal tablets

EFFENTORA™ 800, (800 micrograms) buccal tablets

Fentanyl citrate

Read all of this leaflet carefully before you start taking EFFENTORA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- EFFENTORA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT EFFENTORA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EFFENTORA

3. HOW TO TAKE EFFENTORA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE EFFENTORA

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1. WHAT EFFENTORA IS AND WHAT IT IS USED FOR:

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EFFENTORA contains the active substance fentanyl citrate. EFFENTORA is a pain-relieving medicine known as an opioid, which is used to treat breakthrough pain in adult patients with cancer who are already taking other opioid pain medicines for their persistent (around-the-clock) cancer pain. Breakthrough pain is additional, sudden pain that occurs in spite of you having taken your usual opioid pain-relieving medicines.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EFFENTORA:

Do not take EFFENTORA:

- if you are hypersensitive to fentanyl or to any of the other ingredients of this medicine (listed in **section 6**)
- if you are not regularly using a prescribed opioid medicine (e.g. codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you must not use EFFENTORA, because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop
- if you suffer from severe breathing problems or severe obstructive lung conditions
- if you suffer from short-term pain other than breakthrough pain
- if you are taking a medicine which contains sodium oxybate
- if you are breastfeeding your baby.

EFFENTORA is not recommended for use in children and adolescents below 18 years of age due to the lack of safety data.

Warnings and precautions:

Take special care with EFFENTORA:

Keep using the opioid pain medicine you take for your persistent (around-the-clock) cancer pain during your EFFENTORA treatment.

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Whilst you are being treated with EFFENTORA, do not use other fentanyl treatments previously prescribed for your breakthrough pain. If you still have some of these fentanyl treatments at home, contact your pharmacist to check how to dispose of them.

Store this medicine in a safe and secure place, where other people cannot access it (see **section 5**.

How to store EFFENTORA for more information).

Talk to your doctor before taking EFFENTORA if:

- your other opioid pain medicine taken for your persistent (around-the-clock) cancer pain is not stabilised yet (at the correct dosage your doctor wants it to be)
- you are suffering from any condition that has an effect on your breathing such as asthma, wheezing or shortness of breath
- you use benzodiazepines (see **section 2** under **Other medicines and EFFENTORA**). Using benzodiazepines can increase the chances of getting serious side effects including death
- you have a head injury
- you have an exceptionally slow heart rate or other heart problems
- you have liver or kidney problems, as these organs have an effect on the way in which your system breaks down the medicine
- you have low amount of fluid in the circulation or low blood pressure
- you use antidepressants or antipsychotics, (selective serotonin reuptake inhibitors [SSRIs], serotonin norepinephrine reuptake inhibitors [SNRIs], monoamine oxidase (MAO) inhibitors; see **section 2** under **Do not use EFFENTORA and Other medicines and EFFENTORA**). The use of these medicines with EFFENTORA can lead to a serotonin syndrome, a potentially life-threatening condition (see **section 2** under **Other medicines and EFFENTORA**)
- you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use (see **section 4** under **serious side effects**)
- you have a history of alcoholism or any drug abuse or dependence

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- you drink alcohol; please refer to **section EFFENTORA with food, drink and alcohol**
- you are over 65 years old - you may need a lower dose and any dose increase will be reviewed very carefully by your doctor.

Consult your doctor WHILE using EFFENTORA if:

- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine as prescribed by your doctor.
- you experience a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones.
- you experience sleep-related breathing disorders: Effentora can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood).

The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Long-term use and tolerance:

This medicine contains fentanyl which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using EFFENTORA. This is known as hyperalgesia. Increasing the dose of EFFENTORA may help to further reduce your pain for a while, but it may also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dose or to gradually decrease your use of EFFENTORA.

Dependence and addiction:

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Repeated use of EFFENTORA can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need or how often you need to use it. You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain. The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on EFFENTORA if:

- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ('addiction')
- you are a smoker
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness.

If you notice any of the following signs whilst using EFFENTORA, it could be a sign that you have become dependent or addicted.

- you need to use the medicine for longer than advised by your doctor
- you need to use more than the recommended dose
- you are using the medicine for reasons other than prescribed, for instance, 'to stay clam' or 'help you sleep'
- you have made repeated, unsuccessful attempts to quit or control the use of the medicine
- when you stop taking the medicine you feel unwell (e.g. nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating), and you feel better once using the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely.

Seek URGENT medical advice if:

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- you experience symptoms such as difficulty in breathing or dizziness, swelling of the tongue, lip or throat while using EFFENTORA. These might be early symptoms of a serious allergic reaction (anaphylaxis, hypersensitivity; see **section 4** under **serious side effects**).

What to do if someone accidentally takes EFFENTORA:

If you think someone has accidentally taken EFFENTORA please seek immediate medical assistance.

Try to keep the person awake until emergency help arrives.

If someone has accidentally taken EFFENTORA, they may have the same side effects as described in **section 3** under **If you take more EFFENTORA than you should**.

Children and adolescents:

Do not give EFFENTORA to children below 18 years of age.

Other medicines and EFFENTORA:

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Especially talk to your doctor if you are taking one of the following:

- concomitant use of EFFENTORA and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe EFFENTORA together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking (such as sleeping pills, medicines to treat anxiety, some medicines to treat allergic reactions (antihistamines), or tranquillisers) and follow

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your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- any medicines that might have an effect on the way in which your body breaks down EFFENTORA, such as ritonavir, nelfinavir, amprenavir, and fosamprenavir (medicines that help control HIV infection) or other so-called CYP3A4 inhibitors such as ketoconazole, itraconazole, or fluconazole (used for treatment of fungal infections), troleandomycin, clarithromycin, or erythromycin (medicines for treatment of bacterial infections), aprepitant (used for severe nausea) and diltiazem and verapamil (medicines for treatment of high blood pressure or heart diseases).
- some muscle relaxants - such as baclofen, diazepam (see also **section Warnings and precautions**).
- certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.
- some painkillers for nerve pain (gabapentin and pregabalin).
- medicines called monoamine-oxidase (MAO) inhibitors (used for severe depression) or if taken in the past 2 weeks.
- the risk of side effects increases if you are taking medicines such as certain antidepressants or antipsychotics. EFFENTORA may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38 °C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether EFFENTORA is suitable for you.

EFFENTORA with food, drink and alcohol:

- EFFENTORA may be taken before or after, but not during, meals. You may drink some water before taking EFFENTORA to help moisten your mouth, but you should not drink or eat anything while taking

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the medicine.

- you should not drink grapefruit juice while taking EFFENTORA because it may affect the way your body breaks down EFFENTORA.
- do not drink alcohol while using EFFENTORA. It can increase the risk of experiencing serious side effects including death.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking EFFENTORA.

Do not take EFFENTORA during pregnancy or when breastfeeding your baby.

Driving and using machines:

EFFENTORA may make you feel sleepy or dizzy, have blurred or double vision or have difficulty in concentrating. It is not always possible to predict to what extent EFFENTORA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which EFFENTORA affects you.

EFFENTORA contains sodium:

Each tablet of EFFENTORA 100 micrograms contains 10 mg of sodium. Each tablet of EFFENTORA 200 micrograms, EFFENTORA 400 micrograms, EFFENTORA 600 micrograms and EFFENTORA 800 micrograms contains 20 mg of sodium. You should take this into consideration if you are on a controlled sodium diet and seek advice from your doctor.

3. HOW TO TAKE EFFENTORA:

Do not share medicines prescribed for you with any other person.

Always take EFFENTORA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using EFFENTORA, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see **section 2**).

When you first start taking EFFENTORA, your doctor will work with you to find the dose that will relieve your breakthrough pain. It is very important that you take EFFENTORA exactly as the doctor tells you. The initial dose is 100 micrograms. During determination of your right dose, your doctor may instruct you to take more than one tablet per episode. If your breakthrough pain is not relieved after 30 minutes, take only 1 more tablet of EFFENTORA during the titration period.

Once the right dose has been determined with your doctor, take 1 tablet for an episode of breakthrough pain as a general rule. In the further course of treatment your requirement for analgesic therapy may change. Higher doses may be necessary. If your breakthrough pain is not relieved after 30 minutes, take only 1 more tablet of EFFENTORA during this dose-readjustment period.

Contact your doctor if your right dose of EFFENTORA does not relieve your breakthrough pain. Your doctor will decide if your dose needs to be changed.

Wait at least 4 hours before treating another episode of breakthrough pain with EFFENTORA.

You must let your doctor know immediately if you are using EFFENTORA more than four times per day, as a change may be required to your treatment regimen. Your doctor may change the treatment for your persistent pain; when your persistent pain is controlled again, your doctor may need to change the dose of EFFENTORA. If your doctor suspects EFFENTORA-related increased sensitivity to pain (hyperalgesia), a reduction of your EFFENTORA dose may be considered (see **section 2** under **Warnings and precautions**). For the most effective relief, let your doctor know about your pain and how EFFENTORA is working for you, so that the dose can be changed if needed.

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Do not change doses of EFFENTORA or your other pain medicines on your own. Any change in dosage must be prescribed and monitored by your doctor.

If you are not sure about the right dose, or if you have questions about taking this medicine, you should contact your doctor.

Method of administration:

EFFENTORA effervescent buccal tablets are for oromucosal use. When you place a tablet in your mouth, it dissolves and the medicine is absorbed through the lining of your mouth, into the blood system. Taking the medicine in this way allows it to be absorbed quickly to relieve your breakthrough pain.

Taking the medicine:

- Open the blister only when you are ready to use the tablet. 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 where indicated.
- Peel the blister backing to expose the tablet. Do NOT attempt to push the tablet through the blister, because this can damage the tablet.



- Remove the tablet from the blister unit and immediately place the entire tablet near a molar tooth between the gum and the cheek (as shown in the picture). Sometimes, your doctor may tell you to place the tablet under your tongue instead.

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- If you have a very dry mouth, rinse your mouth with water before inserting the tablet.
- Do not attempt to crush or split the tablet.



- Do not bite, suck, chew, or swallow the tablet, as this will result in less pain relief than when taken as directed.
- The tablet should be left between the cheek and gum until dissolved, which usually takes approximately 14 to 25 minutes.
- You may feel a gentle bubbling sensation between your cheek and gum as the tablet dissolves.
- In case of irritation, you may change the placement of the tablet on the gum.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed with a glass of water.

If you take more EFFENTORA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

- The most common side effects are feeling sleepy, sick or dizzy. If you begin to feel very dizzy, or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away.
- A serious side effect of EFFENTORA is slow and/or shallow breathing. This can occur if your dose of EFFENTORA is too high or if you take too much EFFENTORA. In severe cases taking too much EFFENTORA may also lead to coma. If you feel very dizzy, very sleepy or have slow or shallow

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breathing, seek immediate medical assistance.

- An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

If you forget to take EFFENTORA:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking EFFENTORA:

You should discontinue EFFENTORA when you no longer have any breakthrough pain. You must however continue to take your usual opioid pain-relieving medicine to treat your persistent cancer pain as advised by your doctor. You may experience withdrawal symptoms similar to the possible side effects of EFFENTORA when discontinuing EFFENTORA. If you experience withdrawal symptoms or if you are concerned about your pain relief, you should contact your doctor. Your doctor will evaluate if you need medicine to reduce or eliminate the withdrawal symptoms.

4. POSSIBLE SIDE EFFECTS:

EFFENTORA can have side effects.

Not all side-effects reported for EFFENTORA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EFFENTORA, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using EFFENTORA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- shallow breathing, low blood pressure and shock. EFFENTORA like other fentanyl products can cause very severe breathing problems which can

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lead to death. If you become very sleepy or have slow and/or shallow

breathing

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EFFENTORA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency. A condition in which the adrenal glands do not produce enough hormones
- loss of consciousness, stop in breathing, convulsion (fits)
- severe stomach pain, which may reach to your back, as this could be a sign of inflammation of the pancreas (pancreatitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- weight loss
- fast heart rate
- a deficiency of red cells
- an abnormally low count of a type of white blood cell (neutrophils)
- headache, abnormal taste, sleepiness, sedation, excessive tiredness, weakness, migraine, numbness, shaking

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- shortness of breath, painful throat
- nausea, vomiting, constipation, inflammation of the mouth, dry mouth, diarrhoea, heartburn, loss of appetite, stomach pain, uncomfortable stomach, indigestion, toothache
- excessive sweating
- muscle pain, back pain
- loss of appetite
- oral thrush
- falls
- decreased or raised blood pressure
- at the site of tablet application: pain, ulcer, irritation, bleeding, numbness, loss of sensation, redness, swelling or spots, swelling of arms or legs, tiredness, no energy, chills
- feeling anxious or confused, depression, sleeplessness.

Less frequent side effects:

- decrease in cells that help the blood to clot, decreased haemoglobin and haematocrit (seen in blood results)
- low heart rate
- a low number of platelets in the blood
- reduced consciousness, lack of concentration, loss of balance, problem with speaking
- mental health disorders that primarily affect learning, memory, perception, and problem solving, and include amnesia, dementia, and delirium
- abnormal and involuntary movements
- disturbed or blurred vision, red eye, eye distortion (floaters in the eye, flashes of light)
- ringing in the ear, ear discomfort, spinning
- severe breathing problems, trouble breathing during sleep
- ulcer, loss of sensation, discomfort, unusual colour, soft tissue disorder, tongue disorder, painful or blistered or ulcerated tongue, gum pain, chapped lips, tooth disorder

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- brittle nails
- inflammation of the oesophagus, paralysis of the gut
- ongoing or recurrent burning in the mouth with no obvious cause
- difficulty passing urine
- cold sweat, swollen face, generalised itching, hair loss
- muscle twitching, muscular weakness
- sore throat, fluid-filled sore in mouth
- feeling very warm (hot flushes)
- feeling unwell, chest discomfort, thirst, feeling cold, feeling hot
- lack of sex hormones
- feeling elated, nervous, abnormal, jittery or slow; seeing or hearing things that are not really there (hallucinations), change in mental state, dependence (reliance on the medicine, addiction), disorientation.

Frequency unknown:

- stopped breathing or ineffectively breathing
- fever, prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the newborn which can be life-threatening
- drug tolerance (see **section 2**)
- drug dependence (reliance on the medicine, addiction), using it the wrong way (see **section 2**)
- drug abuse (see **section 2**).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's

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publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of EFFENTORA.

5. HOW TO STORE EFFENTORA:

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the tablets in the original package to protect from moisture.

Keep blister in carton until required for use.

Do not use the tablets after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What EFFENTORA contains:

The active ingredient is fentanyl (as citrate).

The other ingredients are: citric acid, magnesium stearate, mannitol, sodium carbonate, sodium hydrogen carbonate and sodium starch glycolate (Type A).

What EFFENTORA looks like and contents of the pack:

EFFENTORA 100: White to off-white flat-faced, round, beveled tablet. Debossed with Cephalon 'C' on one side and '1' on the other side.

EFFENTORA 200: White to off-white, flat-faced, round, beveled tablet. Debossed with Cephalon 'C' on one side and '2' on the other side.

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: EFFENTORA 100/200/400/600/800
Registration Nos.: EFFENTORA 100: 48/2.9/0054 EFFENTORA 200: 48/2.9/0055 EFFENTORA 400: 48/2.9/0056 EFFENTORA 600: 48/2.9/0057 EFFENTORA 800: 48/2.9/0058	Dosage form & strength: Each effervescent buccal tablet contains 100, 200, 400, 600 and 800 micrograms of fentanyl (as citrate) respectively

EFFENTORA 400: White to off-white, flat-faced, round, beveled tablet. Debossed with Cephalon 'C' on one side and '4' on the other side.

EFFENTORA 600: White to off-white, flat-faced, round, beveled tablet. Debossed with Cephalon 'C' on one side and '6' on the other side.

EFFENTORA 800: White to off-white, flat-faced, round, beveled tablet. Debossed with Cephalon 'C' on one side and '8' on the other side.

EFFENTORA is packed in white, opaque blister cards consisting of PVC/aluminium foil/polyamide/PVC with paper/polyester/aluminium lidding. The blisters are packed in a carton. The tablets are available in blister packs of 4 or 28 tablets per carton. The blister cards consist of 4 tablets per card.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

Tel: +27 11 055 0200

This leaflet was last revised in:

18 February 2025

Registration Numbers:

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: EFFENTORA 100/200/400/600/800
Registration Nos.: EFFENTORA 100: 48/2.9/0054 EFFENTORA 200: 48/2.9/0055 EFFENTORA 400: 48/2.9/0056 EFFENTORA 600: 48/2.9/0057 EFFENTORA 800: 48/2.9/0058	Dosage form & strength: Each effervescent buccal tablet contains 100, 200, 400, 600 and 800 micrograms of fentanyl (as citrate) respectively

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