

**Package leaflet: Information for the user**

- Iremia® 67 micrograms, Sublingual Tablets
- Iremia® 133 micrograms, Sublingual Tablets
- Iremia® 267 micrograms, Sublingual Tablets
- Iremia® 400 micrograms, Sublingual Tablets
- Iremia® 533 micrograms, Sublingual Tablets
- Iremia® 800 micrograms, Sublingual Tablets

Fentanyl

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**This medicine contains Fentanyl which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**What is in this leaflet**

1. What Iremia is and what it is used for
2. What you need to know before you take Iremia
3. How to take Iremia
4. Possible side effects
5. How to store Iremia
6. Contents of the pack and other information

**1. WHAT IREMIA IS AND WHAT IT IS USED FOR**

Iremia contains the active ingredient fentanyl, which belongs to a group of strong pain-relieving medicines called opioids.

Iremia 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 even though you have taken your usual opioid pain-relieving medicines.

Iremia has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IREMIA**

Fentanyl is a strong opioid and should not be used unless you have previously been prescribed other opioids.

This particular formulation is highly addictive. Contact your prescriber if you or a family member has concerns regarding use of this medicine.

**Do NOT use Iremia:**

- if you are allergic to fentanyl or 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 Iremia, because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop (see section 4 "Possible side effects").
- if you have severe breathing problems or severe lung disorder where you have an obstruction;
- if you are currently taking monoamine-oxidase (MAO) inhibitor (medicines for severe depression) or have taken them in the past 2 weeks (see section 2 under "Talk to your doctor or pharmacist BEFORE using Iremia if:");
- if you suffer from short-term pain (e.g. pain from injuries, surgery, headaches or migraines) other than breakthrough pain.
- if you are taking a medicine which contains sodium oxybate.

Do NOT use Iremia if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist BEFORE using Iremia.

**Warnings and precautions**

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

**Store this medicine in a safe and secure place, where other people cannot access it (see section 5). How to store Iremia for more information.**

Talk to your doctor or pharmacist **before** taking Iremia if:

- your other opioid pain medicine taken for your persistent (around-the-clock) cancer pain is not stabilized yet;
- you are suffering from any condition that has an effect on your breathing (such as asthma, wheezing, or shortness of breath);
- you have a head injury or have had any loss of consciousness;
- you have problems with your heart especially slow heart rate, irregular heartbeat, low blood volume or low blood pressure;
- 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 blood pressure due to a low amount of fluid in your circulation
- you are over 65 years old – you may need a lower dose and any dose increase will be reviewed carefully by your doctor
- you have diabetes
- you take antidepressants or antipsychotics (selective serotonin reuptake inhibitors [SSRIs], serotonin norepinephrine reuptake inhibitors [SNRIs], monoamine oxidase inhibitors [MAOIs]. Please refer to the section other medicines and Iremia. The use of these medicines with Iremia can lead to a serotonin syndrome a potentially life-threatening condition (see section 2 under "Other medicines and Iremia").
- you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use (see section 4 under "Serious side effects").
- you use benzodiazepines (see section 2 under "Other medicines and Iremia").  
Using benzodiazepines can increase the chances of getting serious side effects including death.
- you have ever abused or been dependent on opioids or any other drug, alcohol or illegal drugs.
- you drink alcohol; please refer to section Iremia with food, drink and alcohol.
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- you feel you need to take more of Iremia to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

**Important things you should know about fentanyl:**

- This product provides a high dose of opioid that can be fatal if not used appropriately.

**Consult your doctor WHILE using Iremia if:**

- you experience 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.
- 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. 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.

Repeated use of Iremia may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Iremia, it is important that you consult 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 Iremia. This is known as hyperalgesia. Increasing the dose of Iremia 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 Iremia.

**Dependence and addiction**

Repeated use of Iremia 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 to use 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 becoming dependent or addicted on Iremia 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 a problem 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 Iremia, 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 calm' 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:**

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

**Children and adolescents**

Iremia shall not be used by children and adolescents below 18 years.

**Other medicines and Iremia**

Do not use this medicine and tell your doctor or pharmacist

- If you are taking other fentanyl treatments that have been prescribed for your breakthrough pain in the past. If you still have some of these fentanyl treatments at home, check with your pharmacist how to dispose of them.
- If you are using monoamine oxidase (MAO) inhibitors (medicines for severe depression) or have taken them in the past 2 weeks (see section 2 under "Do NOT use Iremia" and "Talk to your doctor or pharmacist BEFORE using Iremia if:").

Tell your doctor or pharmacist before using Iremia if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Concomitant use of Iremia and sedative medicines such as benzodiazepines or related drugs 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 prescribes Iremia 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 (such as sleeping pills, medicines to treat anxiety, some medicine to treat allergic reactions (antihistamines), or tranquilisers) you are taking, and follow 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.
- Some muscle relaxants – such as baclofen, diazepam (see also section "Warnings and precautions").
- Any medicines that might affect how your body breaks down Iremia - such as ritonavir or other medicines that help control HIV infection, other so-called 'CYP3A4 inhibitors' such as ketoconazole, itraconazole, or fluconazole (used for fungal infections) and troleandomycin, clarithromycin, or erythromycin (medicines for bacterial infections) and so-called 'CYP3A4 inducers' such as rifampin or rifabutin (medicines for bacterial infections), carbamazepine, phenobarbital or phenytoin (medicines used to treat convulsions/fits).
- 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).
- Serotonergic medicinal products used to treat depression (antidepressants: such as selective serotonin reuptake inhibitors [SSRIs] and serotonin norepinephrine reuptake inhibitors [SNRIs]) or antipsychotics. The use of these medicines with Iremia can lead to serotonin syndrome a potentially life-threatening condition (see section 2 under "Talk to your doctor or pharmacist BEFORE using Iremia if:" and "Do NOT use Iremia:"). The symptoms of serotonin syndrome may include 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 Iremia is suitable for you.

If you are due to have surgery requiring a general anaesthetic speak with your doctor or nurse.

**Iremia with food, drink and alcohol**

Iremia may be used before or after, but not during, meals. You may drink some water before using Iremia to help moisten your mouth, but you should not drink or eat anything while taking the medicine.

- You should not drink grapefruit juice while using Iremia because it may affect the way your body breaks down Iremia.
- Do not drink alcohol while using Iremia. It can increase the risk of experiencing dangerous side effects, including death.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Pregnancy:**

Do not take Iremia if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If Iremia is used for a long time during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. (see section 4 under "Other side effects with frequency not known"). You should not use Iremia during child-birth because fentanyl may cause breathing difficulties in the new-born child.

**Breast-feeding:**

Do not take Iremia while you are breast-feeding as Fentanyl passes into breast milk and will affect your baby

You should not start breast-feeding until at least 5 days after the last dose of Iremia.

**Driving and using machines**

This medicine may affect you being able to drive or use any tools or machines. You should discuss with your doctor whether it is safe for you to drive, or use any tools or machines in the first few hours after taking Iremia. Do not drive, use tools or operate machinery if you: are feeling sleepy or dizzy; have blurred or double vision; or have difficulty in concentrating. It is important you know how you react to Iremia before driving, using tools or operating machinery.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.

However, you would not be committing an offence if:

- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

**Iremia contains sodium:**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

**3. HOW TO TAKE IREMIA**

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

This medicine should be taken by placing the tablet under your tongue (sublingual use).

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

If your doctor switched you to Iremia, you **must not** use the previous medicine containing fentanyl concurrently for the treatment of your breakthrough pain. Dispose of the previous medicine.

However, keep using the opioid pain medicine you take for your persistent (around-the-clock) cancer pain during your Iremia treatment.

**Initial Phase – Finding the most appropriate dose**

For Iremia to work successfully, your doctor will need to identify the most appropriate dose for treating a single episode of breakthrough pain. Iremia sublingual tablets are available in a range of strengths. You may need to try different strengths of Iremia sublingual tablets over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will help you do this and will work with you to find the best strength of tablet to use.

If you do not get adequate pain relief from one tablet your doctor may ask you to take two tablets to treat an episode of breakthrough pain. Do not take a second tablet unless your doctor tells you to as this may result in overdose. Your doctor will advise you which strength of tablet to use.

**You must always use the dose of Iremia as prescribed by your doctor –** this may be a different dose from that which you have used with other medicines for breakthrough pain.

**Maintenance Phase – Pain you have found the most appropriate dose**

Once you and your doctor have found a dose of Iremia tablets that controls your breakthrough pain you should not take this dose more than four times a day. **A dose of Iremia may consist of more than one tablet.**

If you think that the dose of Iremia that you are using is not controlling your breakthrough pain satisfactorily tell your doctor, as he/she may need to adjust your dose.

You must not change your dose of Iremia unless directed by your doctor. Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

**Taking the medicine**

Iremia should be used sublingually. This means that the tablet should be placed under the tongue where it dissolves rapidly in order to allow fentanyl to be absorbed across the lining of the mouth.

When you get an episode of breakthrough pain, take the dose advised by your doctor as follows:

- If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water.
- Remove the tablet(s) from the blister pack immediately before use.
- Peel back the tab of the foil top of one blister and gently remove the tablet. Do not try to push Iremia sublingual tablets through the foil top.
- Place the tablet under your tongue as far back as you can and let it dissolve completely.
- Iremia will dissolve rapidly under the tongue and be absorbed in order to provide pain relief. It is therefore important that you do not suck, chew or swallow the tablet.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed.
- You should not drink or eat anything until the tablet has completely dissolved under your tongue.

**If you take more Iremia than you should**

- remove any remaining tablets from your mouth,
- tell your caregiver or another person what has happened,
- you or your caregiver should immediately contact your doctor, pharmacist or local hospital and discuss what action to take.

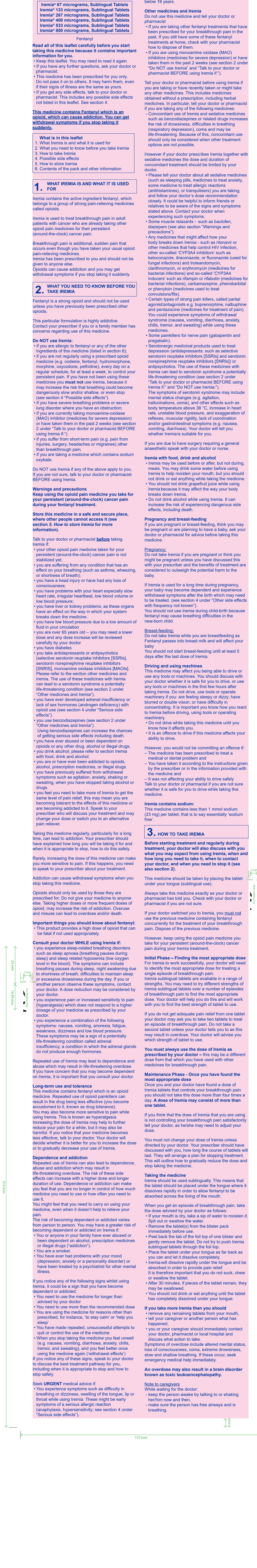
Symptoms of overdose include altered mental status, loss of consciousness, coma, extreme drowsiness, slow and shallow breathing. If these occur, seek emergency medical help immediately.

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

**Note to caregivers**

While waiting for the doctor:

- keep the person awake by talking to or shaking her/him now and then,
- make sure the person has free airways and is breathing.



943mm

25mm

1695mm

315mm

8mm

5mm

2mm

1mm

For Resorption Only

8mm

2mm

5mm

1mm

For Resorption Only

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For Resorption Only

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157 mm

If you think someone has taken Iremia by accident seek emergency medical help immediately.

#### If you forget to take Iremia

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

#### If you stop taking Iremia

You should discontinue Iremia 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. Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of these, contact your doctor.

The most serious side effects are shallow breathing, low blood pressure and shock.

**You or your carer should contact your doctor immediately and call for emergency help if you experience any of the following serious side effects – you may need urgent medical attention:**

- Becoming very sleepy or having slow and/or shallow breathing.
- Difficulty in breathing or dizziness, swelling of the tongue, lip or throat which may be early signs of serious allergic reaction.

#### Note to Carers:

If you see that the patient using Iremia has slow and/or shallow breathing or if you have a hard time waking the person up, take the following steps IMMEDIATELY:

- Using the handle, remove the Iremia unit from the person's mouth and keep it out of the reach of children or pets until it is disposed of.
- CALL FOR EMERGENCY HELP.
- While waiting for emergency help, if the person seems to be breathing slowly, prompt them to breathe every 5-10 seconds.

If you feel excessively dizzy, sleepy or otherwise ill while using Iremia, you should stop taking Iremia and you or your caregiver should contact your doctor immediately and call for emergency help.

Contact your doctor if you experience a combination of the following symptoms:

- Nausea, vomiting, loss of appetite, tiredness, 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.
- Prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the newborn which can be life-threatening (see section 2 under "Pregnancy and breast-feeding").

#### Other side effects

**Very common** (may affect more than 1 in 10 people):

- Nausea/feeling sick, vomiting, constipation, stomach (abdominal) pain
- asthenia (weakness), sleepiness, dizziness, headaches
- shortness of breath/laboured breathing

**Common** (may affect up to 1 in 10 people):

- confusion, anxiety, seeing or hearing things that are not really there (hallucinations), depression, mood swings
- feeling unwell, wind, abdominal bloating, decreased appetite, weight loss
- muscle jerks, feeling of dizziness or "spinning", loss of consciousness, sedation, tingling or numbness, difficulty coordinating movements, increased or altered sensitivity to touch, convulsions (fits)
- dry mouth, taste alteration,
- mouth inflammation, tongue problems (for example, burning sensation or ulcers),
- wind, abdominal bloating, indigestion, decreased appetite, weight loss
- sweating, itchy skin, skin rash
- difficulty passing urine
- accidental injury (for example, falls)
- blurred or double vision.

**Uncommon** (may affect up to 1 in 100 people):

- tooth decay (that can lead to teeth removal), paralysis of the gut, mouth ulcers, gum bleeding
- coma, slurred speech
- abnormal dreams, feeling detached, abnormal thinking, excessive feeling of wellbeing,
- widening blood vessels
- hives

**Frequency not known** (frequency cannot be estimated from the available data):

- flushing, feeling very warm
- diarrhoea
- receding gums, tooth loss, inflammation of the gum
- fatigue
- swelling of arms and legs
- insomnia
- fever (pyrexia)
- withdrawal syndrome (may manifest by the occurrence of the following side effects, nausea, vomiting, diarrhoea, anxiety, chills, tremor and sweating).
- drug tolerance, drug dependence and addiction (see section 2).
- trouble breathing during sleep, severe breathing problems
- bleeding at the site of application
- lack of sex hormones (androgen deficiency)
- drug abuse
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)

Prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the newborn which can be life-threatening (see section 2).

Whilst using Iremia you may experience irritation, pain and ulcer at the application site and gum bleeding

#### Drug Withdrawal

When you stop taking Iremia, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

#### How do I know if I am addicted?

If you notice any of the following signs whilst taking Iremia, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE IREMIA

**The pain-relieving medicine in Iremia is very strong and could be life-threatening if taken accidentally by a child. Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original blister package, in order to protect from light. Keep Iremia in a locked storage space.

**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.**

Do not store the tablet once removed from the blister package. Unused or partially used remaining products must not be disposed of via wastewater or household waste. It should be taken, if possible, to your pharmacist to be disposed of safely. This is a safety precaution and it will also help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Iremia contains

- The active substance is fentanyl. Each sublingual tablet contains 67, 133, 267, 400, 533 or 800 micrograms of fentanyl (as citrate).
- The other ingredients (excipients) are: calcium hydrogen phosphate anhydrous, microcrystalline cellulose, disodium phosphate anhydrous, hypromellose, macrogol, magnesium stearate, maltodextrin, titanium dioxide (E171), triacetin, printing ink (shellac, iron oxide black (E172)).

**What Iremia looks like and contents of the pack**

Iremia 67 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '0' in black ink on one face.

Iremia 133 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '1' in black ink on one face.

Iremia 267 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '2' in black ink on one face.

Iremia 400 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '4' in black ink on one face.

Iremia 533 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '5' in black ink on one face.

Iremia 800 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with '8' in black ink on one face.

The Iremia Sublingual Tablets are available in a peelable, child resistant blister, with pack sizes of 3, 4, 15 or 30 tablets.

**Not all pack sizes may be marketed.**

#### Marketing Authorisation Holder:

Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

#### Manufacturer:

Repton Road, Measham, DE12 7DT, UK

**This leaflet was last revised in February 2025**

CP.FEN.JNT.T.FE.V2P1  
8840400



157 mm

<b>Customer:</b> Kent	<b>Originated by:</b> KBN (AWG)	<b>Colours</b>	
<b>Product:</b> Fentanyl			
<b>Dimensions:</b> 157mm x 943mm			
<b>Item Code:</b> CP.FEN.JNT.T.FE.V2P1 (8840400)			
<b>Proof No and Date:</b> 1 20/02/2025			
<b>Revision:</b> Brand Review			
<b>ARTWORK FOR SUBMISSION</b>			
<b>Supersedes:</b> CP.FEN.JNT.T.FE.V1P2			