

ABSTRAL SUBLINGUAL TABLETS

Fentanyl Citrate (100, 200 and 400 microgram)

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What Abstral is used for

Abstral is a treatment for adults **who must already regularly taking strong pain-relieving medicine (opioids)** for their persistent cancer pain, but require treatment for their breakthrough pain. If you are not sure, talk to your doctor.

Breakthrough pain is pain which occurs suddenly, even though you have taken or used your usual opioid pain-relieving medicine

How Abstral works

The active substance in Abstral sublingual tablets is fentanyl. Fentanyl belongs to a group of strong pain-relieving medicines called opioids.

Abstral should be used sublingually, which 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. Once absorbed, fentanyl starts to work to relieve pain.

Before you use Abstral

- When you must not use it

Do not take Abstral

- if you are allergic to fentanyl or any of the other ingredients of this medicine (listed in section Inactive ingredients).
- if you have severe breathing problems.
- If you are not regularly using 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 Abstral because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop.

- If you suffer from short-term pain other than breakthrough pain.
- if you are being treated with medicines containing sodium oxybate

Talk to your doctor or pharmacist before taking Abstral if you have or have recently had any of the following, as your doctor will need to take account of these when prescribing your dose:

- a head injury, because Abstral may cover up the extent of the injury
- breathing problems or suffer from myasthenia gravis (a condition characterised by muscle weakness).
- if you have problems with your heart especially slow heart rate
- low blood pressure
- liver or kidney disease, as this may require your doctor to more carefully adjust your dose
- a brain tumour and/or raised intracranial pressure (an increase of pressure in the brain which causes severe headache, nausea/vomiting and blurred vision)
- mouth wounds or mucositis (swelling and redness of the inside of the mouth)
- if you take antidepressant or antipsychotics please refer to the sections 'Taking other medicines'
- if you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use.

- Before you start to use it

Before you start treatment with Abstral, you must have been regularly taking or using a prescribed strong pain-relieving medicine, called an opioid, to control your persistent pain. If you have not, this medicine could cause severe breathing difficulties (see section 'Side effects'). If you are not sure, talk to your doctor.

- Taking other medicines

Taking Abstral with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (other than your regular opioid pain-relieving medicine).

- Some medicines may increase or decrease the effects of Abstral. Therefore if you start, change the dose of, or stop therapy with the following medication tell your doctor as they may need to adjust your dose of Abstral: Certain types of antifungal medicines containing e.g. ketoconazole or itraconazole (used to treat fungal infections).
- Certain types of antibiotic medicines called macrolides, containing e.g. erythromycin (used to treat infections).
- Certain types of antiviral medicines called protease inhibitors, containing e.g. ritonavir (used to treat infections caused by viruses).
- Rifampin or rifabutin (medicines used to treat bacterial infections)
- Carbamazepine, phenytoin or phenobarbital (medicines used to treat convulsions/fits).
- Herbal medicines containing St John's wort (Hypericum perforatum). Medicines containing alcohol
- Medicines called monoamine-oxidase (MAO) inhibitors, which are used for severe depression and Parkinson's disease. Tell your doctor if you have taken this type

of medicine within the last two weeks

- 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.

Abstral may add to the effect of medicines that make you feel sleepy (sedative medicines), including:

- other **strong pain relieving medicines** (opioid-type medicines e.g. for pain and cough)
- some painkillers for nerve pain (gabapentin and pregabalin)
- general anaesthetics (used to make you sleep during operations)
- muscle relaxants
- sleeping tablets
- medicines used to treat
 - depression/allergies
 - anxiety (such as benzodiazepines e.g. diazepam) and psychosis
- medicines containing clonidine (used to treat high blood pressure).

Use of Abstral at the same time as medicines that make you feel sleepy (sedative medicines), such as benzodiazepines, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, use of Abstral together with sedative medicines should only be considered when other treatment options are not possible.

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

Please tell your doctor about all sedative medicines 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.

a 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, increases 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 Abstral is suitable for you.

How to use Abstral

- How much to use

Before taking Abstral for the first time your doctor will explain how Abstral should be taken to effectively treat your breakthrough pain.

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

This product should ONLY be used by you according to your doctor's instructions. It should not be used by anyone else as it could present a **SERIOUS** risk to their health, especially in children.

Abstral is a different type of medication from other medicines you may have used to treat your breakthrough pain. You must always use the dose of Abstral as prescribed by your doctor – this may be a different dose from that which you have used with other medicines for breakthrough pain.

Starting Treatment – Finding the most appropriate dose :

For Abstral to work successfully, your doctor will need to identify the most appropriate dose for treating your breakthrough pain. If you do not get adequate pain relief from one dose your doctor may ask you to take an extra dose to treat an episode of breakthrough pain.

Wait at least 2 hours from taking your last dose before treating your next episode of breakthrough pain with Abstral.

Continuing Treatment – Once you have found the most appropriate dose:

Once you and your doctor have found a dose of Abstral that controls your breakthrough pain you should take this dose no more than four times a day. A dose of Abstral may consist of more than one tablet.

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

- When to use it

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 as follows:
 - Separate one of the blister squares from the pack by tearing along the dotted lines/perforations (keep the remaining blister squares together).
 - Peel back the edge of the foil where the arrow is shown and gently remove the tablet. Do not try to push Abstral sublingual tablets through the foil top, as this will damage them.
- Place the tablet under your tongue as far back as you can and let it dissolve completely.
- Abstral 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.
- You should not drink or eat anything until the tablet has completely dissolved under your tongue.

- How long to use it

You should discontinue Abstral 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 Abstral when discontinuing Abstral. 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.

- *If you use too much (overdose)*

If you take more Abstral than you should:

- remove any remaining tablets from your mouth
- tell your carer or another person what has happened
- you or your carer should immediately contact your doctor, pharmacist or local hospital and discuss what action to take
- while waiting for the doctor, keep the person awake by talking to or shaking her/him now and then.

Symptoms of overdose include:

- extreme drowsiness
- slow, shallow breathing
- coma

If these occur, seek emergency medical help immediately.

While you are using it

- *Things you must do*

When taking Abstral, inform your doctor or dentist that you are taking this medicine, if

- you are to have any surgery
- 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

Taking the medicine:

Abstral should be used sublingually, which 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. Once absorbed, fentanyl starts to work to relieve pain.

- *Things you must not do*

Abstral with food, drink and alcohol:

Abstral can make some people feel drowsy. Do not consume alcohol without consulting your doctor as it might make you feel more drowsy than usual.

Do not drink grapefruit juice while you are prescribed Abstral treatment as it may increase the side effects of Abstral.

Pregnancy and breast-feeding:

You must not use Abstral during pregnancy unless you have been specifically told to by your doctor.

Fentanyl can get into breast milk and may cause side effects in the breast-fed infants. Do not use Abstral if you are breast-feeding. You should not start breast-feeding until at least 5 days after the last dose of Abstral.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant or breast-feeding.

- *Things to be careful of*

- Serotonin syndrome: Abstral may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

- Adrenal insufficiency: Long-term use of Abstral may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of Abstral may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Your doctor may need to check you more closely 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 illnesses

Repeated use of Abstral may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Abstral, it is important that you consult your doctor.

Sleep-related breathing disorders

Abstral 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 in maintaining 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.

Driving and using machines:

Abstral may impair your mental and/or physical ability to perform potentially hazardous tasks such as driving or operating machinery.

If you feel dizzy, sleepy or have blurred vision when you take Abstral, do not drive or use machinery.

Side effects

If you start to feel unusually or extremely sleepy or your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help (see also section “If you use too much (overdose)”).

Possible side effects

- nausea
- dizziness, headache, excessive sleepiness
- breathlessness/shortness of breath

- inflammation inside the mouth, vomiting, constipation, dry mouth, sweating, weary/tired/lack of energy
- allergic reaction, trembling/shaking, disturbed or blurred vision, fast or slow heart beat, low blood pressure, memory loss
- depression, suspicious thoughts/feeling afraid for no reason, feeling confused, feeling disorientated, feeling anxious/unhappy/restless, feeling unusually happy/healthy, mood swings
- feeling full all the time, stomach ache, indigestion
- mouth ulcers, problems with tongue, pain in mouth or throat, tightness in throat, lip or gum ulcers
- loss of appetite, loss of or change in sense of smell/taste
- difficulty sleeping or disturbed sleep, disturbance in attention/easily distracted, lack of energy/weakness/loss of strength
- abnormality in skin, rash, itchiness, night sweats, decreased sensitivity to touch, bruising easily
- joint pain or stiffness, stiffness in muscles
- drug withdrawal symptoms (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating), accidental overdose, in males an inability to get and/or keep an erection, feeling generally unwell/swollen tongue, severe breathing problems, falls, flushing, feeling very warm, diarrhoea, convulsion (fits), swelling of arms or legs, seeing or hearing things that are not really there (hallucination), fever, drug dependence (addiction), drug abuse, reduced level or loss of consciousness, itchy rash and 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 ‘While you are using it’).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Abstral

- Storage

Store below 25°C.
Store in the original blister in order to protect from moisture. It is recommended to keep Abstral in a locked storage space

- Disposal

Any unused product should be taken, if possible, bring it to your pharmacist to be disposed of safely. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment

Product Description

- What it looks like

Abstral is a small white sublingual tablet to be inserted under the tongue. It comes in a range of different strengths and shapes. Your doctor will prescribe the strength (shape) and number of tablets suitable for you.

The 100 microgram tablet is a white round tablet

The 200 microgram tablet is a white oval-shaped tablet

The 400 microgram tablet is a white diamond-shaped tablet

Abstral tablets are contained in blisters, available in cartons of 10 or 30 tablets.

- Ingredients

- Active Ingredient

The active substance is fentanyl.

- Inactive ingredients

Mannitol(E421),
silicifiedmicrocrystalline cellulose,
croscarmellose sodium and magnesium stearate.

- MAL number:

Abstral 100: MAL17085055ACZ

Abstral 200: MAL17085056ACZ

Abstral 400: MAL17085057ACZ

Manufacturer

RECIPHARM LEGANÉS S.L.U.

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Product Registration Holder

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