

**A patient & caregiver guide to managing  
breakthrough cancer pain with Abstral  
(fentanyl citrate sublingual tablets)**



This guide is intended for those patients who  
have been prescribed Abstral and their caregivers only.  
Provided as a service to patients by Paladin Labs Inc.,  
Montreal, QC H4P 2T4



## Introduction

The purpose of this booklet is to provide patients and their caregivers with useful information about breakthrough cancer pain and treatment with Abstral (fentanyl citrate sublingual tablets). This information provides a practical approach to Abstral including tips on starting treatment, how to take it and store it, important side effects to look out for, what to do if you take too much and frequently asked questions.

This document summarizes important information contained within the Abstral Consumer Information Leaflet, but is not intended to replace the leaflet, which should still be referred to.

## Contents

1. What is Breakthrough Cancer Pain?
2. How will Abstral help relieve my Breakthrough Cancer Pain?
3. Starting Treatment with Abstral
4. How to take Abstral
5. How to store Abstral
6. Possible Side Effects
7. Frequently Asked Questions
8. Useful Contact Details

## 1. What is Breakthrough Cancer Pain?

In addition to the regular pain for which you are already taking medication, you may be experiencing something called breakthrough cancer pain. It is known by this name because it 'breaks through' the control of your ongoing pain medicine.

### **Breakthrough cancer pain:**

- Pain that 'breaks through' the control of your ongoing pain medicine
- Generally lasts up to 30 minutes
- Severe and intense
- Often unpredictable (but can also be triggered by movement such as walking and coughing)

There is medication available to help relieve your breakthrough cancer pain when it occurs. Your healthcare provider has prescribed a form of breakthrough cancer pain medicine called Abstral and this booklet has been designed to help you use this treatment.

## 2. How will Abstral help relieve my Breakthrough Cancer Pain?

Abstral is an established pain relief medicine, designed specifically to target breakthrough cancer pain.

Abstral is easy to use and dissolves **under your tongue** quickly.

Abstral is designed to provide pain relief quickly, within the early stages of an episode of breakthrough cancer pain.

As with other similar pain medicines, Abstral can cause some side effects and does carry a risk of accidental overdosing and a risk of addiction – your healthcare provider should inform you about how to use Abstral to minimize these risks.

### 3. Starting treatment with Abstral

Because breakthrough cancer pain is a very individual experience and differs from person to person, it is important that you work closely with your healthcare provider to find the right dose for you. Your healthcare provider will rely on the information you provide them in order to help you find the best way of relieving your breakthrough cancer pain. It is important to note that you should also remain on the medicine you are taking to control your regular cancer pain.

#### **Finding your dose**

Abstral is available in a number of different tablet strengths (the packs are colour-coded and the tablets have different shapes so you can tell them apart) to help provide you with the most effective relief from your breakthrough cancer pain. You may need to use different strengths over the course of a few breakthrough cancer pain episodes, to find the most effective dose for you.

You and your healthcare provider will find your personal optimal dose, i.e. the dose that gives you the best pain relief for your breakthrough cancer pain.

**During this time it is important that you:**

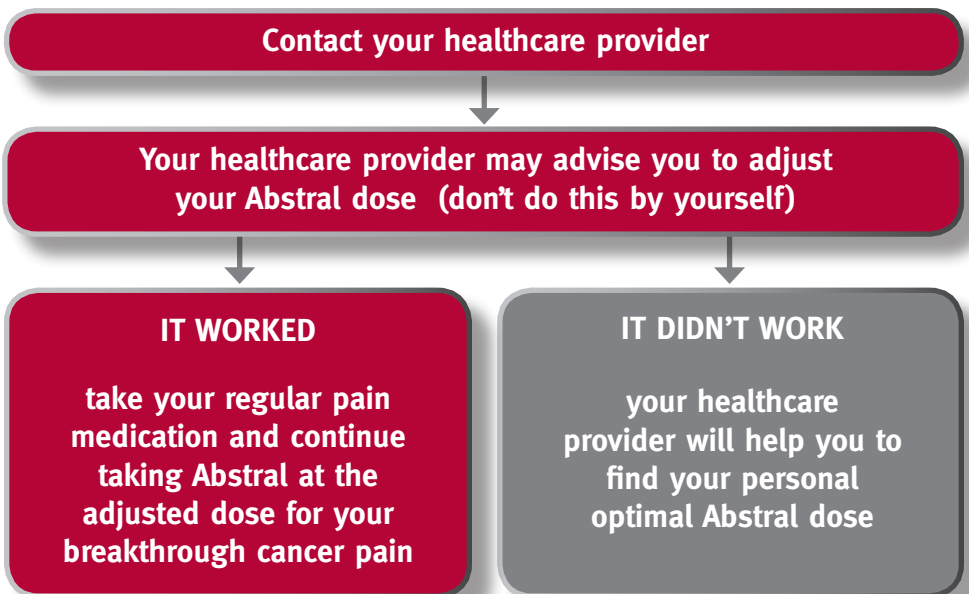
- **Remain patient**
- **Try to keep a record of your pain**
- **Update your healthcare provider regularly**
- **Follow your healthcare provider's instructions carefully**

- You must begin treatment using one 100 mcg Abstral tablet.
- You must not use more than one dose of ABSTRAL for each episode of breakthrough cancer pain:
  - Take 1 dose for an episode of breakthrough cancer pain.
  - If the pain does not get better 30 minutes after taking the first dose of ABSTRAL, you can take other rescue medication (but not ABSTRAL) as discussed with your doctor.
- You must wait at least 2 hours before treating a new episode of breakthrough cancer pain with Abstral.
- You should not treat more than 4 episodes of breakthrough cancer pain per day.

Your healthcare provider will explain this to you. If you have any concerns about this, contact your healthcare provider immediately.

### **What to do if you are not experiencing enough breakthrough cancer pain relief**

If you are not getting enough pain relief for your breakthrough cancer pain episode, this might indicate that your Abstral dose needs adjusting. Remember that Abstral is a powerful medicine and should only be taken as prescribed by your healthcare provider. If you think you are not getting enough pain relief, contact your health care provider as described below. Do not attempt to change the dose of your medication yourself. If you experience any problems you should consult your healthcare provider immediately.

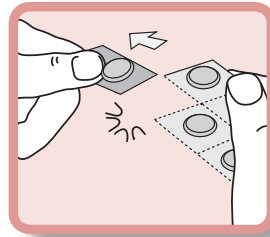


## 4. How to take Abstral

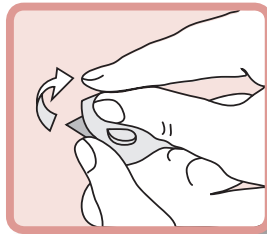
Abstral is a special type of tablet that is absorbed directly into your bloodstream from under your tongue, so it is important that you store it and take it in the right way. Follow the simple step-by-step instructions below. If you are unclear about any of the information provided contact your healthcare provider immediately and discuss your concerns with them.

### Opening your pack

- Keep the tablet in the blister package until ready to use (do not store in a pillbox)
- Keep any unused tablets in the Abstral package to make sure you can recognize them in future and so that important information on Abstral is readily available for reference
- Separate **one** of the blister units from its card by bending and tearing apart along the dotted lines (perforations)



- Peel back the foil starting at the unsealed area where indicated and gently remove the tablet

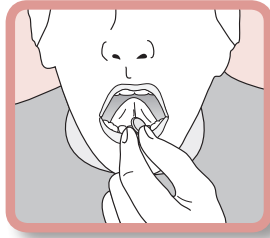


- **Do not try to push the Abstral tablet through the foil as this will damage the tablet**
- Do not try to split the tablet



## Taking your tablet

- If your mouth is dry, take a sip of water to moisten it. Make sure you swallow or spit out the water before taking Abstral
- Immediately place the Abstral tablet under your tongue, as far back as you can, and let it dissolve completely



- Do not bite, chew, suck, or swallow the tablet as this could result in less relief for your breakthrough cancer pain
- Leave the Abstral tablet under your tongue until it has completely dissolved
- You should not eat or drink anything until the tablet has completely dissolved and you can no longer feel it underneath your tongue

## 5. How to store Abstral

- Abstral is a powerful medicine which can be harmful to those for whom it is not prescribed. It should therefore be kept in a locked storage place away from other people, especially children
- Abstral should be stored between 15° and 30°C (59°-86°F) and in the original blister pack to protect it from moisture
- Abstral should not be used beyond the expiry date stated on the packaging
- Return any unused or expired Abstral tablets to your pharmacist or dispose of unopened blisters as soon as you no longer need them by flushing them down the toilet as follows:

1. Remove the Abstral tablet from its blister package
2. Drop the Abstral tablet into the toilet
3. Repeat steps 1 and 2 for each Abstral blister. Flush the toilet after all unneeded blisters have been put in the toilet

Do not flush the Abstral blister packages or cartons down the toilet

## 6. Possible Side Effects

Abstral has similar side effects to those associated with your regular cancer pain relief medicine. If you do experience any of the side effects listed below, or experience any other effects you think are related to taking Abstral, inform your healthcare provider. They may be able to help reduce these while ensuring that you continue to receive effective relief from your breakthrough cancer pain.

Nausea

Vomiting

Constipation

Tiredness

Headache

Dry mouth

Somnolence

Short breath

**Please see the Patient Information Leaflet for full details of possible side effects**

You or a family member should **call your doctor or get emergency medical help immediately** if you have any of the symptoms below:

- trouble breathing
- extreme drowsiness with slowed breathing
- slow, shallow breathing (little chest movement with breathing)
- feel faint, dizzy or confused
- inability to think, talk or walk normally
- seizure and hallucination

These can be symptoms of an overdose of Abstral. Your dose of Abstral may be too high for you. **These symptoms may lead to serious problems or death if not treated immediately. If you have any of these symptoms, do NOT take any more Abstral until you have seen your doctor.**

**In cases of possible overdose try to remove ABSTRAL tablets or any parts of it still remaining in the mouth.**

## **Overdose**

If you follow the instructions above on how to take Abstral and follow the advice of your healthcare provider on how many Abstral tablets to take, it is **extremely unlikely that you will take too much.**

However, in the unlikely event of an overdose you may feel very drowsy or may feel short of breath with only slow shallow breathing. In the event of an overdose take the following steps:

- Immediately remove any tablet(s) or any parts of it still remaining in your mouth
- Tell someone nearby (another person in your house or your nurse/caregiver) what has happened
- Immediately contact your designated healthcare provider (see contact details on the last page of this booklet) or other emergency medical help such as contacting your regional poison control centre or calling 911
- Your nurse/caregiver should keep you awake by talking to you or shaking you gently now and again

## **Risk of addiction**

As with your regular cancer pain relief medicine you may feel the need to take increased doses of Abstral in order to get a sustained level of breakthrough cancer pain relief. To minimise the possibility of addiction it is therefore important that you only take Abstral as prescribed by your healthcare provider. The risk of addiction is very low if you follow the instructions of your healthcare provider. In the event that your breakthrough cancer pain medicine is providing ineffective relief at the prescribed dose, consult your healthcare provider to discuss next steps.

Do not give your medicines to anyone else.

## **Accidental use**

If you suspect that someone has accidentally taken Abstral, seek emergency medical help immediately or call 911 immediately.

## 7. Frequently Asked Questions

**Q. What should I do if I start to feel unusually or extremely sleepy, or if my breathing becomes slow or shallow?**

A. You or your caregiver should immediately contact your doctor or local hospital for emergency help or call 911. Remove any tablets or any parts of it still remaining in the mouth and notify a nurse or caregiver who should keep you awake by talking to you or shaking you gently.

**Q. What should I do if I experience any side effects when taking Abstral?**

A. If you experience any side effects when taking Abstral you should speak to your doctor who may be able to resolve them while still controlling your breakthrough cancer pain.

**Q. When should I take Abstral?**

A. You should take Abstral (as per the instructions in the patient information leaflet) as soon as an episode of breakthrough cancer pain begins.

**Q. How quickly does Abstral work?**

A. Once the tablet has completely dissolved; Abstral begins to work within the early stages of the episode of breakthrough pain.

**Q. What is the maximum number of breakthrough cancer pain episodes I can treat with Abstral treatment in a single day?**

A. You can treat up to 4 episodes with Abstral in one day.

**Q. What should I do if I am still experiencing breakthrough cancer pain?**

A. You should consult your doctor who may adjust your dose of Abstral, reconsider your ongoing regular pain treatment or refer you to a pain specialist.

**Q. Are other medicines available to help control my breakthrough cancer pain?**

A. There are a range of medicines available for controlling breakthrough cancer pain. Your doctor or nurse will be able to advise you about the most effective medicine for your needs.

## 8. Useful Contact Details

If you have any queries about taking Abstral or need any advice while taking this medicine, please contact your doctor/nurse.

Doctor's name \_\_\_\_\_

Hospital/surgery/hospice \_\_\_\_\_

\_\_\_\_\_

Pharmacy's name \_\_\_\_\_

\_\_\_\_\_

Nurse's name \_\_\_\_\_

Hospital/surgery/hospice \_\_\_\_\_

\_\_\_\_\_

Emergency telephone #1 \_\_\_\_\_

Emergency telephone #2 \_\_\_\_\_

Emergency telephone #3 \_\_\_\_\_





Date of preparation: February 2011  
PI011472E