



PATIENT'S GUIDE TO THE SAFE USE OF INSTANYL[®] SINGLE DOSE NASAL SPRAY

Please also refer to the Patient Information Leaflet for
Instanyl[®] (fentanyl citrate) Single Dose Nasal Spray

INTRODUCTION

Dear Patient,

Your doctor has prescribed Instanyl® single dose nasal spray. This guide is intended to help you familiarise yourself with important information related to the treatment of your cancer breakthrough pain, as well as the correct application of the nasal spray. Please make sure you have read the guide carefully before using Instanyl® and keep it for future reference.

Reporting Side Effects

Patients are asked to report any suspected adverse events to HPRA Pharmacovigilance, Website: www.hpra.ie. Alternatively, suspected adverse events should be reported to Takeda Products Ireland Ltd on 1800 937 970 or AE.GBR-IRL@takeda.com

CANCER AND PAIN

What is special about cancer pain?

For people with cancer, pain can affect their quality of life.¹ Pain may be caused by the cancer itself, or it may be caused by cancer treatments or other cancer-related problems.¹ Some pain may have nothing to do with the cancer.

What is breakthrough cancer pain (BTP)?

Some people with cancer have constant pain, which is called background pain. Your doctor will prescribe medication to keep this pain at about the same level over time.¹

Breakthrough cancer pain (BTP) is pain that feels worse than the background pain you may feel most of the time. You may not know when to expect this pain and this can keep you from doing what you need or want to do.

How do I know if I have BTP?

BTP is usually:²

- Moderate to severe.
- Comes on quickly (it can take just a few minutes for the pain to reach its peak).
- Relatively short-lived (it may last only around 30 minutes).

If you have pain that is not controlled by your current medications, tell your doctor. You may be experiencing BTP, or your doctor may need to check if the medications you are taking for background pain are still right for you.

What happens if I have BTP?

People with BTP often need medicines called short-acting opioids, also known as fast-acting or rapid-onset opioids. They act quickly to provide relief, and are used in addition to the medicines taken to treat background pain. ²

Instanyl[®] is an example of a rapid-onset opioid used to treat BTP. It is only suitable for adults who are already taking opioids for the treatment of background cancer pain. ³

2. WHAT IS INSTANYL? HOW DO I USE IT?

Instanyl[®] is a powerful painkiller (opioid) for adults suffering from BTP. ³ BTP is a pain that feels worse than the background pain you may suffer from most of the time, even though you are taking regular opioid pain-relieving medicines.

Only use Instanyl[®] if you:

-  are 18 years of age or older and have cancer, **AND**
-  are already being treated with opioids for background cancer pain, **AND**
-  are suffering with another type of cancer pain that is temporary and feels worse than your background cancer pain, **AND**
-  your doctor or pharmacist have taught you how to use Instanyl[®].

If even one of these points **does not** apply to you, talk to your doctor. Ask your doctor or pharmacist if you have any questions or concerns about Instanyl[®].

Important:

Do not use Instanyl[®] to treat any type of pain that you do not think is related to your cancer, such as short-lasting headaches, muscle pains or toothaches.

What do I need to know about the use of Instanyl[®]?

It is important that you follow your doctor's advice on how to use Instanyl[®].

-  Use one puff (one dose) of Instanyl[®] per BTP episode. If you are still in pain after 10 minutes, you may use at most only one more puff for this episode of BTP.



You should generally wait at least 4 hours before using Instanyl to treat another episode of BTP



Do not treat more than four BTP episodes per day.

If you feel that you need to use Instanyl® more often, consult your doctor for advice. They may need to change your other pain medicines.

In exceptional cases, when a new episode of BTP occurs earlier than 4 hours after your last dose, you can treat it with Instanyl®, but you must wait at least 2 hours since your previous dose before doing so.

If you regularly experience BTP episodes that are less than 4 hours apart, or if you have more than four BTP episodes per day and think that you need to use Instanyl® more often than described above, please consult your doctor who will need to consider whether your regular background opioid therapy may need to be adjusted.

Do not change the dose of Instanyl® or your other pain medicines on your own. Any change in dose must be discussed and agreed with your doctor.

Important:

1. Instanyl® is not the same as other fentanyl products you may have used. Use Instanyl® only as directed by your doctor.
2. Instanyl® is available in three dose strengths. Each strength has a different colour code. You and your doctor may have tried different doses of Instanyl® to determine the effective dose for you. It is important that you use only the dose strength that your doctor has prescribed.

	50 micrograms/dose
	100 micrograms/dose
	200 micrograms/dose

How should I store Instanyl®?

- ➔ Store below 30°C. Do not freeze.
- ➔ Instanyl® can be harmful to children and could cause death. Keep Instanyl® where children cannot see or reach it.

- If a child has accidentally come into contact with Instanyl®, immediately seek medical attention.
- Always store the nasal spray in an upright position.
- Contact your doctor or pharmacist if you have any questions about the storage of Instanyl®.

Important:

Some people abuse opioids such as Instanyl®. Make sure that only you or your responsible caregivers handle or have access to your Instanyl®.

How do I dispose of Instanyl®?

All sprays, whether empty, used, or unused, must be returned to your pharmacist for proper disposal.

How do I use Instanyl® single dose nasal spray?

If your Instanyl® nasal spray looks like one of these sprays, then this guide is for you.

NOTE: Each single-dose container is sealed in a child-resistant blister pack. Do not open the blister pack before you are ready to use the spray. Each single-dose container contains only one dose of Instanyl®. Do not test before use.

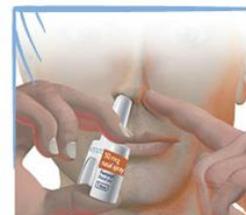


How to use Instanyl® single dose nasal spray:

1. To open, cut with scissors along the line (above the scissors symbol) on the blister pack. Hold the edge of the foil, peel the foil back and take out the nasal spray.
2. Blow your nose if it feels blocked or you have a cold.
3. Gently hold the single dose with your thumb, supporting it at the plunger at the bottom, and your index and middle finger on either side of the spray tip (see figure). Do not press the plunger yet.



4. Bend your head slightly forward.
5. Close one nostril with a finger and insert the spray tip into the free nostril (about 1 cm deep). It does not matter which nostril you use.
6. Press the plunger upwards firmly with your thumb to release the dose, while breathing in gently through your nose. You may not feel the spray in your nose, but you have received the dose when the plunger is fully pressed.
7. Remove the spray container from your nose. Your single-dose nasal spray is now empty.
8. Return all sprays, whether empty, used, or unused, to your pharmacist for proper disposal.
9. If you need to use another single-dose product after 10 minutes to achieve sufficient pain relief, you should use the other nostril for this dose.



INSTANYL®: RISKS OF USE

Talk to your doctor or pharmacist if you have any questions about the use or possible side effects of Instanyl®.

What are some of the possible side effects of Instanyl®?

A full list of possible side effects is included in the Patient Information Leaflet, which can be found within the Instanyl® box. Some possible side effects include:

- ➔ sleepiness
- ➔ dizziness
- ➔ headache
- ➔ Irritation of the throat
- ➔ nausea
- ➔ vomiting
- ➔ flushing or feeling very warm
- ➔ excessive sweating
- ➔ constipation
- ➔ Drug abuse (this can lead to serious problems such as dependence, addiction, overdose, and death)

Overdose

Do not change the dose of Instanyl® or your other pain medication without consultation with your doctor.

Make sure that you and your family/caregivers know the signs of an Instanyl® overdose and seek medical assistance immediately if you experience any of the following signs of overdose:

- ➔ dizziness, difficulty walking or speaking
- ➔ severe fatigue and drowsiness
- ➔ breathing disorders (slow and shallow breathing)
- ➔ slow heartbeat
- ➔ convulsions or seizures
- ➔ unconsciousness
- ➔ in severe cases, overdose with Instanyl® can lead to coma.

If any of the above symptoms occur, your family/caregivers should immediately notify the emergency services by calling 112.

How do I know if I should worry about dependence or addiction?

You might be worried that you will become addicted to opioids. This is a common fear. Talk to your doctor or pharmacist about your concerns.

Some signs that there may be problems with the use of opioids are:

- ➔ You take more of the opioid than your doctor prescribed.
- ➔ You want to stop taking it, but feel like you can't.
- ➔ You crave the opioid.
- ➔ The use of the opioid is affecting your work, home, or social life.
- ➔ You experience unpleasant symptoms if you do not have the opioid. ⁴

If you notice any of these signs, talk to your doctor.

How to best reduce your risk of having a problem with abuse of Instanyl®:

1. Use Instanyl® exactly as prescribed.
2. Talk to your doctor immediately if your pain is not under control or if you have concerns about your symptoms or medications.

Tell your doctor or pharmacist if you have any concerns or questions about your use of opioids. If you have any urgent concerns, contact the emergency numbers provided to you and seek medical help.

A note for caregivers:

To help minimise any potential side effects of treatment, talk to the doctor or medically trained support staff. Please also read the Patient Information Leaflet that comes in the Instanyl® packaging.

For a digital version of this guide, as well as a video version and other helpful materials, see www.medicines.ie



References:

1. Caraceni A, Shkodra M. Cancer pain assessment and classification. *Cancers*. 2019;11:510. doi:10.3390/cancers11040510
2. Fallon M, Giusti R, Aielli F, et al. On behalf of the ESMO Guidelines Committee. Management of cancer pain in adult patients: ESMO clinical practice guidelines. *Ann Oncol*. 2018;29(Suppl 4):iv166–iv191.
3. Instanyl® Product Information, https://www.ema.europa.eu/en/documents/product-information/instanyl-epar-product-information_en.pdf.
4. Centers for Disease Control and Prevention (CDC). Module 5: Assessing and addressing opioid use disorder (OUD). <https://www.cdc.gov/opioids/providers/training/assessing-addressing-oud.html>.