

IMPORTANT SAFETY INFORMATION ABOUT INSTANYL®

Familiarise yourself with this important information and make sure you read the Patient Information Leaflet in the box.

APPROVED INDICATIONS

Instanyl® is only approved for the management of breakthrough pain in adults already receiving background opioid therapy for chronic cancer pain. Breakthrough pain is an additional sudden pain that occurs despite you having taken your usual opioid pain relieving medicines.




PRECAUTIONS WHEN USING INSTANYL®

- ▶ **Only use Instanyl® if:**
 - ▶ you are taking a daily opioid medication for your chronic background cancer pain.
 - ▶ you have been experiencing episodes of breakthrough cancer pain.
 - ▶ you have received proper information and safety precautions from your doctor and pharmacist regarding use of the nasal spray.
- ▶ Do not use Instanyl® to treat any other kind of pain, such as headaches, back pain or toothache.
- ▶ You must carefully follow your doctor's advice on how and when to use Instanyl® and the maximum number of daily doses (puffs) you may take:
 - ▶ One puff of Instanyl® per breakthrough pain episode. If your breakthrough pain is not relieved after 10 minutes, you may use only one additional puff for this episode.
 - ▶ Generally, you should wait 4 hours before treating another episode of breakthrough pain.
 - ▶ No more than four breakthrough pain episodes should be treated per day.
 - ▶ **On exceptional occasions where a new episode occurs earlier, you can use Instanyl® to treat it but you must wait at least 2 hours before doing so.**
 - ▶ **If you regularly have breakthrough pain episodes that are less than 4 hours apart, or if you have more than four breakthrough pain episodes per day and find you may need more frequent dosing of Instanyl® than described above, please contact your doctor for advice. This may mean your regular background opioid therapy needs to be adjusted.**

Do not change the dose of Instanyl® or your other pain medicines on your own. Change in dose must be done together with your doctor.

- ▶ Make yourself and your family/carer aware of the signs of Instanyl® overdose and ensure that you can reach immediate medical assistance, if signs of overdose occur.
- ▶ Signs of overdose can be:
 - ▶ Dizziness, problems walking and talking; extreme drowsiness and sleepiness; slow and shallow breathing, slow heart beat; convulsions (fits or seizures). In serious cases, taking too much Instanyl® can cause coma.

If any of the above signs occur, your carer should contact your doctor or hospital accident and emergency department for expert medical attention.
- ▶ Do not compare prescribed Instanyl® doses with other fentanyl products you may have been prescribed – only your doctor can change your prescribed dose.
- ▶ It is important that you talk to your doctor if you think you are becoming dependent on Instanyl®.
- ▶ Instanyl® is available in three dose strengths and each one has a different colour code – see the colour codes below. You may have used more than one dose strength to get to the most suitable dose for you. However, it is important that you only use the dose strength your doctor decided will best control your breakthrough pain episodes. **If you are ever unsure about which dose strength you should be using, check with your doctor.**

	50 micrograms
	100 micrograms
	200 micrograms

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PRECAUTIONS WHEN STORING INSTANYL®

- ▶ Instanyl® should be kept out of the sight and reach of children because it is harmful to them.
- ▶ If a child is accidentally exposed to Instanyl® it may cause death, please seek immediate medical assistance.
- ▶ Instanyl® should always be kept in its child resistant blister pack until right before you need to use it.
- ▶ It is important that you store Instanyl® in a safe place to avoid misuse by other persons.
- ▶ Only you or a responsible carer should use or handle Instanyl® as it contains medication that is attractive to people who abuse narcotics.



DISPOSAL

- ▶ As with all strong pain treatments, ask your healthcare provider about how to dispose of the Instanyl® Single-Dose Nasal Spray correctly.
- ▶ All unused Instanyl® Single-Dose Nasal Sprays should be returned to your local pharmacy for proper disposal in accordance with local regulations.
- ▶ Instanyl® can be harmful to other people, especially children. Do not throw away any medicines via wastewater or household waste. Any unused single-dose containers should be returned systematically and suitably in the child-resistant blister and discarded according to local requirements or returned to the pharmacy. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Please read the following instructions carefully to learn how to use Instanyl® Single-Dose Nasal Spray:

OPENING OF THE CHILD-RESISTANT BLISTER:

1. Each nasal spray is sealed in a child-resistant blister.

Do not open the blister before you are ready to use the spray. Each nasal spray contains only one dose of Instanyl®.

Do not press the plunger or test the spray before use.

2. To open the blister, cut with scissors along the dotted line on the blister (above the scissors symbol). Hold the edge of the foil, peel the foil back and take the nasal spray out.



HOW TO USE THE INSTANYL® SINGLE-DOSE NASAL SPRAY

PREPARING FOR USE:

1. Blow your nose if it feels blocked or you have a cold.
2. Gently hold the nasal spray with your thumb supporting it at the plunger at the bottom with your index and middle finger on either side of the spray tip (see illustration). **Do not press the plunger yet.**



USING THE NASAL SPRAY:

1. Keep your head in an upright position when taking Instanyl® as shown in the picture.
2. Do not tilt your head backwards when taking Instanyl®.
3. Block one nostril by placing your other index finger against the side of your nose and insert the spray tip into the other nostril (approximately 1 cm). It does not matter which nostril you use. If you have to take a second dose after 10 minutes to get sufficient pain relief, this dose should be taken in the other nostril.
4. Press the plunger upwards firmly with your thumb to release the dose while inhaling gently through the nose and then remove the nasal spray from the nose. You may not feel the dose in your nose, but you have received it when the plunger has been pressed up.
5. Your nasal spray is now empty.

