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INFORMATION FOR THE USER

Instanyl® 50 micrograms/dose nasal spray, solution
Instanyl® 100 micrograms/dose nasal spray, solution
Instanyl® 200 micrograms/dose nasal spray, solution
 Fentanyl

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Instanyl is and what it is used for
2. Before you use Instanyl
3. How to use Instanyl
4. Possible side effects
5. How to store Instanyl
6. Further information

1. WHAT INSTANYL IS AND WHAT IT IS USED FOR

Instanyl belongs to a group of strong painkillers called opioids. Opioids act by blocking the pain signals to the brain.

Instanyl acts very fast and is used for relieving breakthrough pain in adult cancer patients already being treated with opioids for their usual pain. Breakthrough pain is an additional sudden pain that occurs despite you having taken your usual opioid pain relieving medicines.

2. BEFORE YOU USE INSTANYL

Do not use Instanyl:

- if you are hypersensitive (allergic) to fentanyl or any of the other ingredients of Instanyl
- if you have never been treated with opioids before (e.g. codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine)
- if you have serious difficulties breathing or suffer from a serious obstructive lung disease
- if you have previously received facial radiotherapy
- if you suffer from recurrent episodes of nose bleeding

Take special care with Instanyl

- if you suffer from a long-term obstructive lung disease, your breathing may be impaired by Instanyl
- if you have problems with your heart especially slow heart rate, muscle weakness or low blood volume
- if you have problems with your liver or kidneys
- if you have problems with your brain function, e.g. due to a brain tumour, a head injury or increased intracranial pressure
- if you use other nasal spray products e.g. for common cold and allergy

If you experience difficulties breathing while being treated with Instanyl, it is important that you contact your doctor or hospital immediately.

If you experience recurrent nose bleeding or nasal discomfort whilst being treated with Instanyl, you must contact your doctor, who will consider alternative treatment for your breakthrough pain.

If you think you are becoming dependent on Instanyl, it is important that you inform your doctor.

Instanyl should not be used in children and adolescents under 18 years of age.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Instanyl may affect or be affected by other medicines.

Special care should be taken if you are treated with any of the following medicines:

- Any medicines which might normally make you sleepy (have a sedative effect) such as sleeping pills, medicines to treat anxiety, antihistamines, or tranquillisers
- Any medicines that might have an effect on the way in which your body breaks down Instanyl, such as
 - ritonavir, nelfinavir, amprenavir, and fosamprenavir (medicines that help control HIV infection)
 - CYP3A4 inhibitors such as ketoconazole, itraconazole, or fluconazole (used for treatment of fungal infections),
 - troleanandomycine, clarithromycine, or erythromycine (medicines for treatment of bacterial infections),
 - aprepitant (used to treat severe nausea)
 - diltiazem and verapamil (medicines for treatment of high blood pressure or heart diseases)
- Medicines called monoamine-oxidase (MAO) inhibitors (used for severe depression), even if you have been treated with one in the past 2 weeks
- Medicines called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain)
- Other medicines taken via the nose, especially oxymetazoline, xylometazoline and similar medicines, which are used for relief of nose congestions.

Using Instanyl with food and drink

Do not drink alcohol whilst being treated with Instanyl, as it can increase the risk of experiencing dangerous side effects.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Instanyl should not be used during pregnancy unless you have discussed this with your doctor.

Instanyl should not be used during childbirth because fentanyl may cause serious breathing problems in the new-born child.

Instanyl should not be used if you are breast-feeding unless you have discussed this with your doctor.

Fentanyl can pass into the breast milk and may cause side effects to the breast-fed child.

Driving and using machines

You should not drive or use machinery whilst being treated with Instanyl. Instanyl can cause dizziness and drowsiness, which may affect your ability to drive or use machines.

3. HOW TO USE INSTANYL

Always use Instanyl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the treatment or if you have additional questions.

The dose of Instanyl is independent of your usual cancer pain treatment.

When you first start using Instanyl, your doctor will work with you to find the dose that will relieve your breakthrough pain.

The initial dose is one puff of 50 micrograms in one nostril each time you have an episode of breakthrough pain. During the determination of your right dose, your doctor may instruct you to change to a higher dose.

If your breakthrough pain is not relieved after 10 minutes, you may use only one more puff for this episode. You should wait four hours before treating the next episode of breakthrough pain. You can use Instanyl to treat up to four episodes of breakthrough pain per day.

If you experience more than four episodes of breakthrough pain per day, you should contact your doctor, as your usual cancer pain treatment may have to be changed.

In order to keep track of the number of doses of Instanyl used, you should use the tick-boxes in the booklet placed on top of the child-resistant outer box.

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.

Instanyl is for nasal use

Instanyl should be used in the following way:

- You sit or stand in an upright position
- Remove the dust cap from the spray
- Before using the pump for the first time: Pump the spray until a fine mist appears (3 to 4 pumps of the nasal spray are required). It is important that you avoid pointing the spray in the direction of other people.
- Hold the spray upright
- Bend your head slightly forward
- Close one nostril by placing your finger against the side of your nose and insert the spray tip into the other nostril
- Press the pump once quickly while inhaling through the nose
- Always place Instanyl in the child-resistant box after use

If you have not used Instanyl for more than 7 days the pump must be sprayed once in the air before the next dose is taken.

If you use more Instanyl than you should or if you think someone has accidentally used Instanyl

You should contact your doctor, hospital or emergency room for assessment of the risk and for advice if you have taken more Instanyl than you should.

Symptoms of overdose are:

- Sleepiness, drowsiness, dizziness, reduced body temperature, slow heart beat, difficulties coordinating arms and legs.
- In serious cases taking too much Instanyl may cause coma, sedation, convulsions or severe breathing difficulties.
- If you feel any of the above symptoms you should seek immediate medical assistance.

Note to carers

If you see the person taking Instanyl suddenly acting slowly, having difficulties breathing or if you have a difficulties waking the person up you should:

- Immediately call for emergency help
- While waiting for the emergency help, you must try to keep the person awake by talking to or gently shaking the person now and then
- If the person has difficulty breathing, prompt the person to breathe in every 5-10 seconds
- If the person has stopped breathing, you should attempt to resuscitate her/him until emergency help arrives

If you think someone has accidentally taken Instanyl, please seek immediate medical assistance. Try to keep the person awake until emergency help arrives. If someone has accidentally taken Instanyl, they may have the same symptoms as described above for overdose.

If you forget to use Instanyl

If the breakthrough pain is still ongoing, you may take Instanyl as prescribed by your doctor. If the breakthrough pain has stopped, do not take Instanyl until the next episode of breakthrough pain occurs.

If you stop using Instanyl

You should discontinue Instanyl when you no longer have any breakthrough pain.

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You should however continue to take your usual pain relieving medicine to treat your cancer pain. Contact your doctor to confirm the correct dose of your usual medicine if you are not sure.

You may experience withdrawal symptoms similar to the possible side effects of Instanyl when discontinuing Instanyl. If you experience withdrawal symptoms, you should contact your doctor. Your doctor will evaluate if you need medication to reduce or eliminate the withdrawal symptoms.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Instanyl can cause side effects, although not everybody gets them.

The side effects will often stop or reduce in intensity with continued use of the product.

If any of the following very serious side effects occur you should discontinue the treatment and immediately contact your doctor, a hospital or an emergency room:

Severe difficulties breathing, a rattling sound when you breathe in, convulsive pain or extreme dizziness.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)
 Common (affects 1 to 10 users in 100)
 Uncommon (affects 1 to 10 users in 1,000)
 Rare (affects 1 to 10 users in 10,000)
 Very rare (affects less than 1 user in 10,000)
 Not known (frequency cannot be estimated from the available data)

Side effects reported after use of Instanyl:

Common side effects: Sleepiness, dizziness even with difficulties keeping balance, headache, irritation of the throat, nausea, vomiting, flushing, feeling very warm, excessive sweating.

Uncommon side effects: Dependency on the medicine, sleeplessness, drowsiness, convulsive muscle contractions, abnormal sensation of the skin even unpleasant, change of taste, motion sickness, low blood pressure, difficulties breathing, nose bleeds, nasal ulcer, runny nose, constipation, inflammation of the mouth, dry mouth, skin pain, itching of the skin, fever.

You should tell your doctor if you experience recurrent episodes of nose bleeding or nasal discomfort.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INSTANYL

The pain-relieving medicine in Instanyl is very strong and can be life-threatening to children. Instanyl must be kept out of reach and sight of children. Always place the nasal spray in the child-resistant box after use. Do not use Instanyl after the expiry date which is stated on the bottle as EXP. Store below 30°C. Keep the bottle stored upright. Do not freeze. If Instanyl nasal spray is frozen the spray pump may crack. If uncertain of how the pump has been stored, you should check the spray pump before use.

Instanyl that has passed the expiry date or is no longer required, may still contain enough medicine to be harmful to other people, especially children. Instanyl should not be disposed of via wastewater or household waste. Any used or unused bottles should be systematically discarded according to local requirements or returned to the pharmacy in the child-resistant outer box. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Instanyl contains

The active substance is fentanyl. The content is:

50 micrograms/dose: 1 ml contains fentanyl citrate equivalent to 500 micrograms fentanyl. 1 puff (100 microlitre) contains 50 micrograms fentanyl.

100 micrograms/dose: 1 ml contains fentanyl citrate equivalent to 1,000 micrograms fentanyl. 1 puff (100 microlitre) contains 100 micrograms fentanyl.

200 micrograms/dose: 1 ml contains fentanyl citrate equivalent to 2,000 micrograms fentanyl. 1 puff (100 microlitre) contains 200 micrograms fentanyl.

The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, and purified water

What Instanyl looks like and contents of the pack

Instanyl is a clear, colourless nasal spray, solution. It is contained in a brown glass bottle with a metering pump.

The nasal spray is supplied in a child-resistant outer box and comes in three different pack sizes: 1.8 ml (equal to 10 doses), 2.9 ml (equal to 20 doses) and 5.0 ml (equal to 40 doses).

Not all pack sizes may be marketed.

The labelling of the three Instanyl strengths is differentiated by colour:

50 micrograms/dose labelling is orange
 100 micrograms/dose labelling is purple
 200 micrograms/dose labelling is greenish-blue.

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu>

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