This medicine has been prescribed for you and is:

• for treating moderate to severe pain
• for treating pain in cancer patients
• for providing pain relief during labour
• for treating severe pain due to injury
• for providing pain relief before and after surgery

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. Contact your doctor when experiencing such symptoms.

This leaflet contains fentanyl which can cause drowsiness. You can get withdrawal symptoms if you stop receiving it suddenly.

What is in this leaflet
1. What Fentanyl 50 micrograms/ml Injection is and what it is used for
2. What you need to know before you are given Fentanyl 50 micrograms/ml Injection
3. How Fentanyl 50 micrograms/ml Injection is given
4. How much Fentanyl 50 micrograms/ml Injection should be given
5. How to store Fentanyl 50 micrograms/ml Injection
6. What Fentanyl 50 micrograms/ml Injection looks like and contains
7. Possible side effects
8. How to handle it if you get the medicine accidentally
9. How to dispose of Fentanyl 50 micrograms/ml Injection
10. Contact information

Package leaflet: Information for the patient
Fentanyl 50 micrograms/ml Injection

1. What Fentanyl 50 micrograms/ml Injection is and what it is used for

This medicine has been prescribed for you and is:

• for treating moderate to severe pain
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• for providing pain relief during labour
• for treating severe pain due to injury
• for providing pain relief before and after surgery

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. Contact your doctor when experiencing such symptoms and stated above.

Key facts

• This medicine contains fentanyl which can cause drowsiness. You can get withdrawal symptoms if you stop receiving it suddenly.

How to use Fentanyl 50 micrograms/ml Injection

You should NOT be given Fentanyl 50 micrograms/ml Injection if you:

• are allergic to Fentanyl 50 micrograms/ml injection, drugs similar to morphine or related substances, or any of the ingredients listed in section 6.

Your prescriber will discuss your treatment and how and when the injection will be given.

To induce calmness

• You should not be given Fentanyl 50 micrograms/ml Injection during pregnancy because there may be harmful effects on the developing baby. Fentanyl 50 micrograms/ml Injection should not be used during childbirth as it may affect the baby's breathing.

If you receive Fentanyl 50 micrograms/ml Injection during pregnancy, your baby may be born with symptoms of withdrawal. These symptoms may need to be treated if they occur after birth. If you are pregnant, talk to your doctor or nurse about the possible risks and benefits of receiving Fentanyl 50 micrograms/ml Injection during pregnancy.

You should not be given Fentanyl 50 micrograms/ml Injection if you are pregnant or think you might be pregnant. You should not be given Fentanyl 50 micrograms/ml Injection if you are breast-feeding. You should not breast-feed if you have just been receiving Fentanyl 50 micrograms/ml Injection.

You should not be given Fentanyl 50 micrograms/ml Injection:

• if you have any breathing problems or a lung condition for example, asthma, chronic bronchitis or emphysema.
• if you have liver or kidney disease.
• if you have alcoholism.
• if you have had a recent head injury.
• if you have had an operation where you needed all or most of your small intestine.
• if you have had an allergic reaction to fentanyl.
• if you have been given an operation or had an accident that affected your abdomen or bowel.
• if you have had surgery in the past 24 hours.
• if you have had surgery to remove or treat appendicitis.
• if you have been given an operation or had an accident that affected your intestines.

If you have any in doubt or before the dose is changed, contact the prescriber who will discuss your treatment and the injection schedule with you.

Your nurse or doctor will give you the injection.

Contact your doctor when experiencing such symptoms and stated above.
If you are given more Fentanyl 50 micrograms/ml Injection than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much or you begin to experience breathing difficulties, muscle stiffness or tremors, you should tell the person keeping the injection to stop. You must tell the person giving the injection if you feel unwell, and you feel better once receiving the injection.

4. Possible side effects

The following side effects have been reported:

• Delirium (symptoms may include a combination of confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
• Dependence and addiction (see section "How do I know if I am addicted?"
• Spasm of the sphincter of Oddi (pain in stomach/abdomen)
• Slow or shallow breathing
• Stopping of the heart
• Muscle twitching
• Convulsions (fits or seizures)
• Serious allergic reaction which may cause breathing complications, which include: itching, difficulty breathing, or swelling of lips, tongue, or throat
• Slurred speech
• 10 ml clear glass ampoules: packs of 5 or 10
• 5 ml clear glass ampoules: packs of 5 or 10
• 2 ml clear glass ampoules: packs of 5 or 10

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme - see details on how to complete the form for the Yellow Card. You can also report side effects via the National Reporting Scheme for NRHA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

Fentanyl 50 micrograms/ml Injection contains the active substance Fentanyl citrate. Fentanyl 50 micrograms/ml Injection each 1 ml of solution contains the equivalent of 50 micrograms of base fentanyl.

The other ingredients are sodium chloride, water for injections, and hydrochloric acid or sodium hydroxide.

5. How to store Fentanyl 50 micrograms/ml Injection

Keep this medicine out of the sight and reach of children.

Your injection will be stored at less than 25°C and protected from light.

Do not use this medicine after the expiry date which is stated on the label/carton after "EXP:"

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

Fentanyl 50 micrograms/ml Injection includes and looks like the contents of the pack

Fentanyl 50 micrograms/ml Injection is a clear, colourless and sterile solution for injection.

The following pack sizes are available for Fentanyl 50 micrograms/ml Injection:

• 10 ml clear glass ampoules: packs of 5 or 10
• 5 ml clear glass ampoules: packs of 5 or 10
• 2 ml clear glass ampoules: closed with a bromodirol rubber stopper: packs of 1

Not all ampoule and pack sizes may be marketed.

The marketing authorisation number of this medicine is PL 01502/002

Marketing Authorisation Holder

Hameln rds a.s.
Horná 36
31789 Hameln
Germany

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31789 Hameln
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For any information about this medicine, please contact the Marketing Authorisation Holder

This leaflet was last revised in May 2020.