

ASPEN FENTANYL solution for injection

fentanyl citrate

Consumer Medicine Information

WARNINGS

Limitations of use

Aspen Fentanyl should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them

Hazardous and harmful use

Aspen Fentanyl poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Aspen Fentanyl can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Aspen Fentanyl and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate

Use of other medicines while using Aspen Fentanyl

Using Aspen Fentanyl with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Aspen Fentanyl.

What is in this leaflet

This leaflet answers some of the common questions people ask about ASPEN FENTANYL. It does not contain all the information that is known about ASPEN FENTANYL.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ASPEN FENTANYL against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What ASPEN FENTANYL is used for

ASPEN FENTANYL is a powerful drug used to relieve pain and produce sleepiness.

It can be used as a premedication before an operation, or with a general anaesthetic during an operation. It can also be used after painful operations to reduce the pain that you feel.

ASPEN FENTANYL belongs to a group of medicines called opioid (narcotic) analgesics.

It works by changing the messages that are sent to the brain about pain.

Your doctor will have explained why you are being treated with ASPEN FENTANYL and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may prescribe this medicine for another use.

ASPEN FENTANYL can be addictive, but when it is used only to relieve or prevent pain it is unlikely to become habit forming.

Before you are given it

When you must not use it

You should not be given ASPEN FENTANYL if you are pregnant or breastfeeding unless your doctor says it is safe.

Ask your doctor about the risks and benefits involved.

We do not know if it is safe for you to be given ASPEN FENTANYL while you are pregnant. It may affect your baby if it is given early

in pregnancy or in the last weeks before your baby is due.

We do not know if your baby can take in ASPEN FENTANYL from breast milk if you are breastfeeding.

ASPEN FENTANYL solution for injection should only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not passed.

Before you are given it

You must tell your doctor if:

1. you have been given ASPEN FENTANYL before and had any problems with it.
2. you have any allergies to any ingredients listed at the end of this leaflet, other opioid analgesics (strong pain killers) e.g. morphine or pethidine, or any other substances.

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

3. you have any of these medical conditions:
 - problems with your breathing such as severe asthma, severe bronchitis or emphysema
 - a history of fits or head injuries
 - myasthenia gravis (muscle weakness)
 - heart problems
 - liver or kidney problems
 - you are taking MAO (monoamine oxidase) Inhibitors or have taken them within the last 14 days (ask your pharmacist if you are unsure)
 - safe use in children under two year of age has not been established
 - history of drug dependence.

It may not be safe for you to be given ASPEN FENTANYL if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

medicines that you buy without a prescription at the chemist, supermarket or health food shop.

These medicines may affect the way ASPEN FENTANYL works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you are given any ASPEN FENTANYL.

How ASPEN FENTANYL is given

ASPEN FENTANYL will be given to you by injection by an experienced doctor and you will be under constant supervision.

The injection may be given into a vein or into a muscle. It may be given before, during or after surgery.

Your doctor will prescribe the correct dose based on factors such as your age, bodyweight, physical status and medical condition.

How long to take it

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Aspen Fentanyl given to the mother during labour can cause breathing

problems and signs of withdrawal in the newborn.

If you take too much (Overdose):

The doctor or nurse giving you ASPEN FENTANYL will be experienced in its use, so it is extremely unlikely that you will be given too much.

However, the first sign of overdosage is often muscle spasm, followed by a marked slowing of your breathing, accompanied by a bluish tinge on the skin. You will probably lose consciousness.

ASPEN FENTANYL doses should be carefully worked out, so problems with overdosage are unlikely. There are other drugs, e.g. naloxone or nalorphine, which can be used if needed to reverse the effects of too much ASPEN FENTANYL.

If you or someone else receive too much (overdose), and experience one or more of the symptoms below call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then.

You should follow the above steps even if someone other than you have accidentally used Aspen Fentanyl that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much Aspen Fentanyl you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Things to be careful of:

You can become addicted to Aspen Fentanyl even if you take it exactly as prescribed. Aspen Fentanyl may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

As with all other opioid containing products, your body may become used to you taking Aspen Fentanyl. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Aspen Fentanyl suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance to Aspen Fentanyl may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given ASPEN FENTANYL.

This medicine helps most people suffering severe pain, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

After you have been given ASPEN FENTANYL you will probably feel light-headed, dizzy, sleepy and you may feel quite strange, especially if you are not lying down.

Tell your doctor or nurse if you notice any of the following side effects and they worry you.

ASPEN FENTANYL may cause slowing down of breathing or muscle spasm.

ASPEN FENTANYL sometimes causes:

- changes in blood pressure (higher or lower)
- dizziness
- nausea (feeling sick)
- vomiting
- blurred vision
- itching
- euphoria (exaggerated sense of well-being).

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects after being given ASPEN FENTANYL.

After taking it

Storage

If you are storing ASPEN FENTANYL at home keep them in the original pack in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep medicines where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

Disposal

Make sure that you return to your doctor or pharmacist any injections that have passed the use by (expiry) date marked on the pack, or if you have any left over when your doctor says you no longer need to be given ASPEN FENTANYL injections.

Product Description

ASPEN FENTANYL solution for injection is a clear, colourless solution in a glass ampoule.

Available in packs of 5 or 10 ampoules.

ASPEN FENTANYL solution for injection is available in two strengths:

- 100 micrograms/2 mL
- 500 micrograms/10 mL

Ingredients

Active ingredient:

Each ASPEN FENTANYL injection contains fentanyl citrate 50 microgram/mL as the active ingredient.

Inactive ingredients:

- sodium chloride
- water for injections.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

Australian Registration Numbers:

100 micrograms/2 mL: AUST R 170929

500 micrograms/10 mL: AUST R 170931

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