Remifentanil-AFT

Remifentanil (as the hydrochloride) 1mg, 2 mg and 5 mg, Powder for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Remifentanil-AFT. It does not contain all of the available information. 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 Remifentanil-AFT against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What Remifentanil-AFT is used for

Remifentanil-AFT is an anaesthetic used with other anaesthetic medicines, to produce and/or maintain heavy sleep during your operation. If you are a cardiac patient, it may also be used to help relieve any pain immediately after your operation.

Remifentanil-AFT may also be used for patients in the Intensive Care unit to maintain sedation and relieve pain.

Remifentanil-AFT belongs to a group of medicines called opioids. It differs from other medicines in this group by its very quick onset and very short duration of action.

Your doctor may have prescribed Remifentail-AFT for another reason. Ask your doctor if you have any questions about why Remifentanil-AFT has been prescribed for you.

Remifentanil-AFT can be addictive but this is unlikely to happen when it is only used during your operation.

Before you are given Remifentanil-AFT

When you must not be given it

You must not be given Remifentanil-AFT if you have ever had an allergic reaction to remifentanil hydrochloride or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- wheezing,
- swelling of the lips/mouth,
- difficulty in breathing,
- hayfever, rash ("hives") or
- fainting

Before you are given Remifentanil-AFT

You must tell your doctor if:

- **you have had any adverse reactions during an operation.**
- **you have had any type of allergic reaction to any opioid medicine e.g. morphine, fentanyl, pethidine, codeine, or to any medicine used during anoperation.** You may have an increased risk of being allergic to Remifentanil-AFT if you are allergic to other opioids.
- **you are allergic to any other medicine or any other substance, e.g. foods, dyes or preservatives.**
- **you have or have had any of the following medical conditions:**
  - slow heart beat,
  - low blood pressure,
  - chest or breathing problems.
- **you are pregnant, intend to become pregnant, are breast feeding or plan to breast feed.** Remifentanil-AFT is not recommended during pregnancy or when breast-feeding. Your doctor will discuss the potential risks and benefits of you being given Remifentanil-AFT if you are pregnant or breast-feeding.

If you have not told your doctor about any of the above, make sure you tell him/her before you are given Remifentanil-AFT.

Taking other medicines:

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you have recently been taking medicines for blood pressure or heart problems e.g. beta blockers or calcium channel blockers.

Some medicines, such as benzodiazepines, may interfere with how Remifentanil-AFT works. Your doctor or pharmacist will be able to tell you what to do when being given Remifentanil-AFT with other medicines.

How Remifentanil-AFT is given

Remifentanil-AFT is given into a vein as either:
- a slow injection, or
- a slow infusion.

by an anaesthetist or other highly trained doctor. You will never be expected to give yourself this medication. The dosage will vary according to many factors e.g. your body weight and the type of operation you are having.

While using Remifentanil-AFT

If you are discharged early following treatment with Remifentanil-AFT or any other anaesthetic agents, do not drive or operate machinery.

Side effects

Check with your doctor as soon as possible if you have any concerns after being given Remifentanil-AFT, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Remifentanil-AFT can have side-effects.

The most common side-effects are:

- slow breathing
- breathlessness
- slow heart beat
- drop in blood pressure
- increased blood pressure which may cause a headache or sensation of warmth or flushing.
- muscle stiffness
- shivering
- nausea
- vomiting
- aches

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Your doctor or pharmacist will be able to answer any questions you may have.Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

Overdose

Because Remifentanil-AFT will only be given by a doctor trained in its use, it is unlikely that you will receive an overdose. Should the doctor think you have received more Remifentanil-AFT than you need, he/she will either slow down the rate at which he/she is giving you the medicine or stop giving it to you altogether.

Storage

Remifentanil-AFT powder for injection should be stored at or below 25 ºC.

To reduce microbiological hazards, reconstituted Remifentanil-AFT solutions should be used as soon as practicable after reconstitution. If storage is necessary, hold at 2-8 °C for not more than 24 hours.

Remifentanil-AFT contains no antimicrobial preservative. Use in one patient on one occasion only.

Other ingredients

Remifentanil-AFT also contains glycine and hydrochloric acid which is used to adjust the pH.

If you want to know more

Talk to your doctor or pharmacist if you have any questions about Remifentanil-AFT. Remifentanil is available in glass vials in three strengths:

- Remifentanil-AFT 1 mg, powder for injection containing remifentanil (as hydrochloride) 1 mg: packs of 5 vials per carton: AUST R 193697
- Remifentanil-AFT 2 mg, powder for injection containing remifentanil (as hydrochloride) 2 mg; packs of 5 vials per carton: AUST R 194069
- Remifentanil-AFT 5 mg, powder for injection containing remifentanil (as hydrochloride) 5 mg; packs of 5 vials per carton: AUST R 193698

Sponsor

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