

ULTIVA™ Injection

Remifentanyl hydrochloride 1mg and 2mg vials

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about ULTIVA. 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 ULTIVA 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 ULTIVA is used for

ULTIVA is an anaesthetic used with other anaesthetic medicines, to produce and/or maintain heavy sleep during your operation. It may also be used to help relieve any pain immediately following your operation.

ULTIVA may also be used for patients in the Intensive Care Unit to maintain sedation and relieve pain.

ULTIVA 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 ULTIVA for another reason.

Ask your doctor if you have any questions about why ULTIVA has been prescribed for you.

As with other opioids, ULTIVA can be addictive. This is unlikely to happen when ULTIVA is only used during your operation.

Before you are given ULTIVA

When you must not receive ULTIVA

- **You must not receive ULTIVA if you have ever had an allergic reaction to remifentanyl 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, lumpy rash ("hives") or fainting.

Before you receive ULTIVA:

You must tell your doctor if:

- **you have had any adverse reactions during an operation.**
- **you have had any type of allergic reaction to opioid medicines (e.g., morphine, fentanyl, pethidine, codeine), or to any medicines used during an operation.**

You probably have an increased chance of being allergic to ULTIVA if you are allergic to other opioids.

- **you are allergic to any other medicines or any other substance, such as foods, dyes or preservatives.**
- **you have or have ever 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.**

Like most medicines, ULTIVA is not recommended in pregnancy and breast-feeding. However, your doctor will discuss the possible risks and benefits of

being given ULTIVA if you are pregnant or breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given ULTIVA.

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 (known as beta-blockers or calcium channel blockers).

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

How ULTIVA is given

ULTIVA can be given into a vein in two ways:

- as a slow injection, or
- as a slow infusion.

ULTIVA will be administered 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 such as your body weight and the type of operation you have.

While you are using ULTIVA

Things to be careful of:

If you are discharged early, following treatment with ULTIVA 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 problems after receiving ULTIVA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ULTIVA can cause some side-effects.

The most commonly reported 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/flushing.
- muscle stiffness
- shivering
- nausea
- vomiting
- aches

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

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

Product description

What ULTIVA looks like

ULTIVA is supplied as 1 mg or 2 mg of white to off-white powder in a clear, glass vial.

Ingredients

ULTIVA contains the active ingredient remifentanyl (as hydrochloride) 1mg or 2mg per vial. Other ingredients are glycine and hydrochloric acid. The powder is dissolved in a suitable sterile liquid before use. ULTIVA does not contain gluten or lactose.

Manufacturer

Your ULTIVA is supplied by:

GlaxoSmithKline NZ Ltd
Quay Tower
Cnr Albert and Customs St
Private Bag 106600
Downtown Auckland
New Zealand

Ph: (09) 367 2900

Fax (09) 367 2910

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

The information provided applies only to: **ULTIVA™**.
ULTIVA is a trademark of the GlaxoSmithKline Group of Companies.

This leaflet is copyrighted to GlaxoSmithKline and may be reproduced but not altered in any way.

Prepared January 2005
Version 1.0