

DBL™ Remifentanyl powder for injection

Remifentanyl hydrochloride

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about DBL Remifentanyl powder for injection. 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 DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection is used for

DBL Remifentanyl powder for injection 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 following your operation.

DBL Remifentanyl powder for injection may also be used for patients in the Intensive Care Unit to maintain sedation and relieve pain.

DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection for another reason.

Ask your doctor if you have any questions about why DBL Remifentanyl powder for injection has been prescribed for you.

As with other opioids, DBL Remifentanyl powder for injection can be addictive. This is unlikely to happen when DBL Remifentanyl powder for injection is only used during your operation.

Before you are given DBL Remifentanyl powder for injection

When you must not receive DBL Remifentanyl powder for injection

You must not receive DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection, 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 DBL Remifentanyl powder for injection 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, DBL Remifentanyl powder for injection is not recommended in pregnancy and breast-feeding. However, your doctor will discuss the possible risks and benefits of being given DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection.

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 DBL Remifentanyl powder for injection. Your doctor or pharmacist will be able to tell you what to do when being given DBL Remifentanyl powder for injection with other medicines.

How DBL Remifentanyl powder for injection is given

DBL Remifentanyl powder for injection can be given into a vein in two ways:

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

DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection

Things to be careful of

If you are discharged early, following treatment with DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection, even if you do not think the problems are connected

with the medicine or are not listed in this leaflet.

Like other medicines, DBL Remifentanyl powder for injection 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 DBL Remifentanyl powder for injection looks like

DBL Remifentanyl powder for injection is supplied as 1mg, 2mg or 5mg of white to off-white powder in a clear, glass vial.

Ingredients

DBL Remifentanyl powder for injection contains the active ingredient remifentanyl (as hydrochloride) 1mg, 2mg or 5mg per vial. Other ingredients are glycine and Dilute Hydrochloric acid and Sodium Hydroxide. The powder is dissolved in a suitable sterile liquid before use.

DBL Remifentanyl powder for injection does not contain gluten or lactose.

Storage

Unopened DBL Remifentanyl powder for injection vials are stored below 25°C. The 1mg presentation is protected from light.

Manufacturer

Your DBL Remifentanyl powder for injection is supplied by:

Pfizer Australia Pty Ltd
Sydney NSW

Toll Free Number: 1800 675 229
www.pfizer.com.au

Further Information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Do not throw this leaflet away. You may need to read it again.

This leaflet was prepared on December 2019.

The information provided applies only to:
DBL™ Remifentanil powder for injection.
DBL™ Remifentanil powder for injection 1
mg: AUST R 195553
DBL™ Remifentanil powder for injection 2
mg: AUST R 195554
DBL™ Remifentanil powder for injection 5
mg: AUST R 195555