

REMIFENTANIL VIATRIS

remifentanil (as hydrochloride)

Consumer Medicine Information

WARNING

Limitations of use

REMIFENTANIL VIATRIS 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

REMIFENTANIL VIATRIS 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

REMIFENTANIL VIATRIS 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 REMIFENTANIL VIATRIS 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 REMIFENTANIL VIATRIS

Using REMIFENTANIL VIATRIS 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 low blood pressure, 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 REMIFENTANIL VIATRIS.

What is in this leaflet

This leaflet contains answers to some common questions about REMIFENTANIL VIATRIS.

It does not contain all the information available on REMIFENTANIL VIATRIS.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given REMIFENTANIL VIATRIS 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 with the medicine.

You may need to read it again.

What REMIFENTANIL VIATRIS is used for

REMIFENTANIL VIATRIS 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.

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

REMIFENTANIL VIATRIS 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 REMIFENTANIL VIATRIS for another reason.

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

Addiction

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

Dependence

As with all other opioid containing products, your body may become used to you using REMIFENTANIL VIATRIS. Using it may result in physical dependence. Physical

dependence means that you may experience withdrawal symptoms if you stop receiving REMIFENTANIL VIATRIS suddenly.

Tolerance

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

Withdrawal

If you stop receiving 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.

REMIFENTANIL VIATRIS given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Before you are given REMIFENTANIL VIATRIS

When you must not receive it

You must not use REMIFENTANIL VIATRIS if you do not have an allergy to:

- any medicine containing remifentanil
- any of the ingredients listed at the end of this leaflet
- other pain-relieving medicines which are similar to fentanyl and which are related to the class of medicines known as opioids

Symptoms of an allergic reaction may be mild or severe. They may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Before you receive REMIFENTANIL VIATRIS

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 REMIFENTANIL VIATRIS if you are allergic to other opioids.
- you are allergic to any other medicines, 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
 - diseases of the gallbladder or bile ducts inside or outside the liver
 - inflammation of the pancreas (pancreatitis)
- you are pregnant, intend to become pregnant, are breast-feeding or plan to breast feed. Like most medicines, REMIFENTANIL VIATRIS is not recommended in pregnancy and breast-feeding. However, your doctor will discuss the possible risks and benefits of being given REMIFENTANIL VIATRIS 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 REMIFENTANIL VIATRIS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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, other pain relievers, antihistamines, antidepressants (monoamine oxidase inhibitors or MAOIs) and alcohol, may interfere with REMIFENTANIL VIATRIS.

Your doctor or pharmacist will be able to tell you what to do when being given REMIFENTANIL VIATRIS with other medicines.

How REMIFENTANIL VIATRIS is given

REMIFENTANIL VIATRIS can be given into a vein in two ways:

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

REMIFENTANIL VIATRIS 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 REMIFENTANIL VIATRIS

Things to be careful of

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

Side effects

All medicines have unwanted side effects. Sometimes they are serious, most of the time they are not. In cases of serious side effects, you may need prompt medical attention.

REMIFENTANIL VIATRIS can cause the following commonly reported side-effects:

- 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

Do not be alarmed by this list of possible side effects. You may not experience any of them. If you need to know more about the drug, please consult your doctor. Also please be sure to tell your doctor of any unusual effects or symptoms.

Tell your doctor if you are using antidepressants such as MAOIs before you start using REMIFENTANIL VIATRIS. Using these medicines with opioids may cause various symptoms related to serotonin syndrome.

Ask your doctor or pharmacist 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.

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.

After using REMIFENTANIL VIATRIS

Storage

REMIFENTANIL VIATRIS should be kept in a cool dry place in the original container, where the temperature stays below 25°C.

The reconstituted solution should be used immediately, but if necessary, can be kept in a refrigerator between 2°C and 8°C for not more than 24 hours after mixing. Do not freeze.

Product description

What it looks like

REMIFENTANIL VIATRIS is a white to off-white powder and is supplied in a glass vial.

REMIFENTANIL VIATRIS is available in packs of 5 vials.

Ingredients

Each vial contains 1 mg, 2 mg or 5 mg of remifentanil (as hydrochloride).

Inactive ingredients:

- glycine
- hydrochloric acid (for pH adjustment).

Supplier

Alphapharm Pty Ltd trading as Viatris

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30 - 34 Hickson Road
Millers Point NSW 2000
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Australian registration numbers:

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REMIFENTANIL VIATRIS 2 mg - AUST R 163902

REMIFENTANIL VIATRIS 5 mg - AUST R 163903

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