

REMIFENTANIL VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

1. Why am I receiving REMIFENTANIL VIATRIS?

REMIFENTANIL VIATRIS contains the active ingredient remifentanyl. REMIFENTANIL VIATRIS is an anaesthetic used with other anaesthetic medicines, to produce and/or maintain heavy sleep during your operation.

For more information, see Section [1. Why am I receiving REMIFENTANIL VIATRIS?](#) in the full CMI.

2. What should I know before receiving REMIFENTANIL VIATRIS?

Do not use if you have ever had an allergic reaction to remifentanyl or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before receiving REMIFENTANIL VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REMIFENTANIL VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How REMIFENTANIL VIATRIS is given

- REMIFENTANIL VIATRIS can be given in a vein in two ways: as a slow injection, or as a slow infusion.
- REMIFENTANIL VIATRIS will be given to you by an anaesthetist or a doctor. You will never be expected to give yourself this medication.

More information can be found in Section [4. How REMIFENTANIL VIATRIS is given](#) in the full CMI.

5. What should I know while receiving REMIFENTANIL VIATRIS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you have been given REMIFENTANIL VIATRIS.
Driving or using machines	<ul style="list-style-type: none">• If you are discharged early following treatment with REMIFENTANIL VIATRIS, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol while using REMIFENTANIL VIATRIS. Alcohol may interfere with REMIFENTANIL VIATRIS.• Tell your doctor if you drink alcohol.
Looking after the medicine	<ul style="list-style-type: none">• REMIFENTANIL VIATRIS should be kept in a cool dry place in the original container, where the temperature stays below 25°C.

For more information, see Section [5. What should I know while receiving REMIFENTANIL VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Some common side effects are: slow breathing, breathlessness, slow heartbeat, a drop in blood pressure, an increase in blood pressure (which may cause a headache, or a sensation of warmth/flushing), muscle stiffness, shivering, nausea, vomiting, and aches.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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.

REMIFENTANIL VIATRIS

Active ingredient: *remifentanyl (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking REMIFENTANIL VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking REMIFENTANIL VIATRIS.**

Where to find information in this leaflet:

1. [Why am I receiving REMIFENTANIL VIATRIS?](#)
2. [What should I know before receiving REMIFENTANIL VIATRIS?](#)
3. [What if I am taking other medicines?](#)
4. [How REMIFENTANIL VIATRIS is given](#)
5. [What should I know while receiving REMIFENTANIL VIATRIS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I receiving REMIFENTANIL VIATRIS?

REMIFENTANIL VIATRIS contains the active ingredient **remifentanyl**. 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.

REMIFENTANIL VIATRIS is used in the following ways:

- As 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.

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

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 misused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body might get used to REMIFENTANIL VIATRIS over time. 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, you might need more of the medicine to get 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.

Call or speak to your doctor straight away if you experience any of the above symptoms.

2. What should I know before receiving REMIFENTANIL VIATRIS?

Warnings

Do not use REMIFENTANIL VIATRIS if:

- You are allergic to remifentanyl, other pain-relieving medicines which are similar to fentanyl and which are related to the class of medicines known as opioids, or any of the ingredients listed at the end of this leaflet.
- Symptoms of an allergic reaction may be mild or severe. They may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue, or other parts of the body
 - o rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have had any adverse reactions during an operation
- have had any type of allergic reaction to opioid medicines (e.g. morphine, fentanyl, pethidine, codeine), or 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.
- are allergic to any other medicines, foods, dyes, or preservatives
- have or have ever had any of the following medical conditions:
 - o slow heartbeat
 - o low blood pressure
 - o chest or breathing problems
 - o diseases of the gallbladder or bile ducts inside or outside the liver
 - o inflammation of the pancreas (pancreatitis)

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Sleep related breathing disorder

REMIFENTANIL VIATRIS may cause sleep-related breathing disorders.

This includes disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen levels in the blood). Symptoms can include:

- breathing pauses during sleep
- night awakening due to shortness of breath
- difficulties to maintain sleep or excessive drowsiness during the day

If you or another person observe these symptoms, contact your doctor.

Adrenal insufficiency

This means that your adrenal glands (small glands above your kidneys) are not able to make certain important hormones. Symptoms can include:

- nausea (feeling sick)
- vomiting
- anorexia
- fatigue
- weakness
- dizziness
- low blood pressure

Your doctor may request blood tests to determine if this is occurring in your body.

Endocrine effects (hormonal effects)

Opioid drugs like REMIFENTANIL VIATRIS, may affect the hypothalamic-pituitary-adrenal axis (HPA) (the body's stress response system), or the hypothalamic-pituitary-gonadal (HPG) axis (the reproductive hormonal system). Symptoms can include:

- low libido
- impotence (erectile dysfunction)
- absence of the menstrual cycle in women
- infertility

Tell your doctor if you experience any of these symptoms.

Gastrointestinal disorder

Problems with your oesophagus (food pipe) may occur as a result of using opioid medicines such as REMIFENTANIL VIATRIS. Symptoms can include:

- difficulty swallowing (dysphagia)
- regurgitation (reflux)
- chest pain

Tell your doctor if you experience any of these symptoms.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most medicines, REMIFENTANIL VIATRIS is not recommended in pregnancy and breastfeeding. However, your doctor will discuss the possible risks and benefits of being given REMIFENTANIL VIATRIS if you are pregnant or breastfeeding.

Using REMIFENTANIL VIATRIS for a long-time during pregnancy can cause the baby to have withdrawal symptoms after birth.

3. What if I am taking other medicines?

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

Some medicines may interfere with REMIFENTANIL VIATRIS and affect how it works. These include:

Benzodiazepines, other pain relievers, antihistamines, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), or cannabis. Your doctor or pharmacist will be able to tell you what to do when being given REMIFENTANIL VIATRIS.

Tell your doctor if you have recently been taking medicines for blood pressure or heart problems (known as beta-blockers or calcium channel blockers).

Serotonin syndrome

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REMIFENTANIL VIATRIS.

4. How REMIFENTANIL VIATRIS is given

REMIFENTANIL VIATRIS can be given in 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.

If you have been given too much REMIFENTANIL VIATRIS

If you or someone else has received too much REMIFENTANIL VIATRIS (overdose) and experience one or more of the symptoms below, urgent medical attention is required.

Keep the person awake by talking to them or gently shaking them every now and then.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- go to the Emergency Department at your nearest hospital.

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

- Symptoms of an overdose may include:
- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits (twitching or jerking)

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

5. What should I know while receiving REMIFENTANIL VIATRIS?

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

You must not drink alcohol while using REMIFENTANIL VIATRIS. Alcohol may interfere with REMIFENTANIL VIATRIS.

Looking after the medicine

- 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">• slow breathing• breathlessness• slow heartbeat• drop in blood pressure• increased blood pressure which may cause a headache or sensation of warmth/flushing• muscle stiffness• shivering• nausea• vomiting• aches	Speak to your doctor if you have any of these side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REMIFENTANIL VIATRIS contains

Active ingredient (main ingredient)	remifentanil
Other ingredients (inactive ingredients)	glycine hydrochloric acid

Do not take this medicine if you are allergic to any of these ingredients.

What REMIFENTANIL VIATRIS looks like

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

This medicine is available in packs of 5 vials.

Australian registration numbers

REMIFENTANIL VIATRIS 1 mg vial - AUST R 163901

REMIFENTANIL VIATRIS 2 mg vial - AUST R 163902

REMIFENTANIL VIATRIS 5 mg vial - AUST R 163903

Who distributes REMIFENTANIL VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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