1.5.5.2 Proposed Patient Information Leaflet - clean

SCHEDULING STATUS: S6

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

REMIFENTANIL 1 mg VIATRIS (powder for concentrate for solution for injection or infusion)

REMIFENTANIL 2 mg VIATRIS (powder for concentrate for solution for injection or infusion)

REMIFENTANIL 5 mg VIATRIS (powder for concentrate for solution for injection or infusion)

Remifentanil hydrochloride 1 mg/2 mg/5 mg powder for concentrate for solution for injection or infusion

Read all of this leaflet carefully before you are given REMIFENTANIL VIATRIS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **REMIFENTANIL VIATRIS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT REMIFENTANIL VIATRIS CONTAINS:

• The active substance is remifentanil hydrochloride. Each vial contains remifentanil base as remifentanil hydrochloride 1 mg or 2 mg or 5 mg.

• The other ingredients are glycine and hydrochloric acid (for pH adjustment).

2. WHAT REMIFENTANIL VIATRIS IS USED FOR:

Remifentanil is an anaesthetic belonging to a group of medicines called opioids (substances that have a morphine-like action in the body).

REMIFENTANIL VIATRIS is used:

- to help put you to sleep before an operation,
- to keep you asleep and stop you feeling pain during an operation, to make you feel sleepy and stop you feeling pain while you receive treatment in an Intensive Care Unit.

3. BEFORE YOU ARE GIVEN REMIFENTANIL VIATRIS:

You must not be given REMIFENTANIL VIATRIS:

- If you are allergic (hypersensitive) to remifentanil or any of the other ingredients in **REMIFENTANIL VIATRIS**.
- If you allergic (hypersensitive) to any other opioid medicines, such as fentanyl.
- As the only medicine for induction of anaesthesia.

As glycine is present in the formulation, **REMIFENTANIL VIATRIS** must not be given for epidural and intrathecal use (injection into the spine (vertebral column) low area).

Special care should be taken with REMIFENTANIL VIATRIS:

Tell your doctor or healthcare professional before being administered

REMIFENTANIL VIATRIS:

• If you have had any undesirable and/or unexpected effects during anaesthesia.

• If you have been told that you are allergic to any medicines used during an operation.

• If you have had any respiratory disorders (problems with your breathing).

• If have heart disorders (slow or irregular heart rhythm).

• If have been told your blood pressure is low (hypotension),

• If have severe liver disorders (hepatic failure).

• If suffer from myasthenia gravis (a serious muscle sickness)

While under treatment with **REMIFENTANIL VIATRIS**:

• You may experience:

- respiratory disorders (too shallow or too slow breathing),
- muscular stiffness. This effect depends on the dose and the administration speed. For this reason, when given as a single slow administration into your vein (slow bolus injection), **REMIFENTANIL VIATRIS** should not be given to you in less than 10 seconds,
- low blood pressure (hypotension) or slowdown of heart rhythm (bradycardia).

If it happens, your doctor will perform an appropriate and specific treatment. He/she will adjust the dose you are being given and the administration speed.
Your doctor will make sure you have fully regained a satisfactory general condition before allowing you to leave the recovery room.

Receiving REMIFENTANIL VIATRIS with food and drink:

You will be undergoing an operation and will therefore not eat or drink until you have fully recovered.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving **REMIFENTANIL VIATRIS.**

Inform your doctor if you are pregnant or planning to get pregnant, or breast-feeding.

REMIFENTANIL VIATRIS should generally not be used during pregnancy, unless otherwise indicated by your doctor.

Your must not breast-feed for 24 hours after the administration of **REMIFENTANIL VIATRIS.**

Driving and using machinery:

• **REMIFENTANIL VIATRIS** may cause you to feel light-headed or drowsy which could interfere with your ability to drive or use machines.

• When your **REMIFENTANIL VIATRIS** treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

Taking other medicines with REMIFENTANIL VIATRIS:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

The following medicines may interact with REMIFENTANIL VIATRIS:

• Medicines for your heart or blood pressure, such as beta-blockers

or calcium channel blockers.

Athletes:

Athletes should be warned that **REMIFENTANIL VIATRIS** contains an active substance that could give a positive result in anti-doping tests.

4. HOW REMIFENTANIL VIATRIS WILL BE GIVEN TO YOU:

You will never be expected to give yourself REMIFENTANIL VIATRIS. It will always be given to you by a qualified health professional and under carefully controlled conditions.

Dosage:

The dose you will receive will depend on:

- the operation that you have,
- how much pain you will be in,
- how sleepy the medical staff want you to be in the Intensive Care Unit.

The dose varies from one patient to another.

It depends on your age, your body mass and your general health condition.

Your doctor will decide on a dose which is right for you. He/she may adjust it depending on the effects obtained during the anaesthesia.

Method of administration:

You will be given **REMIFENTANIL VIATRIS** by intravenous route.

REMIFENTANIL VIATRIS can be given:

- as a single injection into your vein (bolus injection),
- as a continuous infusion into your vein. This is where the medicine is slowly given to you over a long period of time.

A specific infusion technique will be used to avoid any accidental administration in particular at the end of anaesthesia.

Duration of treatment:

Your doctor will decide on the duration of therapy which is appropriate for you and the operation you have.

If you are given too much REMIFENTANIL VIATRIS:

Since a healthcare professional will administer **REMIFENTANIL VIATRIS**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Effects when treatment with REMIFENTANIL VIATRIS is stopped:

REMIFENTANIL VIATRIS may produce a dependency.

If you have any further questions on the use of **REMIFENTANIL VIATRIS**, please ask your doctor or pharmacist.

5. POSSIBLE SIDE-EFFECTS:

REMIFENTANIL VIATRIS can cause side-effects.

If any of the following happens, treatment with **REMIFENTANIL VIATRIS** should be stopped immediately:

• If you develop an allergic reaction which may include swelling of your eyelids, face, lips, mouth or tongue, shortness or shallow breathing or temporarily stopping breathing, skin rash, irregular skin patches and itching.

• If you develop a slow down or absence of a heartbeat.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **REMIFENTANIL VIATRIS.**

Tell your doctor immediately if you notice any of the following:

• Muscle stiffness.

• Low blood pressure (hypotension).

• Increase in blood pressure (hypertension).

These are all serious side-effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Nausea, vomiting.

- Post-operative shivering.
- Weight gain.
- Local pain at administration site.

Less frequent:

- Problems with breathing due to lack of oxygen in the blood (hypoxia).
- Constipation.
- Post-operative aches.

Frequency not known:

- Sleepy feeling (sedation) during recovery from general anaesthesia.
- Headache.

Not all side-effects reported for **REMIFENTANIL VIATRIS** are included in this leaflet. Should your general health worsen while receiving **REMIFENTANIL VIATRIS**, please tell your doctor, pharmacist or other health care professional.

If you notice any side-effects not mentioned in this leaflet, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF REMIFENTANIL VIATRIS:

KEEP OUT OF REACH OF CHILDREN.

Do not use **REMIFENTANIL VIATRIS** after the expiry date which is stated on the carton and label.

Store at or below 25 ºC.

Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at 25 ºC.

Chemical and physical-in-use stability of the diluted solution has been demonstrated for 4 hours at 25 ºC.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Do not remove the vial from the carton until required for use.

Vials, which have already been used, should be disposed by your health professional.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MYLAN REMIFENTANIL:

REMIFENTANIL VIATRIS will be available in packs of 5 vials.

After reconstitution the solution contains 1 mg/ml, if prepared as recommended.

REMIFENTANIL 1 mg VIATRIS is packed in a colourless glass 3 ml vial with a grey stopper and flip-off cap.

REMIFENTANIL 2 mg VIATRIS is packed in a colourless glass 3 ml vial with a grey stopper and flip-off cap.

REMIFENTANIL 5 mg VIATRIS is packed in a colourless 6 ml vial with a grey stopper and flip-off cap.

8. IDENTIFICATION OF MYLAN REMIFENTANIL:

REMIFENTANIL VIATRIS is a sterile, endotoxin-free, preservative-free, white to off-white, dehydrated powder.

The reconstituted solution is clear, colourless and practically free from particulate material.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

REMIFENTANIL 1 mg VIATRIS: 45/2.9/0658

REMIFENTANIL 2 mg VIATRIS: 45/2.9/0659

REMIFENTANIL 5 mg VIATRIS: 45/2.9/0660

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando,

Johannesburg, 1609

11. DATE OF PUBLICATION:

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