PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S6

REMIFENTANIL 1 MG B. BRAUN sterile powder for solution for injection or infusion

REMIFENTANIL 2 MG B. BRAUN sterile powder for solution for injection or infusion

REMIFENTANIL 5 MG B. BRAUN sterile powder for solution for injection or infusion

Remifentanil

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healh care provider.

What is in this leaflet

1. What REMIFENTANIL B. BRAUN is and what it is used for

REMIFENTANIL B. BRAUN 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 B. BRAUN** may be used to stop you feeling pain or while you are having an operation.

- **REMIFENTANIL B. BRAUN** may be used to relieve pain while you are under controlled mechanical ventilation in an Intensive Care Unit.

2. What you need to know before you use REMIFENTANIL B. BRAUN

REMIFENTANIL B. BRAUN should not be administered to you:

- if you are hypersensitive (allergic) to remifentanil, or any of the other ingredients of **REMIFENTANIL B. BRAUN** (listed in Section 6) or fentanyl derivates (such as alfentanil, fentanyl, sufentanil). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue. You may know this from earlier experience.
- as injection into the spinal canal
- as sole medicine to initiate anaesthesia
- In pregancy and lactation
- Together with nitrous oxide and oxygen alone at altitutes above sea level
- Without artificial ventilation

Warnings and precautions

Before you receive **REMIFENTANIL B. BRAUN**, tell your doctor if you:

- ever had any adverse reactions during an operation
- ever had any allergic reactions or if you have been told that you are allergic to:
  - any medicine used during an operation
  - opioid medicine (e.g. morphine, fentanyl, pethidine, codeine), see also section above **"you should not be given REMIFENTANIL B. BRAUN "**
- suffer from impaired lung and/or liver function (you may be more sensitive for breathing difficulties)

Take special care with **REMIFENTANIL B. BRAUN** and tell your doctor:

- if you have a fast heart rate or feel agitated when the treatment is stopped;
- if you have stiff muscles;
- If you struggle to breath;

- If you feel faint or dizzy or have a very slow heart beat.

Elderly

If used for an operation under general anaesthesia, the initial dose of **REMIFENTANIL B. BRAUN** should be appropriately reduced in elderly patients.

Elderly or weak patients (caused by decreased blood volume and/or low blood pressure) are more sensitive to suffer from cardiac or circulatory disturbances.

Children

REMIFENTANIL B. BRAUN is not recommended in neonates and infants (children under the age of one year). There is little experience of use of **REMIFENTANIL B. BRAUN** to treat children of this age in intensive care units.

Other medicine and REMIFENTANIL B. BRAUN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or taditional medicines.)

This is especially important with the following medicine as they may interact with your **REMIFENTANIL B. BRAUN**:

- medicine for blood pressure or heart problems (known as beta-blockers or calcium channel blockers). These medicines may increase the effect of **REMIFENTANIL B. BRAUN** on your heart (lowering of your blood pressure and your heart beat).
- Other sedative medicine, such as benzodiazepines. These medicines increase the risk of drowsiness, difficulties in breathing, coma and may be life-threatening. Your doctor or pharmacist will alter the dose of these medicines when you are being given **REMIFENTANIL B. BRAUN**.
- Other opiods.
- Certain antidepressants.
- Medicines to treat migraine (triptans) or to treat vomiting.

- Medicines for the treatment of depression such as Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) and Monoamine Oxidase Inhibitors (MAOIs). It is not recommended to use these medicines at the same time as REMIFENTANIL B.BRAUN as they may increase the risk of serotonin syndrome, a potentially life-threatening condition.

The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.

- It may still be all right for you to receive **REMIFENTANIL B. BRAUN** and your doctor will be able to decide what is suitable for you.

REMIFENTANIL B. BRAUN with alcohol

After having received **REMIFENTANIL B. BRAUN** you should not drink alcohol until fully recovered.

Pregnancy and breastfeeding

REMIFENTANIL B. BRAUN should not be given to pregnant women. **REMIFENTANIL B. BRAUN** is not recommended during labour or a Caesarian section.

If you are given this medicine during labour or close to childbirth, it can affect your baby's breathing. You and your baby will be monitored for signs of excessive sleepiness and difficulty breathing.

It is recommended that you stop breastfeeding for 24 hours after **REMIFENTANIL B. BRAUN** has been given to you. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before this medicine is given to you.

Driving and using machines

This medicine is only used in hospitalized patients. If you are discharged early, after you have been given **REMIFENTANIL B. BRAUN**, you must not drive, operate machinery, or work in dangerous situations. You should not go home alone.

3. How to use REMIFENTANIL B. BRAUN

This medicine must only be given under carefully controlled conditions and emergency equipment has to be available. This medicine will be given by or under the supervision of an experienced doctor who is familiar with the use and action of the type of medicine.

You will never be expected to give yourself this medicine. It wil be given to you by a person who is qualified to do so.

The usual dosing and the duration of your infusion will be worked out by the doctor and can vary according to factors as your body weight, age, physical fitness, other medicines you are given and the type of operation you have.

REMIFENTANIL B. BRAUN can be given:

- as a single injection into your vein (intravenous bolus injection)
- as a continuous infusion (normally through a pump) into your vein. This is where the medicine is given to you over a period of time

If you receive more REMIFENTANIL B. BRAUN than you should or if you miss a dose of REMIFENTANIL B. BRAUN.

Since a health care provider will administer **REMIFENTANIL B. BRAUN**, he/she will control the dosage, it is unlikely that you will be given too much or that you will miss a dose. However, in the event of overdosage your doctor will manage the overdosage.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

REMIFENTANIL B. BRAUN can have side effects.

Not all side effects reported for **REMIFENTANIL B. BRAUN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **REMIFENTANIL B. BRAUN**, please consult your health care provider for advise.

The following side effects may be serious and demand immediate treatment:

Frequent

- breathing stops (apnoea)

Less frequent

- severe allergic reactions including shock, circulatory failure and heart attack in patients receiving **REMIFENTANIL B. BRAUN** with one or more anaesthetic medicines
- slow heart beat followed by heart block in patients receiving **REMIFENTANIL B. BRAUN** with onder or more anaesthetic medicine

Frequency not known

- conculsions (seizures)
- heart block

Other side effects

Frequent

- muscle stiffness
- feeling nausea
- vomiting
- low blood pressure (hypotension)
- slow heart beat (bradycardia)
- shallow breathing (respiratory depression)
- itching
- shivering after the operation
- high blood pressure (hypertension) after the operation
- cough

Less frequent

- constipation
- pain after the operation
- oxygen deficiency (hypoxia)
- sleepiness (during rcovering from the operation)

Frequency not known

- medicine tolerance
- irregular heartbeat (arrhythmia)

Discontinuation of treatment

Symptoms following withdrawal of **REMIFENTANIL B. BRAUN** including fast heart rate, high blood pressure and extreme arousal have been reported infrequently upon abrupt cessation, particularly after prolonged administration of more than 3 days.

Long-term use of **REMIFENTANIL B. BRAUN** can lead to dependence.

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

Reporting of side-effects

If you get side-effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **REMIFENTANIL B. BRAUN.**

5. How to store REMIFENTANIL B. BRAUN

- Keep this medicine out of reach of children.

  This medicine will be stored in the hospital pharmacy and the pharmacist will ensure:
- This medicine is not used after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.
- Is stored at or below 25 ˚C.
- Is not refrigerated or frozen.
- The solution is clear and free of particles and the container is not damaged.
- It is not disposed of in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What REMIFENTANIL B. BRAUN contains

- The active substance is remifentanil.

- Each vial contains either 1 mg, 2 mg or 5 mg of remifentanil (as hydrochloride)
- After reconstitution as directed each ml contains 1 mg remifentanil.
- The other ingredients are glycine and hydrochloric acid.

What REMIFENTANIL B. BRAUN looks like and contents of the pack

REMIFENTANIL B. BRAUN is a white to off white or yellow sterile powder for solution for injection or infusion. It is supplied in colourless glass vials.

Package size:

REMIFENTANIL 1 MG B. BRAUN sterile powder for solution for injection or infusion: 5 vials per pack.

REMIFENTANIL 2 MG B. BRAUN sterile powder for solution for injection or infusion: 5 vials per pack.

REMIFENTANIL 5 MG B. BRAUN sterile powder for solution for injection or infusion: 5 vials per pack.

Not all pack sizes may be marketed.

Holder of Certification of Registration

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REMIFENTANIL 2 MG B. BRAUN - 50/2.9/0962

REMIFENTANIL 5 MG B. BRAUN - 50/2.9/0963