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SCHEDULING STATUS

S6

1 NAME OF THE MEDICINE

Sufentanil 5 µg/ml 2 ml Viatris (solution for injection)

Sufentanil 5 µg/ml 10 ml Viatris (solution for injection)

2 QUALITIVE AND QUANTITIVE COMPOSITION

Sufentanil Citrate equivalent to 5 µg/ml of sufentanil base

Excipients with a known action or effect:

Sufentanil 5 µg/ml 2 ml Viatris contains:

Contains: Sodium chloride 900 mg with sodium content 7.08 mg per 2 ml.

Sufentanil 5 µg/ml 10 ml Viatris:

Contains: Sodium chloride 900 mg with sodium content 35,41 mg per 10 ml.

Sugar free

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear colourless solution. Free from visible foreign material.

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4 CLINICAL PARTICULARS

4.1 Therapeutic indications

SUFENTANIL VIATRIS is administered intravenously as an analgesic adjunct in the maintenance of balanced general anaesthesia in surgical procedures requiring endotracheal intubation and ventilation.

SUFENTANIL VIATRIS administered by epidural route is indicated for:

- Postoperative pain management following general surgery, thoracic or orthopaedic procedures and Caesarean sections.
- As an analgesic adjunct to epidural bupivacaine with or without adrenaline (epinephrine) during labour and vaginal deliveries.

4.2 Posology and method of administration

Posology

The dosage of SUFENTANIL VIATRIS should be individualised.

Factors to be considered in determining the dose are age, body mass, physical status, underlying pathological condition, use of other medicines, type of anaesthesia to be used and duration of the surgical procedure.

In obese patients the dosage of SUFENTANIL VIATRIS should be determined based on standard body mass.

Compatibility:

If desired, SUFENTANIL VIATRIS may be mixed with sodium chloride or glucose intravenous infusions.

Such dilutions are compatible with plastic infusion sets.

They should be used within 24 hours of preparation.

Administration as an analgesic adjunct to nitrous oxide/oxygen:

Droperidol may be given to reduce the incidence of nausea and vomiting.

INTRAVENOUS ADMINISTRATION

Adults:

Initial dose: 1 – 8 µg/kg administered with nitrous oxide/oxygen. The duration of action is 1 – 8 hours depending on the dose.

Maintenance dose: 0,1 – 0,5 µg/kg, as needed, when movement and/or changes in vital signs indicate surgical stress or lightening of analgesia.

Supplemental dosages should be individualised and adjusted to the remaining operative time anticipated.

Special populations for intravenous administration

Elderly (65 years of age and older)

The dose should be reduced in the elderly and in debilitated patients.

Patients with severe renal impairment and end-stage renal failure

The dosage of SUFENTANIL VIATRIS should be reduced in patients with severe renal impairment and end-stage renal failure.

SUFENTANIL VIATRIS should be titrated with caution in these patients.

Such patients also require prolonged post-operative monitoring.

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Paediatric population

No dosing recommendations can be made.

EPIDURAL ADMINISTRATION

Proper placement of a needle or catheter in the epidural space should be verified before SUFENTANIL VIATRIS is injected to assure that unintentional intravascular or intrathecal administration does not occur. Unintentional intravascular injection of SUFENTANIL VIATRIS could result in potentially serious overdose including acute truncal muscular rigidity and apnoea. Unintentional intrathecal injection of the full sufentanil, bupivacaine epidural doses and volume could produce effects of high spinal anaesthesia including prolonged paralysis and delayed recovery. If analgesia is inadequate, the placement and integrity of the catheter should be verified prior to administration of any additional epidural meducines.

SUFENTANIL VIATRIS should be administered by slow injection.

With epidural administration, caution should be exercised in the presence of respiratory depression and in the presence of foetal distress. Epidural administration requires that the patient should be in a high care environment with continuous supervision.

The patient should be closely monitored for at least 2 hours after each dose, as early respiratory depression may occur.

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Post-operative management of pain – Adults:

An initial dose of 30 – 50 µg/kg may be expected to provide adequate pain relief for up to 4 – 6 hours. Additional boli of 25 µg may be administered if there is evidence of lightening of analgesia. There should be a minimum interval of 1 hour between doses.

Analgesic adjunct during labour and vaginal deliveries:

The recommended dosage is 10 – 15 µg administered with 10 ml bupivacaine 0,125 % with or without adrenaline. SUFENTANIL VIATRIS and bupivacaine should be mixed together before administration. Doses can be repeated twice (for a total of three doses) at not less than one-hour intervals until delivery.

Special populations for epidural administration

Elderly patients (65 years of age and older)

The dose should be reduced in the elderly and in debilitated patients.

Paediatric population

SUFENTANIL VIATRIS must be administered to children epidurally only by anaesthesiologists specifically trained in paediatric epidural anaesthesia and in management of respiratory depressant effects of opioids. Appropriate resuscitation equipment, including airway securing devices and an opioid antagonist must be readily available.

Paediatric patients must be monitored for signs of respiratory depression for at least 2 hours after epidural administration of SUFENTANIL VIATRIS.

The safety and efficacy of epidural use of SUFENTANIL VIATRIS in paediatric patients has not been established, as limited data are available.

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Children < 1 year

No data are available for epidural administration of SUFENTANIL VIATRIS to newborns and infants younger than 3 months, and limited data are available for children between 3 months and 1 year. Safety and efficacy of SUFENTANIL VIATRIS in children younger than 1 year have not been established (*see sections 4.4*). Therefore, no dosing recommendations can be made for children in this age group.

Children ≥ 1 year

A single bolus dose of 0,25 – 0,75 µg/kg SUFENTANIL VIATRIS given intra-operatively provided pain relief for a period, which ranged from 1 to 12 hours. The duration of effective analgesia is influenced by the surgical procedure and concomitant use of epidural amide local anaesthetic medicines.

Method of administration

Administered intravenously.

Administration by epidural route.

4.3 Contraindications

- SUFENTANIL VIATRIS is contraindicated in patients with a known intolerance to sufentanil, opioids in general or to any of the excipients.
- Intravenous use in labour or before clamping of the cord during caesarean section is contraindicated due to the possibility of respiratory depression in the new-born infant. This is in contrast to the epidural use in labour, during which SUFENTANIL VIATRIS

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in doses up to 30 µg does not influence the condition of the mother or the newborn (*see section 4.6*).

- Do not administer epidural SUFENTANIL VIATRIS in the presence of:
- severe haemorrhage or shock,
- septicaemia,
- infection at the injections site,
- disturbances in blood morphology and/or anticoagulant therapy, ~~or~~
- other concomitant therapy or medical conditions which could contraindicate the technique of epidural administration,
- patients on monoamine oxidase inhibitors (MAOIs) within the previous 2 weeks (*see section 4.5*).
- Safety in pregnancy and lactation has not been established.

4.4 Special warnings and precautions for use

Respiratory depression is dose related and can be reversed by the specific narcotic antagonist, naloxone, but a repeated dose of the antagonist may be necessary because the duration of respiratory depression may last longer than the duration of action of the opioid antagonist.

Marked respiratory depression accompanies profound analgesia.

It can persist in the post-operative period, and if SUFENTANIL VIATRIS has been given intravenously it can recur. Patients must therefore remain under appropriate surveillance.

Resuscitation equipment and narcotic antagonists should be readily available.

Hyperventilation during anaesthesia may alter the patient's response to CO_2 thus affecting respiration post-operatively.

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The incidence and severity of early respiratory depression with epidural administration may be less if epinephrine (adrenaline) is added.

Vital signs should be monitored routinely.

Concomitant use of SUFENTANIL VIATRIS and central nervous system (CNS) depressants, especially benzodiazepines or related medicines, in spontaneous breathing patients, may increase the risk of profound sedation, respiratory depression, coma and death. If a decision is made to administer SUFENTANIL VIATRIS concomitantly with a central nervous system (CNS) depressant, especially a benzodiazepine or a related medicine, the lowest effective dose of both medicines should be administered, for the shortest period of concomitant use. Patients should be carefully monitored for signs and symptoms of respiratory depression and profound sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (*see section 4.5)*.

Respiratory depression may follow intravenous or epidural use of SUFENTANIL VIATRIS.

Vital signs should be monitored continuously and routinely.

Acute truncal muscular rigidity that may make manual ventilation difficult, may follow intravenous administration of SUFENTANIL VIATRIS.

Induction of muscle rigidity, which may also involve the thoracic respiratory muscles, can occur but the risk may be reduced if intravenous injections are administered slowly. A neuromuscular blocking agent compatible with the patient's condition may be administered prophylactically to prevent muscle rigidity or to induce muscle relaxation after rigidity occurs.

Non-epileptic myoclonic movements can occur.

SUFENTANIL VIATRIS should be used with caution in patients with cardiac dysrhythmias because of its weak cholinergic activity.

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Bradycardia and possibly cardiac arrest can occur when SUFENTANIL VIATRIS is combined with non-vagolytic muscle relaxants. Bradycardia associated with the concomitant use of succinylcholine and sufentanil has been reported. Bradycardia can be treated with atropine.

Opioids such as SUFENTANIL VIATRIS may induce hypotension, especially in hypovolaemic patients. Appropriate measures to maintain a stable arterial pressure should be taken.

The use of rapid bolus injections of SUFENTANIL VIATRIS should be avoided in patients with compromised intracerebral compliance; in such patients the transient decrease in the mean arterial pressure has occasionally been accompanied by a short-lasting reduction of the cerebral perfusion pressure.

It is recommended that the dosage be reduced in elderly and debilitated patients. SUFENTANIL VIATRIS should be titrated with caution in patients with any of the following conditions:

- uncontrolled hypothyroidism,
- pulmonary disease,
- decreased respiratory reserve,
- alcoholism,
- impaired hepatic or renal function,
- increased intracranial pressure.

Such patients also require prolonged post-operative monitoring.

With epidural administration, caution should be exercised in the presence of respiratory depression or compromised respiratory function and in the presence of foetal distress. The patient should be closely monitored for at least 2 hours after each dose, as late respiratory depression may occur.

Paediatric population

- The safety and efficacy of epidural SUFENTANIL VIATRIS in children younger than 1 year have not been established.

SUFENTANIL VIATRIS contains sodium

Sufentanil 5 µg/ml 2 ml Viatris:

This medicine contains less than 1 mmol sodium (23 mg) per 2 ml that is to say essentially 'sodiumfree'.

Sufentanil 5 µg/ml 10 ml Viatris:

This medicine contains 35,41 mg sodium per 10 ml, equivalent to 1,77 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicines and other forms of Interaction

- **Anaesthetics, epidural conduction, spinal:**

  Alterations in respiration caused by high levels of spinal or epidural blockade may be additive to SUFENTANIL VIATRIS -induced alterations in respiratory rate and alveolar ventilation; also, the vagal effects of fentanyl derivatives may be more

pronounced in patients with high levels of spinal or epidural anaesthesia, possibly leading to bradycardia and/or hypotension.

- **Antihypertensives or diuretics or hypotension-producing medicines:**

  Hypotensive effects of these medicines may be potentiated when they are used concurrently with SUFENTANIL VIATRIS; patients should be monitored for excessive fall in blood pressure during and following concurrent use.

- **Benzodiazepines:**

  Premedication with a benzodiazepine such as diazepam, lorazepam or midazolam may decrease the dose of SUFENTANIL VIATRIS required for induction of anaesthesia and decrease the time loss of consciousness with induction doses; also, administration of a benzodiazepine prior to or during surgery may decrease the risk of patient recall of surgical events postoperatively; however, these potential benefits must be weighed against the potential risks of concurrent use, such as an increased risk of severe hypotension associated with decreases in systemic vascular resistance, increased risk of respiratory depression, and delayed recovery time, especially when the benzodiazepine is administered intravenously.

- **Beta-adrenergic blocking agents:**

  Pre-operative chronic use of systemic beta-adrenergic blocking agents may decrease the frequency and/or severity of hypertensive responses to surgery, especially during sternotomy and sternal spread in cardiac or coronary artery surgery. However, chronic pre-operative use of systemic beta-adrenergic blocking agents or ophthalmic beta-adrenergic blocking agents (especially levobunolol or timolol) may also increase the risk of initial bradycardia following induction doses of SUFENTANIL VIATRIS.

- **Buprenorphine and other partial mu-receptor agonists:**

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Use of buprenorphine as presurgical medicines prior to SUFENTANIL VIATRIS-assisted anaesthesia should be undertaken with caution because this partial mu-receptor agonist has high affinity for, and dissociates slowly from, the mu-receptor and may therefore decrease the therapeutic effects of a subsequently administered mu-receptor agonist.

- **Cimetidine or erythromycin:**

  Concurrent use of cimetidine or erythromycin with SUFENTANIL VIATRIS can cause reduced clearance of alfentanil, can prolong recovery from alfentanil, and may increase the risk of respiratory depression; other inhibitors of cytochrome P450 3A4 enzymes have not been tested; however, chronic preoperative administration or perioperative use of hepatic enzyme inhibitors may decrease plasma clearance and prolong the duration of action of SUFENTANIL VIATRIS.
- CNS depression-producing medicines, other, including those commonly used as pre-anaesthetic medication or for induction, supplementation, or maintenance of anaesthesia. Concurrent use with SUFENTANIL VIATRIS may result in increased CNS depressant, respiratory depressant, and hypotensive effects; caution is recommended, and the dosage of each agent should be carefully titrated. It is recommended that initial dosage of other opioid agonist analgesics used during recovery from SUFENTANIL VIATRIS -assisted anaesthesia be decreased to as low as one fourth to one third of the usual recommended dose.
- **Monoamine oxidase (MAO) inhibitors:**

  Caution is recommended when using SUFENTANIL VIATRIS in patients who have received an MAO inhibitor within 14 days because concurrent use of MAO inhibitors with pethidine has resulted in unpredictable, severe, and sometimes fatal reactions,

including immediate excitation, sweating, rigidity, and severe hypertension, or in some patients, hypotension, severe respiratory depression, coma, seizures, hyperpyrexia, and vascular collapse. Monoamine oxidase inhibitors (MOAIs) must therefore be discontinued 2 weeks prior to the administration of SUFENTANIL VIATRIS (*see section 4.3).*

- **Nalbuphine or pentazocine:**

  These opioid agonist/antagonist analgesics may partially antagonise the analgesic, respiratory depressant, and CNS depressant effects of SUFENTANIL VIATRIS; however, because of their agonist activity, concurrent use of these agents also has the potential to produce additive CNS, respiratory, and hypotensive effects; the extent to which antagonistic or additive effects will predominate may depend upon dosage of SUFENTANIL VIATRIS, with antagonism being more likely with low to moderate doses.

- **Naloxone:**

  Naloxone antagonises the analgesic, hypotensive, CNS and respiratory depressant effects of SUFENTANIL VIATRIS; dosage of the antagonist should be carefully titrated when used to reverse the effects of SUFENTANIL VIATRIS used during surgery in order to achieve the desired effect without interfering with control of postoperative pain or inducing other adverse effects. Naloxone also reverses skeletal muscle rigidity induced by SUFENTANIL VIATRIS.

- **Naltrexone:**

  Usual doses of SUFENTANIL VIATRIS will be ineffective if administered to a patient receiving naltrexone, which blocks the therapeutic effects of opioid analgesics. If possible, alternative (non-opioid) medicines should be used prior to, during, and

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following surgery, because administration of increased doses of opioids to override naltrexone blockade of opioid receptors may result in increased and more prolonged respiratory depression and/or circulatory collapse. Naltrexone should be discontinued several days prior to elective surgery if administration of SUFENTANIL VIATRIS is unavoidable.

- **Neuromuscular blocking agents:**

  Concurrent use with high doses of SUFENTANIL VIATRIS may reduce the initial dosage requirement for a non-depolarising neuromuscular blocking agent. It is recommended that a peripheral nerve stimulator be used to determine dosage. Concurrent use of a neuromuscular blocking agent prevents, or reverses muscle rigidity induced by SUFENTANIL VIATRIS.
- A non-serovagolytic neuromuscular blocking agent such as succinylcholine will not decrease the risk of bradycardia or hypotension induced by SUFENTANIL VIATRIS; however, in some patients, especially those with compromised cardiac function and/or those receiving a beta-adrenergic blocking agent pro-operatively, concurrent use may increase the incidence and/or severity of these effects.
- Respiratory depressant effects of neuromuscular blocking agents may be additive to respiratory depressant effects of SUFENTANIL VIATRIS. Although increased or prolonged respiratory depression or paralysis (apnoea) may occur, clinical significance is minimal while the patient is being mechanically ventilated. However, patients should be carefully monitored during and following concurrent use, especially if there is a possibility of incomplete reversal of neuromuscular blockade postoperatively.
- **Nitrous oxide:**

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In addition to the increased CNS depressant, respiratory depressant, and hypotensive effects that may occur when SUFENTANIL VIATRIS is used concurrently with any CNS depressant, concurrent use of nitrous oxide with high doses of these agents may decrease mean arterial pressure, heart rate, and cardiac output. These effects may be more pronounced in patients with poor left ventricular function.

- **Phenothiazines:**

  In addition to the increased CNS depressant, respiratory depressant, and hypotensive effects that may occur when a phenothiazine is used concurrently with SUFENTANIL VIATRIS, some phenothiazines increase, while others decrease the effects of SUFENTANIL VIATRIS supplements to anaesthesia; however, the effect of various phenothiazines on SUFENTANIL VIATRIS -assisted anaesthesia has not been determined.

- **Cytochrome P450 3A4 (CYP3A4) inhibitors:**

  Sufentanil is metabolised mainly via the human cytochrome P450 3A4 enzyme. However, no in vivo inhibition by erythromycin (a known CYP3A4 enzyme inhibitor) has been observed.

  Although clinical data are lacking, in vitro data suggest that other potent CYP3A4 enzyme inhibitors (e.g. fluconazole, ketoconazole, itraconazole, ritonavir, diltiazem and cimetidine) may inhibit the metabolism of sufentanil. This could increase the risk of prolonged or delayed respiratory depression. The concomitant use of such medicines requires special patient care and observation; in particular, it may be necessary to lower the dose of SUFENTANIL VIATRIS.

- **Serotonergic medicines:**

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Co-administration of SUFENTANIL VIATRIS with a serotonergic medicine, such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or monoamine oxidase inhibitors (MAOIs) (*see sub-header Monoamine Oxidase Inhibitor*), may increase the risk of serotonin syndrome, a potentially life-threatening condition.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy and lactation has not been established.

SUFENTANIL VIATRIS added to epidural bupivacaine in total doses up to 30 µg has no detrimental effect on the mother or the newborn, but intravenous use is contraindicated in labour. SUFENTANIL VIATRIS crosses the placenta.

An antidote for the newborn should always be at hand.

Breastfeeding

SUFENTANIL VIATRIS is excreted in human breast milk. Caution should be exercised when SUFENTANIL VIATRIS is administered to a breastfeeding woman. Infants exposed to sufentanil citrate injection, as in SUFENTANIL VIATRIS, through breast milk should be monitored for excess sedation and respiratory depression. Withdrawal symptoms can occur in breastfed infants when maternal administration of an opioid analgesic is stopped, or when breastfeeding is stopped. A woman should not breastfeed her infant for 12 – 24 hours after receiving SUFENTANIL VIATRIS.

Fertility

Chronic use of opioids may cause reduced fertility in females and males of reproductive potential. It is not known whether these effects on fertility are reversible.

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4.7 Effects on ability to drive and use machines

Patients should only drive or operate a machine, perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. make legally binding decisions, if sufficient time has lapsed (at least 24 hours) after administration of SUFENTANIL VIATRIS. Alcohol should not be consumed during that period.

4.8 Undesirable effects

Tabulated list of adverse reactions

Body system	**Undesirable effect**	
	Frequent	**Less frequent**
Infections and Infestations:		Rhinitis
Immune system disorders:		Hypersensitivity
Psychiatric disorders:		Apathy, nervousness
Nervous system disorders:	Dizziness, headache, sedation, neonatal tremor.	Ataxia, neonatal dyskinesia, dystonia, hyperreflexia, hypertonia, neonatal hypokinesia, somnolence.
Eye disorders:		Visual disturbance
Cardiac disorders:	Tachycardia	Dysrhythmia, abnormal electrocardiogram, atrioventricular block, bradycardia, cyanosis.
Vascular disorders:	Pallor, hypotension, hypertension.	

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Respiratory, thoracic and mediastinal disorders:	Neonatal cyanosis.	Bronchospasm, cough, dysphonia, hiccups, hypoventilation, respiratory disorder.
Gastrointestinal disorders:	Nausea, vomiting	
Skin and subcutaneous tissue disorders:	Pruritus, skin discolouration.	Allergic dermatitis, dry skin, hyperhidrosis, rash, neonatal rash.
Musculoskeletal, connective tissue and bone disorders:	Muscle twitching	Muscle rigidity, back pain, neonatal hypotonia.
Renal and urinary disorders:	Urinary incontinence, urinary retention	
General disorders and administrative site conditions:	Pyrexia	Chills, hypothermia, decreased body temperature, injection site pain, injection site reaction, pain
Investigations		Increased body temperature

Post-marketing experience

Body System	Undesirable effect
	Not known
Immune system disorders:	Anaphylactic shock, anaphylactic reaction, anaphylactoid reaction
Nervous system disorders:	Coma, convulsion, involuntary muscle contractions
Eye disorders:	Miosis
Cardiac disorders:	Cardiac arrest (*also see section 4.4)*
Vascular disorders:	Shock

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Respiratory, thoracic and mediastinal disorders:	Respiratory arrest, apnoea, respiratory depression, pulmonary oedema, laryngospasm (*also see sections 4.3 and 4.4*)
Skin and subcutaneous tissue disorders:	Erythema
Musculoskeletal, connective tissue and bone disorders:	Muscle spasms (*also see section 4.4*)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (*see section 4.8)*.

Symptoms:

SUFENTANIL VIATRIS overdose manifests itself as an extension of its pharmacological actions. Depending on the individual sensitivity, the clinical picture is determined primarily by the degree of respiratory depression. This varies from bradypnoea to apnoea.

Treatment:

Treatment should be symptomatic and supportive.

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Hypoventilation or apnoea need oxygen to be administered and respiration should be assisted or controlled as indicated. A specific narcotic antagonist such as naloxone, should be used as indicated to control the respiratory depression. This does not preclude the use of more intermediate countermeasures. If the respiratory depression lasts longer than the effect of the antagonist, additional doses of the antagonist may be required.

If depressed respiration is associated with muscular rigidity, an intravenous neuromuscular blocking agent might be required to facilitate assisted or controlled respiration.

The patients should be carefully observed and adequate fluid intake and body warmth should be maintained. If hypotension is severe or if it persists, the possibility of hypovolaemia should be considered, and if present, it should be controlled with appropriate parenteral fluid administration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PHARMACOLOGICAL CLASSIFICATION:

A.2.9 Central nervous system depressants. Narcotic analgesics

Pharmacotherapeutic group: opioid anaesthetics, ATC code: N01AH03

Pharmacodynamic effects:

Sufentanil is an opioid analgesic.

5.2 Pharmacokinetic properties

Absorption:

After parenteral administration, sufentanil citrate has a rapid onset and short duration of action.

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Distribution:

Terminal elimination half-life of sufentanil is about 2,5 hours.

Sufentanil is extensively bound to plasma proteins (about 92 %).

Biotransformation:

The liver metabolises sufentanil and in the small intestine it is metabolised by N-dealkylation and O-demethylation.

Elimination:

The metabolites are excreted in the urine. About 80 % of a dose is excreted within 24 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid solution (for pH adjustment)

Sodium hydroxide solution (for pH adjustment)

Sodium chloride

Water for injection.

6.2 Incompatibilities

If desired, SUFENTANIL VIATRIS may be mixed with sodium chloride or glucose intravenous infusions (*see section 4.2)*.

Such dilutions are compatible with plastic infusion sets.

They should be used within 24 hours of preparation.

6.3 Shelf life

24 months

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6.4 Special precautions for storage

Store at or below 25 ˚C.

Protect from light.

Keep in the carton until required for use.

For single use only or discard unused portion after initial opening.

6.5 Nature and contents of container

SUFENTANIL VIATRIS is supplied in a clear colourless Type I ampoule.

10 x 2 ml and 10 x 10 ml ampoules are packed in a polystyrene container or a carton.*

*Not all packs may be marketed.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

Any unused product or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF THE CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando

Johannesburg, 1609

Republic of South Africa

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8 REGISTRATION NUMBER(S)

Sufentanil 5 µg/ml 2 ml Viatris Solution for Injection: 41/2.9/0625

Sufentanil 5 µg/ml 10 ml Viatris Solution for Injection: 41/2.9/0626

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 November 2014

10 DATE OF REVISION OF TEXT

TBA