1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

NIMBEX 2 mg/ml 2,5 ml Injection

NIMBEX 2 mg/ml 5 ml Injection

NIMBEX 2 mg/ml 10 ml Injection

NIMBEX 5 (5 mg/ml) Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule of NIMBEX 2 mg/ml (2,5 ml) contains 2 mg/ml cisatracurium, as the besylate.

Sugar free

Each ampoule of NIMBEX 2 mg/ml (5 ml) contains 2 mg/ml cisatracurium, as the besylate.

Sugar free

Each ampoule of NIMBEX 2 mg/ml (10 ml) contains 2 mg/ml cisatracurium, as the besylate.

Sugar free

Each vial of NIMBEX 5 contains 5 mg/ml cisatracurium, as the besylate.

Sugar free

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Injection.

NIMBEX is a clear, pale yellow or greenish yellow solution, free from visible particulate matter.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NIMBEX is used during surgical procedures to relax skeletal muscles and to facilitate controlled ventilation. NIMBEX is suitable for endotracheal intubation especially where subsequent muscle relaxation is required.

4.2 Posology and method of administration

Posology

Use by intravenous bolus injection:

Tracheal Intubation: The recommended intubation dose of NIMBEX for adults is 0,15 mg/kg. This dose produces good to excellent conditions for tracheal intubation 120 seconds following injection. Higher doses will shorten the time to onset of neuromuscular block. The following table summarises mean pharmacodynamic data when NIMBEX was administered at doses of 0,1 to 0,4 mg/kg to healthy adult patients during opioid (thiopentone/fentanyl/midazolam) or propofol anaesthesia.

Initial NIMBEX Injection Dose (mg/kg)	Anaesthetic Background	Time to 90 % T_1[a] Suppression (min)	Time to Maximum T_1[a] Suppression (min)	Time to 25 % Spontaneous T_1[a] Recovery (min)
0,1	Opioid	3,4	4,8	45
0,15	Propofol	2,6	3,5	55

0,2	Opioid	2,4	2,9	65
0,4	Opioid	1,5	1,9	91
[a] Single twitch response as well as the first component of the Train-of-Four response of the adductor pollicis muscle following supramaximal electrical stimulation of the ulnar nerve.				

Maintenance: Neuromuscular block can be extended with maintenance doses of NIMBEX. A dose of 0,03 mg/kg provides approximately 20 minutes of additional clinically effective neuromuscular block during opioid or propofol anaesthesia. Consecutive maintenance doses do not result in progressive prolongation of effect.

Spontaneous Recovery: Once spontaneous recovery from neuromuscular block is underway, the rate is independent of the NIMBEX dose. During opioid or propofol anaesthesia, the median times from 25 to 75 % and from 5 to 95 % recovery are approximately 13 and 30 minutes, respectively.

Reversal: Neuromuscular block following NIMBEX administration is reversible with standard doses of anticholinesterase medicines. The mean times from 25 to 75 % recovery and to full clinical recovery (T_4:T_1 ratio ≥0,7) are approximately 4 and 9 minutes respectively, following administration of the reversal medicine at an average of 10 % T_1 recovery.

Paediatric population aged 1 month to 12 years

Tracheal Intubation: As in adults, the recommended intubation dose of NIMBEX is 0,15 mg/kg administered rapidly over 5 to 10 seconds. This dose produces good to excellent conditions for tracheal intubation 120 seconds following injection of NIMBEX. Pharmacodynamic data for this dose are presented in the tables below. If a shorter clinical duration is required, pharmacodynamic data suggest that a dose of 0,1 mg/kg may produce similar intubation conditions at 120 to 150 seconds

In paediatric patients aged 1 month to 12 years, NIMBEX has a shorter clinically effective duration and a faster spontaneous recovery profile than those observed in adults under similar anaesthetic conditions. Small differences in the pharmacodynamic profile were observed between the age ranges 1 to 11 months and 1 to 12 years which are summarised in the tables below.

Paediatric population aged 1 to 11 months

Initial NIMBEX Dose (mg/kg)	Anaesthetic Background	Time to 90 % Suppression (min)	Time to Maximum Suppression (min)	Time to 25 % Spontaneous T_1 Recovery (min)
0,15	Halothane	1,4	2,0	52
0,15	Opioid	1,4	2,0	47

Paediatric population aged 1 to 12 years

Initial NIMBEX Dose (mg/kg)	Anaesthetic Background	Time to 90 % Suppression (min)	Time to Maximum Suppression (min)	Time to 25 % Spontaneous T_1 Recovery (min)
0,08	Halothane	1,7	2,5	31
0,1	Opioid	1,7	2,8	28
0,15	Halothane	2,3	3,0	43
0,15	Opioid	2,6	3,6	38

Halothane may be expected to extend the clinically effective duration of a dose of NIMBEX by up to 20 %. No information is available on the use of NIMBEX in children during isoflurane anaesthesia but these medicines may also be expected to extend the clinically effective duration of a dose of NIMBEX by up to 20 %.

Maintenance: Neuromuscular block can be extended with maintenance doses of NIMBEX. A dose of 0,02 mg/kg provides approximately 9 minutes of additional clinically effective neuromuscular block during halothane anaesthesia. Consecutive maintenance doses do not result in progressive prolongation of effect.

Spontaneous Recovery: Once recovery from neuromuscular block is underway, the rate is independent of the NIMBEX dose administered. During opioid or halothane anaesthesia, the median times from 25 to 75% and from 5 to 95% recovery are approximately 11 and 28 minutes, respectively.

Reversal: Neuromuscular block following NIMBEX administration is reversible with standard doses of anticholinesterase medicines. The mean times from 25 to 75% recovery and to full clinical recovery (T_4:T_1 ratio ≥0,7) are approximately 2 and 5 minutes respectively, following administration of the reversal medicine at an average of 13% T_1 recovery.

Use by intravenous infusion:

Adults and children aged 2 to 12 years

Maintenance of neuromuscular block may be achieved by infusion of NIMBEX. An initial infusion rate of 3 μg/kg/min (0,18 mg/kg/hr) is recommended to restore 89 to 99% T_1 suppression following evidence of spontaneous recovery. After an initial period of stabilisation of neuromuscular block, a rate of 1 to 2 μg/kg/min (0,06 to 0,12 mg/kg/hr) should be adequate to maintain block in this range in most patients.

Reduction of the infusion rate by up to 40% may be required when NIMBEX is administered during isoflurane or enflurane anaesthesia (see section 4.5). The infusion rate will depend upon the concentration of cisatracurium in the infusion solution, the desired degree of neuromuscular block, and the patient's weight. The following table provides guidelines for delivery of undiluted NIMBEX.

Infusion Delivery Rate of NIMBEX 2 mg/ml

Patient Weight (kg)	**Dose (μg/kg/min)**				**Infusion Rate**
	1,0	**1,5**	**2,0**	**3,0**	
20	0,6	0,9	1,2	1,8	ml/hr

70	2,1	3,2	4,2	6,3	ml/hr
100	3,0	4,5	6,0	9,0	ml/hr

Steady rate continuous infusion of NIMBEX is not associated with a progressive increase or decrease in neuromuscular blocking effect.

Following discontinuation of infusion of NIMBEX, spontaneous recovery from neuromuscular block proceeds at a rate comparable to that following administration of a single bolus.

Neonates aged less than 1 month:

No dosage recommendation for neonates can be made until further information becomes available.

Special populations

Elderly population

No dosing alterations are required in elderly patients. In these patients NIMBEX has a similar pharmacodynamic profile to that observed in young adult patients, but as with other neuromuscular blocking medicines, it may have a slightly slower onset.

Renal impairment

No dosing alterations are required in patients with renal failure. In these patients, NIMBEX has a similar pharmacodynamic profile to that observed in patients with normal renal function, but it may have a slightly slower onset.

Hepatic impairment

No dosing alterations are required in patients with end-stage liver disease. In these patients NIMBEX has a similar pharmacodynamic profile to that observed in patients with normal hepatic function but it may have a slightly faster onset.

Cardiovascular disease

NIMBEX has been used to provide neuromuscular block in patients undergoing cardiac surgery. When administered by rapid bolus injection (over 5 to 10 seconds) to patients with serious cardiovascular disease, NIMBEX has not been associated with clinically significant cardiovascular effects in any dose studied (up to and including 0,4 mg/kg (8x ED_{95}).

Intensive Care Unit (ICU) patients

NIMBEX may be administered by bolus dose and/or infusion to adult patients in the ICU. An initial infusion rate of NIMBEX of 3 μg/kg/min (0,18 mg/kg/hr) is recommended for adult ICU patients. There may be wide interpatient variation in dosage requirements and these may increase or decrease with time. In clinical studies the average infusion rate was 3 μg/kg/min range 0,5 to 10,2 μg/kg/min (0,03 to 0,6 mg/kg/h). The median time to full spontaneous recovery following long-term (up to 6 days) infusion of NIMBEX in ICU patients was approximately 50 minutes.

Infusion Delivery Rate of NIMBEX 5 mg/ml

Patient Weight (kg)	**Dose (μg/kg/min)**				**Infusion Rate**
	1,0	**1,5**	**2,0**	**3,0**	
70	0,8	1,2	1,7	2,5	ml/hr
100	1,2	1,8	2,4	3,6	ml/hr

The recovery profile after infusions of NIMBEX to ICU patients is independent of duration of infusion.

Patients undergoing hypothermic cardiac surgery

There have been no studies of NIMBEX in patients undergoing surgery with induced hypothermia (25 to 28 °C). The rate of infusion required to maintain adequate surgical relaxation under these conditions may be expected to be significantly reduced.

Method of administration

NIMBEX is used by intravenous bolus injection and intravenous infusion.

4.3 Contraindications

NIMBEX is contraindicated in:

- Patients with hypersensitivity to cisatracurium, atracurium, or benzenesulphonic acid or to any excipients in NIMBEX (see section 6.1).
- Pregnancy and lactation, as the use and safety of NIMBEX has not been established in women who are pregnant and breastfeeding.
- Neonates, as NIMBEX has not been studied in this patient population.

4.4 Special warnings and precautions for use

Hypersensitivity

CISATRACURIUM, AS IN NIMBEX, PARALYSES THE RESPIRATORY MUSCLES AS WELL AS OTHER SKELETAL MUSCLES BUT HAS NO EFFECT ON CONSCIOUSNESS OR PAIN THRESHOLD. NIMBEX SHOULD ONLY BE ADMINISTERED BY OR UNDER THE SUPERVISION OF AN ANAESTHETIST OR OTHER CLINICIANS WHO ARE FAMILIAR WITH THE USE AND ACTION OF NEUROMUSCULAR BLOCKING MEDICINES. FACILITIES FOR TRACHEAL INTUBATION, AND MAINTENANCE OF PULMONARY VENTILATION AND ADEQUATE ARTERIAL OXYGENATION MUST BE AVAILABLE. MONITORING OF NEUROMUSCULAR FUNCTION IS RECOMMENDED DURING THE USE OF NIMBEX IN ORDER TO INDIVIDUALISE DOSAGE REQUIREMENTS.

Great caution should be exercised when administering NIMBEX to patients who have shown allergic hypersensitivity to other neuromuscular blocking medicines since a high rate of cross-reactivity (greater than 50%) between neuromuscular blocking medicines has been reported (see section 4.3).

Product specific topics

Cisatracurium, as NIMBEX, does not have significant vagolytic or ganglion-blocking properties. Consequently, NIMBEX has no clinically significant effect on heart rate and will not counteract the bradycardia produced by many anaesthetic medicines or by vagal stimulation during surgery.

Patients with myasthenia gravis and other forms of neuromuscular disease have shown greatly increased sensitivity to non-depolarising blocking medicines. An initial dose of not more than 0,02 mg/kg NIMBEX is recommended in these patients.

Severe acid-base and/or serum electrolyte abnormalities may increase or decrease the sensitivity of patients to neuromuscular blocking medicines.

NIMBEX has not been studied in patients with a history of malignant hyperthermia. Studies in malignant hyperthermia-susceptible pigs indicated that cisatracurium does not trigger this syndrome.

Cisatracurium, as in NIMBEX, has not been studied in patients with burns; however, as with other non-depolarising neuromuscular blocking medicines, the possibility of increased dosing requirements and shortened duration of action must be considered if NIMBEX is administered to these patients.

NIMBEX is hypotonic and must not be administered into the infusion line of a blood transfusion.

ICU Patients:

When laudanosine, a metabolite of cisatracurium, as in NIMBEX, was administered to experimental animals, high concentrations were associated with hypotension and, in some species, cerebral excitation. In the most sensitive animal species, these effects occurred at laudanosine plasma concentrations similar to those that have been observed in some ICU patients following prolonged infusion of atracurium.

Consistent with the decreased infusion rate requirements of NIMBEX, plasma laudanosine concentrations are approximately one third those following atracurium infusion.

There have been reports of seizures in ICU patients who have received atracurium, and other medicines. These patients usually had one or more medical conditions predisposing to seizures (e.g. cranial trauma, hypoxic encephalopathy, cerebral oedema, viral encephalitis, uremia). A causal relationship to laudanosine has not been established.

Paediatric population

There is no information on the use of cisatracurium, as in NIMBEX, in neonates aged less than one month since it has not been studied in this patient population.

4.5 Interaction with other medicines and other forms of interaction

Many medicines have been shown to influence the magnitude and/or duration of action of non-depolarising neuromuscular blocking medicines, including the following:

Increased effect:

Anaesthetics:

Volatile medicines such as enflurane, isoflurane and halothane; Ketamine.

Other non- depolarising neuromuscular blocking medicines.

Other medicines:

Antibiotics, including the aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincomycin and clindamycin.

Antidysrhythmic medicines, including propranolol, calcium channel blockers, lignocaine, procainamide, and quinidine.

Diuretics, including furosemide and possibly thiazides, mannitol and acetazolamide.

Magnesium salts.

Lithium salts.

Ganglion blocking medicines: trimetaphan, hexamethonium.

Rarely, certain medicines may aggravate or unmask latent myasthenia gravis or actually induce a myasthenic syndrome; increased sensitivity to non-depolarising neuromuscular blocking medicines might result. Such medicines include various antibiotics, beta-blockers (propranolol, oxprenolol), antidysrhythmic medicines (procainamide, quinidine), anti-rheumatic medicines (chloroquine, D-penicillamine), trimetaphan, chlorpromazine, steroids, phenytoin and lithium.

Administration of suxamethonium to prolong the effects of non-depolarising neuromuscular blocking medicines may result in a prolonged and complex block which can be difficult to reverse with anticholinesterases.

Decreased effect:

Phenytoin, carbamazepine: a decreased effect is seen after prior chronic administration of phenytoin or carbamazepine.

Anticholinesterases: Treatment with anticholinesterases such as donepezil, commonly used in the treatment of Alzheimer's disease may shorten the duration and diminish the magnitude of neuromuscular blockade with cisatracurium, as in NIMBEX.

No effect:

Suxamethonium: Prior administration of suxamethonium has no effect on the duration of neuromuscular block following bolus doses of NIMBEX or on infusion rate requirements.

4.6 Fertility, pregnancy and lactation

The use of NIMBEX is contraindicated in pregnancy and lactation (see section 4.3.)

Pregnancy

There are no adequate data from the use of NIMBEX in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition, and postnatal development. The potential risk for humans is unknown.

NIMBEX should not be used during pregnancy (see section 4.3).

Breastfeeding

It is not known whether cisatracurium, as in NIMBEX, or its metabolites are excreted in human milk. A risk to the breastfed infant cannot be excluded. As a precaution breastfeeding should be discontinued during treatment with NIMBEX.

Fertility

Fertility studies have not been performed.

4.7 Effects on ability to drive and use machines

This precaution is not relevant to the use of NIMBEX.

NIMBEX will always be used in combination with a general anaesthetic and therefore the usual precautions relating to performance of tasks following general anaesthesia apply.

NIMBEX has minor influence on the ability to drive or operate machinery.

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that NIMBEX does not adversely affect their ability to do so safely (see section 4.8).

4.8 Undesirable effects

a) Summary of the safety profile

No adverse experiences occurred during the clinical development programme that were considered to be reasonably attributable to NIMBEX. Adverse experiences, considered possibly attributable, occurred with a frequency of less than 0,5 %. These were cutaneous flushing or rash, bradycardia, hypotension and bronchospasm.

b) Tabulated list of adverse reactions

System organ class	Common	Uncommon	Very Rare
Immune system disorders			Anaphylactic reaction, anaphylactic shock
Cardiac disorders	Bradycardia		
Vascular disorders	Hypotension	Cutaneous flushing	
Respiratory, thoracic and mediastinal disorders		Bronchospasm	
Skin and subcutaneous tissue disorders		Rash	
Musculoskeletal and connective tissue disorders			Myopathy, muscle weakness

c) Description of selected adverse reactions

Immune system disorders

Anaphylactic reactions of varying degrees of severity have been observed after the administration of neuromuscular blocking medicines, including anaphylactic shock.

Severe anaphylactic reactions have been reported in patients receiving NIMBEX in conjunction with one or more anaesthetics.

Musculoskeletal and connective tissue disorders

There have been some reports of persistent muscle weakness and/or myopathy following prolonged use of NIMBEX in severely ill patients in the ICU. Most patients were receiving concomitant corticosteroids. These events have been reported infrequently in association with cisatracurium, as in NIMBEX, and a causal relationship has not been established.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

4.9 Overdose

Symptoms

Prolonged muscle paralysis and its consequences are expected to be the main signs of overdosage with NIMBEX.

Treatment

It is essential to maintain pulmonary ventilation and arterial oxygenation until adequate spontaneous respiration returns. Full sedation will be required since consciousness is not

impaired by NIMBEX. Recovery may be accelerated by the administration of anticholinesterase medicines once evidence of spontaneous recovery is present.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class**:** A 17.1 Peripherally-acting muscle relaxants.

Pharmacotherapeutic group: Neuromuscular blocking agent

ATC code: M03AC11

Mechanism of action

Cisatracurium is an intermediate-duration, non-depolarising benzylisoquinolinium skeletal muscle relaxant. Cisatracurium binds to cholinergic receptors on the motor-end-plate to antagonise the action of acetylcholine, resulting in a competitive block of neuromuscular transmission. This action is readily reversed by anticholinesterase medicines such as neostigmine or edrophonium.

5.2 Pharmacokinetic properties

Biotransformation

Cisatracurium undergoes degradation in the body at physiological pH and temperature by Hofmann elimination to form laudanosine and the monoquaternary acrylate metabolite. The monoquaternary acrylate undergoes hydrolysis by non-specific plasma esterases to form the monoquaternary alcohol metabolite.

Pharmacokinetics in Adult patients: The ED_{95} (dose required to produce 95 % depression of the twitch response of the adductor pollicis muscle to stimulation of the ulnar nerve) of cisatracurium is estimated to be 0,05 mg/kg bodyweight during opioid anaesthesia (thiopentone/fentanyl/midazolam). The ED_{95} of cisatracurium besylate in children during

halothane anaesthesia is 0,04 mg/kg. Non-compartmental pharmacokinetics of cisatracurium are independent of dose in the range studied (0,1 to 0,2 mg/kg, i.e. 2 to 4 x ED_{95}). Pharmacokinetic parameters after doses of 0,1 and 0,2 mg/kg NIMBEX administered to healthy adult surgical patients are summarised in the table below.

Parameter	**Range of mean values**
Clearance	4,7 to 5,7 ml/min/kg
Volume of distribution at steady state	121 to 161 ml/kg
Elimination half-life	22 to 29 min

Pharmacokinetics in Elderly Patients: There are no clinically important differences in the pharmacokinetics of cisatracurium in elderly and young adult patients.

Pharmacokinetics in Patients with Renal Impairment: There are no clinically important differences in the pharmacokinetics of cisatracurium in patients with end-stage renal failure and in healthy adult patients. The recovery profile of cisatracurium is unchanged in the presence of renal failure.

Pharmacokinetics in Patients with Hepatic Impairment: There are no clinically important differences in the pharmacokinetics of cisatracurium in patients with end-stage liver disease and in healthy adult patients. The recovery profile was unchanged.

Pharmacokinetics During Infusions: The pharmacokinetics of cisatracurium after infusions of NIMBEX are similar to those after single bolus injection. The recovery profile after infusion of NIMBEX is independent of duration of infusion and is similar to that after single bolus injections.

Pharmacokinetics in Intensive Care Unit (ICU) Patients: The pharmacokinetics of

cisatracurium in ICU patients receiving prolonged infusions are similar to those in healthy surgical adults receiving infusions or single bolus injections. The recovery profile after infusions of NIMBEX in ICU patients is independent of duration of infusion. When laudanosine was administered to experimental animals, high concentrations were associated with hypotension and, in some species, cerebral excitation. However, there is no evidence that laudanosine has caused such effects in man even after prolonged infusions of cisatracurium to ICU patients with impaired renal and/or hepatic function.

Elimination

Elimination of cisatracurium is largely organ independent but the liver and kidneys are primary pathways for the clearance of its metabolites. These metabolites do not possess neuromuscular blocking activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

NIMBEX 2 mg/ml (2,5 ml, 5 ml, 10 ml), NIMBEX 5:

Benzenesulfonic acid solution 32 % *w/v* (for pH adjustment), water for injection

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

NIMBEX is not chemically stable when diluted with Lactated Ringer's Injection.

Since NIMBEX is stable only in acidic solutions it should not be mixed in the same syringe or administered simultaneously through the same needle with alkaline solutions, e.g. sodium thiopentone. It is not compatible with ketorolac, trometamol or propofol injectable emulsion.

6.3 Shelf Life

NIMBEX 2 mg/ml (2,5 ml)

24 months at 5 ºC

NIMBEX 2 mg/ml (5 ml)

24 months at 5 ºC

NIMBEX 2 mg/ml (10 ml)

24 months at 5 ºC

NIMBEX 5 mg/ml (30 ml)

24 months at 5 ºC

6.4 Special precautions for storage

Unopened ampoule/vial:

Store between 2 °C and 8 °C.

Do not freeze.

Protect from light.

In addition, the diluted solution can be stored at 5 °C or 25 °C.

This medicine is marketed as a single dose ampoule/vial and any unused portion of the solution must be discarded.

The ampoule/vial must not be removed from the outer carton until such time as it is required for administration.

6.5 Nature and contents of container

NIMBEX 2 mg/ml (2,5 ml) Injection: Box of 5 ampoules

NIMBEX 2 mg/ml (5 ml) Injection: Box of 5 ampoules

NIMBEX 2 mg/ml (10 ml) Injection: Box of 5 ampoules

NIMBEX 5: Box with one 30 ml vial

Not all packs and pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Diluted NIMBEX is physically and chemically stable for at least 12 hours at 5 °C and 25 °C at concentrations between 0,1 and 2,0 mg/ml in the following infusion fluids, in either polyvinyl chloride (PVC) or polypropylene containers:-

Sodium Chloride (0,9 % *w/v*) Intravenous Infusion, Glucose (5 % *w/v*) Intravenous Infusion, Sodium Chloride (0,18 % *w/v*) and Glucose (4 % *w/v*) Intravenous Infusion, Sodium Chloride (0,45 % *w/v*) and Glucose (2,5 % *w/v*) Intravenous Infusion.

However, since the medicine contains no antimicrobial preservative dilution should be carried out immediately prior to use, administration should commence as soon as possible thereafter, and any remaining solution should be discarded.

NIMBEX has been shown to be compatible with the following commonly used peri-operative medicines, when mixed in conditions simulating administration into a running intravenous infusion via a Y-site injection port:alfentanil hydrochloride, droperidol, fentanyl citrate, midazolam hydrochloride and sufentanil citrate. Where other medicines are administered through the same indwelling needle or cannula as NIMBEX, it is recommended that each medicine be flushed through with an adequate volume of a suitable intravenous fluid, e.g. Sodium Chloride Intravenous Infusion 0,9 % (w/v).

When a small vein is selected as the injection site, NIMBEX should be flushed through the vein with a suitable intravenous fluid, e.g. Sodium Chloride Intravenous Infusion (0,9% w/v).

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacare Limited

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBERS

NIMBEX 2 mg/ml (2,5 ml) Injection: 31/17.1/0255

NIMBEX 2 mg/ml (5 ml) Injection: 31/17.1/0444

NIMBEX 2 mg/ml (10 ml) Injection: 31/17.1/0445

NIMBEX 5 Injection: 31/17.1/0256

9. DATE OF FIRST AUTHORISATION

27 November 1998

10. DATE OF REVISION OF TEXT

24 February 2023

Die Afrikaanse Professionele Inligting is op versoek beskikbaar.

Mediese Blitslyn: 0800 118 088.

NAMIBIA

Nimbex 2 mg/ml (2,5 ml): NS2 04/17.1/0929

Nimbex 2 mg/ml (5 ml): NS2 04/17.1/0928

Nimbex 2 mg/ml (10 ml): NS2 04/17.1/0927

Nimbex 5: NS2 04/17.1/0935

BOTSWANA

Nimbex 2 mg/ml (2,5 ml): S2 BOT1502681

Nimbex 2 mg/ml (5 ml): S2 BOT1502681A

Nimbex 2 mg/ml (10 ml): S2 BOT1502681B

ZIMBABWE

Nimbex 2 mg/ml (2,5 ml): PP 2014/1.3/4915

Nimbex 2 mg/ml (5 ml): PP 2014/1.3/4916

Nimbex 2 mg/ml (10 ml): PP 2014/1.3/4917

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