SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

SUGAMMADEX EQUITY 100 mg/mL solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL solution for injection contains 100 mg sugammadex (as sugammadex sodium).

Each 2 mL vial contains 200 mg sugammadex (as sugammadex sodium).

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear and colourless to slightly yellow-brown solution free from visible particles.

The pH is between 7 and 8 and osmolality is between 300 and 500 mOsm/kg.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SUGAMMADEX EQUITY is indicated for the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium.

SUGAMMADEX EQUITY is also indicated for the immediate reversal of neuromuscular blockade at 3 minutes after administration of rocuronium.

For the paediatric population SUGAMMADEX EQUITY is only recommended for routine reversal of rocuronium induced blockade in children above 7 years of age.

4.2 Posology and method of administration

Posology:

SUGAMMADEX EQUITY should be administered under the supervision of an anaesthetist.

The use of an appropriate neuromuscular monitoring technique is recommended to monitor the recovery of the neuromuscular blockade. When certain medicines that may cause displacement interactions are administered parenterally within 7,5 hours of SUGAMMADEX EQUITY, patients should be monitored for signs of recurrence of neuromuscular blockade.

The recommended dose of SUGAMMADEX EQUITY depends on the level of neuromuscular blockade to be reversed. The recommended dose does not depend on the anaesthetic regimen.

SUGAMMADEX EQUITY can be used to reverse different levels of rocuronium or vecuronium induced neuromuscular blockade.

Routine reversal of neuromuscular blockade

A dose of 4 mg/kg SUGAMMADEX EQUITY is recommended if recovery has reached at least 1 – 2 post-tetanic counts (PTC) following rocuronium or vecuronium induced blockade (see section 4.4).

A dose of 2 mg/kg SUGAMMADEX EQUITY is only recommended if spontaneous recovery has reached the reappearance of T_2 (shallow blockade) following rocuronium or vecuronium induced blockade (see section 4.4).

Immediate reversal

If there is a clinical need for immediate reversal at 3 minutes following administration of rocuronium, a dose of 16 mg/kg SUGAMMADEX EQUITY is recommended. There is no data to recommend the use of SUGAMMADEX EQUITY for immediate reversal following vecuronium induced blockade.

Special populations:

Renal impairment

For mild and moderate renal impairment (creatinine clearance ≥ 30 and < 80 mL/min): The dose recommendations are the same as for adults without renal impairment.

The use of SUGAMMADEX EQUITY in patients with severe renal impairment, including patients requiring dialysis (CrCl < 30 mL/min), is not recommended (see section 4.4). Studies in patients with severe renal impairment do not provide sufficient safety information to support the use of SUGAMMADEX EQUITY in these patients.

Elderly patients

After administration of SUGAMMADEX EQUITY at reappearance of T_2 following a rocuronium induced blockade, the median time to recovery of the T_4/T_1 ratio to 0,9 in adults (18 to 64 years) was 2,2 minutes; in elderly adults (65 to 74 years) it was 2,6 minutes and in very elderly adults (75 years or more) it was 3,6 minutes. Even though the recovery times in elderly patients tend to be slower, the same dose recommendation as for adults should be followed (see section 4.4).

Obese patients

In obese patients, the dose of SUGAMMADEX EQUITY should be based on actual body weight. The same dose recommendations as for adults should be followed.

Hepatic impairment

For mild to moderate hepatic impairment: As SUGAMMADEX EQUITY is mainly excreted renally no dose adjustments are required.

Studies in patients with hepatic impairment have not been conducted. Caution should be exercised when considering the use of SUGAMMADEX EQUITY in patients with severe hepatic impairment or when hepatic
impairment is accompanied by coagulopathy (see section 4.4).

Paediatric population

The data for the paediatric population are limited. There is insufficient information on the use of SUGAMMADEX EQUITY for children < 7 years of age. There is no information on SUGAMMADEX EQUITY use for neonates. Therefore, SUGAMMADEX EQUITY is not recommended for use in these populations.

Children and adolescents

For **routine reversal** of rocuronium induced blockade at reappearance of T_2 in children and adolescents (7 to 17 years) 2 mg/kg SUGAMMADEX EQUITY is recommended.

Immediate reversal in children and adolescents has not been investigated and is therefore not recommended.

SUGAMMADEX EQUITY 100 mg/mL may be diluted to 10 mg/mL to increase the accuracy of dosing in the paediatric population, 7 years and older.

Method of administration:

SUGAMMADEX EQUITY should be administered intravenously as a single bolus injection. The bolus injection may be given rapidly, within 10 seconds, directly into a vein or into an existing IV line.

For information on compatibility of SUGAMMADEX EQUITY with infusion solutions, see section 6.6.

4.3 Contraindications

Hypersensitivity to sugammadex sodium or to any of the components of SUGAMMADEX EQUITY (see section 6.1).

4.4 Special warnings and precautions for use

SUGAMMADEX EQUITY is not to be used to reverse depolarising neuromuscular blocking medicines.

Wating times for re-administration with non-depolarising neuromuscular blocking medicines (NMBM) after reversal with SUGAMMADEX EQUITY.

Re-administration of rocuronium or vecuronium after a recommended dose reversal (up to 4 mg/kg of SUGAMMADEX EQUITY):

Minimum waiting time	**NMBM and dose to be administered**
5 minutes	1,2 mg/kg rocuronium
4 hours	0,6 mg/kg rocuronium or 0,1 mg/kg vecuronium

When rocuronium 1,2 mg/kg is administered within 30 minutes after reversal with SUGAMMADEX EQUITY, the onset of neuromuscular blockade may be delayed up to approximately 4 minutes and the duration of neuromuscular blockade may be shortened up to approximately 15 minutes.

Based on PK modelling the recommended waiting time in patients with mild or moderate renal impairment for re-use of 0,6 mg/kg rocuronium or 0,1 mg/kg vecuronium after routine reversal with SUGAMMADEX EQUITY should be 24 hours. If a shorter waiting time is required, the rocuronium dose for a new neuromuscular blockade should be 1,2 mg/kg.

Re-administration of rocuronium or vecuronium after immediate reversal (16 mg/kg SUGAMMADEX EQUITY): A waiting time of 24 hours is recommended.

If neuromuscular blockade is required before the recommended waiting time has passed, a **nonsteroidal neuromuscular blocking medicine** should be used. The onset of a depolarising neuromuscular blocking medicine might be slower than expected, because a substantial fraction of post-junctional nicotinic receptors may still be occupied by the neuromuscular blocking medicine.

Medicine hypersensitivity

Medical practitioners should be prepared for the possibility of medicine hypersensitivity reactions (including anaphylactic reactions) and take the necessary precautions.

Renal impairment

SUGAMMADEX EQUITY is not recommended for use in patients with severe renal impairment, creatinine clearance < 30 mL/min, including patients requiring dialysis (see section 5.2).

Because of the estimated prolonged half-life of sugammadex in severe renally impaired patients, a full neuromuscular blockade may not be achieved after re-use of 0,6 mg/kg rocuronium or 0,1 mg/kg vecuronium within 24 hours after SUGAMMADEX EQUITY reversal.

Marked bradycardia

Marked bradycardia has been observed within minutes after the administration of sugammadex, as in SUGAMMADEX EQUITY for reversal of neuromuscular blockade. Cases of bradycardia with cardiac arrest have been reported (see section 4.8). Patients should be closely monitored for haemodynamic changes during and after reversal of neuromuscular blockade. Treatment with anticholinergic medicines such as atropine should be administered if clinically significant bradycardia is observed.

Monitoring respiratory function during recovery

Ventilatory support is mandatory for patients until adequate spontaneous respiration is restored following reversal of neuromuscular block. Even if recovery from neuromuscular blockade is complete, other medicines used in the peri- and post-operative period could depress respiratory function and therefore ventilatory support might still be required.
Should neuromuscular blockade re-occur following extubation, adequate ventilation should be provided.

Effect on haemostasis
In a study in volunteers, doses of 4 mg/kg and 16 mg/kg of sugammadex, as in SUGAMMADEX EQUITY resulted in maximum mean prolongations of aPTT by 17 and 22 % respectively and of PT (INR) by 11 and 22 % respectively. These limited mean aPTT and PT (INR) prolongations were of short duration (≤ 30 minutes).

There was no clinically relevant effect of sugammadex 4 mg/kg alone or in combination with anticoagulants on the incidence of peri- or post-operative bleeding complications.

In patients receiving post-operative prophylactic anticoagulation this pharmacodynamic interaction is not clinically relevant. Caution should be exercised when considering the use of sugammadex in patients receiving therapeutic anticoagulation for a pre-existing or comorbid condition.

In *in-vitro* experiments additional aPTT and PT prolongation was noted for sugammadex, as in SUGAMMADEX EQUITY in combination with vitamin K antagonists, unfractionated heparin, low molecular weight heparinoids, rivaroxaban and dabigatran.

Patients with known coagulopathies and in patients who receive a dose of 16 mg/kg sugammadex, coagulation parameters should be carefully monitored according to routine clinical practice.

Delayed recovery

Conditions associated with prolonged circulation time such as cardiovascular disease, old age (see section 4.2 for the time to recovery in elderly patients), or oedematous state (e.g. severe hepatic impairment) may be associated with longer recovery times.

Hepatic impairment

SUGAMMADEX EQUITY is not metabolised nor excreted by the liver; therefore dedicated studies in patients with hepatic impairment have not been conducted. Hepatic impairment may be accompanied by coagulopathy (see the information on the *Effect on haemostasis* above).

Light anaesthesia

When neuromuscular blockade was reversed intentionally in the middle of anaesthesia in clinical trials, signs of light anaesthesia were noted occasionally (movement, coughing, grimacing and sucking of the tracheal tube). If neuromuscular blockade is reversed, while anaesthesia is continued, additional doses of anaesthetic and/or opioid should be given as clinically indicated.

Use in intensive care unit

SUGAMMADEX EQUITY has not been investigated in patients receiving rocuronium or vecuronium in the ICU setting.

Use for reversal of neuromuscular blocking medicines other than rocuronium or vecuronium

SUGAMMADEX EQUITY should not be used to reverse block induced by nonsteroidal neuromuscular blocking medicines such as succinylcholine or benzylisoquinolinium compounds.

SUGAMMADEX EQUITY should not be used for reversal of neuromuscular blockage induced by steroidal neuromuscular blocking medicines other than rocuronium or vecuronium, since there are no efficacy and safety data for these situations. Limited data are available for reversal of pancuronium induced blockage, but it is advised not to use SUGAMMADEX EQUITY in this situation.

4.5 Interactions with other medicines and other forms of interaction

The information reported in this section is based on binding affinity between sugammadex and other medicines, non-clinical experiments, clinical studies and simulations using a model taking into account the pharmacodynamic effect of neuromuscular blocking medicines and SUGAMMADEX EQUITY.

Based on these data, no clinically significant pharmacodynamic interaction with other medicines are expected, with the exception of toremifene, fusidic acid and hormonal contraceptives. For these medicines, a clinically relevant interaction could not be excluded.

No clinically relevant interactions were reported during the clinical development. Due to the administration of certain medicines after sugammadex, theoretically rocuronium or vecuronium could be displaced from SUGAMMADEX EQUITY. As a result, recurrence of neuromuscular blockade might be observed. In this situation the patient must be ventilated.

Administration of medicines which caused displacement should be stopped in case of an infusion. In situations when potential displacement interactions can be anticipated, patients should be carefully monitored for signs of re-occurrence of blockade (approximately up to 15 minutes), after parenteral administration of another medicine occurring within a period of 7,5 hours after SUGAMMADEX EQUITY administration.

SUGAMMADEX EQUITY should be used cautiously when co-administered with:

Toremifene

For toremifene, which has a relatively high affinity constant and relatively high plasma concentrations, some displacement of vecuronium or rocuronium from the complex with SUGAMMADEX EQUITY could occur.

The recovery of the train of four ratio, T_4/T_1, to 0,9 could therefore be delayed in patients who have received toremifene on the same day of surgery (see section 4.4).

Intravenous administration of fusidic acid

The use of fusidic acid in the pre-operative phase may cause some delay in the recovery of the T_4/T_1 ratio to 0,9.

No recurrence of neuromuscular blockade is expected in the post-operative phase, since the infusion rate of fusidic acid is over a period of several hours and the blood levels are cumulative over 2 to 3 days.

Hormonal contraceptives

In a simulation performed with a PK-PD model, it was found that the interaction between 4 mg/kg SUGAMMADEX EQUITY and a progestogen could lead to a decrease in progestogen exposure (34 % of AUC) similar to the decrease seen when a daily dose of an oral contraceptive is taken 12 hours too late, which might lead to a reduction in effectiveness.

Therefore, the administration of a bolus dose of SUGAMMADEX EQUITY is considered to be equivalent to one missed daily dose of oral contraceptive steroids.

Please refer to the missed dose advice in the package insert of the oral contraceptive, for any action required if an oral contraceptive is taken on the same day that SUGAMMADEX EQUITY is administered.

In the case of non-oral hormonal contraceptives, the patient must use an additional non-hormonal contraceptive method for the next 7 days.

Interactions due to the lasting effect of rocuronium or vecuronium

When medicines which potentiate neuromuscular blockade are used in the post-operative period special attention should be paid to the possibility of recurrence of neuromuscular blockade. Please refer to the professional information of rocuronium or vecuronium for a list of the specific medicines

which potentiate neuromuscular blockade. In case recurrence of neuromuscular blockade is observed, the patient may require mechanical ventilation and re-administration of SUGAMMADEX EQUITY.

Interference with laboratory tests

SUGAMMADEX EQUITY has been shown to interfere with the serum progesterone assay. This interference was observed in plasma samples spiked with a concentration of SUGAMMADEX EQUITY in the same range as obtained for C_{max} after a dose of 16 mg/kg.

Paediatric population

No formal interaction studies have been performed. The above-mentioned interactions for adults and the warnings should also be taken into account for the paediatric population.

4.6 Fertility, pregnancy and lactation

Pregnancy:

The safety of SUGAMMADEX EQUITY in pregnant women has not been established.

Breastfeeding:

Excretion of SUGAMMADEX EQUITY in human milk has not been studied, but can be expected based on pre-clinical data. Caution should be exercised when administering SUGAMMADEX EQUITY to breastfeeding women.

Fertility:

The effects of SUGAMMADEX EQUITY on human fertility has not been investigated. Animal studies to evaluate fertility do not reveal harmful effects.

4.7 Effects on ability to drive and use machines

SUGAMMADEX EQUITY has no influence on the ability to drive and use machines. Patients should not drive, use machinery, or perform tasks that require concentration until they are certain that SUGAMMADEX EQUITY does not adversely affect their ability to do so safely (see section 4.8).

4.8 Undesirable effects

Tabulated list of adverse reactions:

Immune system disorders *Less frequent:*	Medicine hypersensitivity reations
Nervous system disorders *Frequent:*	Dysgeusia
Respiratory, thoracic and mediastinal disorders *Frequent:*	Cough
Injury, poisoning and procedural complications *Frequent (with sub-optimal doses):* *Frequent:*	Prolonged neuromuscular blockade Anaesthetic complication, Airway complication of anaesthesia, Procedural hypotension, Procedural complication.

Description of selected adverse reactions:

Airway complication of anaesthesia

Airway complications of anaesthesia included bucking against the endotracheal tube, coughing, mild bucking, arousal reaction during surgery, coughing during the anaesthetic procedure or during surgery or contra breath (spontaneous breath of patient, anaesthetic procedure related).

Procedural complication

Procedural complications included coughing, tachycardia, bradycardia, movement and increase in heart rate.

Anaesthetic complications

Anaesthetic complications, indicative of the restoration of neuromuscular function, including movement of a limb or the body or coughing during the anaesthetic procedure or during surgery, grimacing, or sucking on the endotracheal tube, were judged to be related to treatment in about 1 % of the patients and in none of the placebo group. Most occurrences of anaesthetic complications were mild to moderate.

Recurrence of neuromuscular blockade

In clinical studies with patients treated with rocuronium or vecuronium, where sugammadex (as in SUGAMMADEX EQUITY) was administered using a dose labelled for the depth of neuromuscular blockade, an incidence of 0,20 % was observed for recurrence of neuromuscular blockade as based on neuromuscular monitoring or clinical evidence.

The use of lower than recommended doses may lead to an increased risk of recurrence of neuromuscular blockade after initial reversal and is not recommended.

In cases where recurrence of neuromuscular blockade is observed, the patient must be ventilated.

Medicine hypersensitivity reactions

Hypersensitivity reactions, including anaphylaxis, have occurred in some patients and volunteers (for information on volunteers, see *Information on healthy volunteers* below). In clinical trials of surgical patients these reactions were reported uncommonly and for post-marketing reports the frequency is unknown.

These reactions varied from isolated skin reactions to serious systemic reactions (i.e. anaphylaxis, anaphylactic shock) and have occurred in patients with no prior exposure to SUGAMMADEX EQUITY.

Symptoms associated with these reactions can include: Flushing, urticaria, erythematous rash, (severe) hypotension, tachycardia, swelling of the tongue, swelling of the pharynx, bronchospasm and pulmonary obstructive events. Severe hypersensitivity reactions can be fatal.

Information on healthy volunteers

Hypersensitivity reactions, including anaphylaxis, have been observed with SUGAMMADEX EQUITY. In a study in healthy volunteers, hypersensitivity reactions were reported frequently with sugammadex 16 mg/kg and less frequently with sugammadex 4 mg/kg or placebo.

The most common adverse reaction in pooled healthy volunteers was dysgeusia (10 %).

Marked bradycardia

In post-marketing, cases of marked bradycardia and bradycardia with cardiac arrest have been observed within minutes after administration of sugammadex (see section 4.4).

Additional information on special populations:

Pulmonary patients

In post-marketing data and in one dedicated clinical trial in patients with a history of pulmonary complications bronchospasm was reported as a possibly related adverse event.

Paediatric patients

A limited database suggests that the safety profile of sugammadex (up to 4 mg/kg) in paediatric patients above 7 years old, was similar to that in adults.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of SUGAMMADEX EQUITY is important. It allows continued monitoring of the benefit/risk balance of SUGAMMADEX EQUITY. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website.

4.9 Overdose

SUGAMMADEX EQUITY can be removed using haemodialysis with a high-flux filter, but not with a low-flux filter. Based upon clinical studies, SUGAMMADEX EQUITY concentrations in plasma are reduced with a high-flux filter by about 70 % after a 3 to 6 hour dialysis session.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.11 Other medicines acting on the central nervous system.

Pharmacotherapeutic group: All other therapeutic products, antidotes.

ATC code: V03AB35.

Mechanism of action:

Sugammadex sodium injection is a modified cyclodextrin. It is a selective relaxant binding medicine (SRBM) which forms a complex with the neuromuscular blocking medicines rocuronium and vecuronium, and it reduces the amount of neuromuscular blocking medicine available to bind to nicotinic receptors in the neuromuscular junction. This results in the reversal of neuromuscular blockade induced by rocuronium and vecuronium.

Pharmacodynamic effects:

Sugammadex has been administered in doses ranging from 0,5 mg/kg to 16 mg/kg in dose response studies of rocuronium induced blockade (0,6; 0,9; 1,0 and 1,2 mg/kg rocuronium bromide with and without maintenance doses) and vecuronium induced blockade (0,1 mg/kg vecuronium bromide with or without maintenance doses) at different time points/depths of blockade. In these studies a clear dose-response relationship was observed.

5.2 Pharmacokinetic properties

The sugammadex pharmacokinetic parameters were calculated from the total sum of non-complex-bound and complex-bound concentrations of sugammadex. Pharmacokinetic parameters such as

clearance and volume of distribution are assumed to be the same for non-complex-bound and complex-bound sugammadex in anaesthetised subjects.

Distribution:

The observed steady-state volume of distribution of sugammadex sodium is approximately 11 to 14 litres in adult patients with normal renal function (based on conventional, non-compartmental pharmacokinetic analysis). Neither sugammadex nor rocuronium binds to plasma proteins or erythrocytes. Sugammadex sodium exhibits linear kinetics in the dose range of 1 to 16 mg/kg when administered as an IV bolus dose.

Biotransformation:

No metabolites of sugammadex have been observed and only renal excretion of the unchanged product was observed as the route of elimination.

Elimination:

In adult anaesthetised patients with normal renal function the elimination half-life of sugammadex sodium is about 2 hours and the estimated plasma clearance is about 88 mL/min. A mass balance study demonstrated that > 90 % of the dose was excreted within 24 hours. Ninety-six percent (96 %) of the dose was excreted in urine, of which at least 95 % could be attributed to unchanged sugammadex. Excretion via faeces or expired air was < 0,02 % of the dose. Administration of sugammadex sodium to healthy volunteers resulted in increased renal elimination of rocuronium in complex.

Special populations:

Renal impairment and age

In a pharmacokinetic study comparing patients with severe renal impairment to patients with normal renal function, sugammadex levels in plasma were similar during the first hour after dosing and thereafter the levels decreased faster in the control group. Total exposure to sugammadex was prolonged, leading to approximately 17-fold higher exposure in patients with severe renal impairment.

Low concentrations of sugammadex are detectable for at least 48 hours post-dose in patients with severe renal insufficiency.

In a second study comparing patients with moderate or severe renal impairment to patients with normal renal function, sugammadex clearance progressively decreased and $t_{½}$ was progressively prolonged with declining renal function. Exposure was 2-fold and 5-fold higher in patients with moderate and severe renal impairment, respectively. Sugammadex concentrations were no longer detectable beyond 7 days post-dose in patients with severe renal insufficiency.

Predicted pharmacokinetic parameters of sugammadex by age group and renal function based on compartmental modelling are presented below:

Selected patient characteristics			Predicted PK parameters		
Demographics	Renal function (creatinine clearance in mL/min)		Clearance in mL/min (CV)	Volume of distribution at steady state in litres	Elimination half-life in hours (CV)
Adult 40 years 75 kg	Normal	100	84 (22 %)	11,9	2,0 (19 %)
	Impaired	50 30 10	48 (22 %) 29 (23 %) 9 (19 %)	13,1 13,7 14,2	3,6 (20 %) 6,1 (21 %) 20,3 (20 %)
Elderly 75 years 75 kg	Normal	80	72 (26 %)	12,4	2,4 (23 %)
	Impaired	50 30 10	49 (22 %) 29 (22 %) 8 (19 %)	13,1 13,7 14,2	3,5 (19 %) 6,1 (21 %) 21,0 (23 %)
Adolescent 15 years 56 kg	Normal	95	76 (20 %)	9,3	1,7 (17 %)
	Impaired	48 29 10	45 (24 %) 26 (22 %) 7 (18 %)	10,1 10,5 10,9	3,0 (21 %) 5,2 (19 %) 17,8 (18 %)

Child 7 years 23 kg	Normal	51	40 (21 %)	4,3	1,5 (16 %)
	Impaired	26	20 (20 %)	4,5	2,9 (19 %)
		15	11 (27 %)	4,6	5,2 (24 %)
		5	3 (22 %)	4,7	19,4 (23 %)

Mean and coefficient of variation (CV in %) are presented. For volume of distribution, no CV could be estimated from the model.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment)

Sodium hydroxide (for pH adjustment)

Water for injection.

6.2 Incompatibilities

SUGAMMADEX EQUITY must not be mixed with other medicines except those mentioned in section 6.6.

Physical incompatibility has been reported with verapamil, ondansetron and ranitidine.

6.3 Shelf life

3 years.

After first opening and dilution chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C and 2 °C to 8 °C.

From a microbiological point of view, the diluted 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° C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store at or below 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

For storage conditions after first opening and dilution, see section 6.3.

6.5 Nature and contents of container

2 mL type I clear class vial with a 13 mm grey rubber stopper and sealed with a 13 mm red aluminium flip-off seal.

Pack size: 10 vials.

6.6 Special precautions for disposal and other handling

SUGAMMADEX EQUITY can be injected into the intravenous line of running infusion with 0,9 % sodium chloride; 5 % dextrose; 0,45 % sodium chloride and 2,5 % dextrose; 5 % dextrose in 0,9 % sodium chloride; Ringer's lactate solution and Ringer's solution to a final concentration 10 mg/mL.

The infusion line should be adequately flushed (e.g. with 0,9 % sodium chloride) between administration of SUGAMMADEX EQUITY and other medicines.

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

7. HOLDER OF CERTIFICATE OF REGISTRATION

Equity Pharmaceuticals (Pty) Ltd

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Nellmapius Drive

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8. REGISTRATION NUMBER

56/2.11/1193

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 March 2025

10. DATE OF REVISION OF THE TEXT