1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

VERSUDEX 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of VERSUDEX contains sugammadex octasodium equivalent to 100 mg sugammadex.

Each vial of 2 ml contains sugammadex octasodium equivalent to 200 mg sugammadex.

Sugar free.

Each ml contains up to 9,7 mg sodium.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

VERSUDEX is a clear, colourless to slightly yellow brown solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

VERSUDEX is indicated for:

- the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium,

- the immediate reversal of neuromuscular blockade at 3 minutes after administration of rocuronium.

VERSUDEX 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

VERSUDEX 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 VERSUDEX, patients should be monitored for signs of recurrence of neuromuscular blockade.

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

VERSUDEX 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 VERSUDEX is recommended if recovery has reached 1 to 2 post-tetanic counts (PTC) (profound blockade) following administration of rocuronium or vecuronium induced blockade (see section 4.4).

A dose of 2 mg/kg VERSUDEX 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 VERSUDEX is recommended. There is no data to recommend the use of VERSUDEX 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 VERSUDEX 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 VERSUDEX in these patients.

Elderly population

After administration of VERSUDEX 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 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 VERSUDEX 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 VERSUDEX 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 VERSUDEX 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 (one study only for reversal of rocuronium induced blockade at reappearance of T_2). There is insufficient information on the use of VERSUDEX for children < 7 years of age. There is no information on VERSUDEX use for neonates.

Therefore VERSUDEX is not recommended for use in these populations.

Children and adolescents

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

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

VERSUDEX 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

For intravenous administration.

VERSUDEX 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 (see section 6.6).

VERSUDEX has only been administered as a single bolus injection in clinical trials.

4.3. Contraindications

VERSUDEX is contraindicated in:

- Patients with hypersensitivity to sugammadex, sodium or to any excipients in VERSUDEX (see section 6.1).

4.4. Special warnings and precautions for use

VERSUDEX is not to be used to reverse depolarising neuromuscular blocking agents (NMBA).

As is normal post-anaesthetic practice following neuromuscular blockade, it is recommended to monitor the patient in the immediate post-operative period for untoward events including recurrence of neuromuscular blockade.

Waiting times for re-administration with neuromuscular blocking agents (NMBA) after reversal with VERSUDEX.

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

A	Minimum waiting time	NMBA (e.g. Esmeron and Norcuron) and dose to be administered
B	5 minutes	1,2 mg/kg rocuronium
C	4 hours	0,6 mg/kg rocuronium or 0,1 mg/kg vecuronium

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 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):

A waiting time of 24 hours is recommended.

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

Hypersensitivity

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

Renal impairment

VERSUDEX is not recommended for use in patients with severe renal impairment, creatinine clearance < 30 mL/min, including requiring dialysis (see section 4.2 and section 5.2).

Because of the estimated prolonged half-life of sugammadex, as contained in VERSUDEX, 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 reversal.

Marked bradycardia

Marked bradycardia has been observed within minutes after the administration of VERSUDEX 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 *in-vitro* experiments additional activated partial thromboplastin time (aPTT) and prothrombin time (PT) prolongation was noted for VERSUDEX in combination with vitamin K antagonists, unfractionated heparin, low molecular weight heparinoids, rivaroxaban and dabigatran.

In a study in volunteers, doses of 4 mg/kg and 16 mg/kg of sugammadex, as contained in VERSUDEX, 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).

Based on the clinical database there was no clinically relevant effect of sugammadex, as contained in VERSUDEX, alone or in combination with anticoagulants on the incidence of peri- or post-operative bleeding complications.

Since there is no information on the use of VERSUDEX in patients with known coagulopathies, coagulation parameters and haemostasis should be carefully monitored according to routine clinical practice.

An increased risk of bleeding cannot be excluded in patients:

- with hereditary vitamin K dependent clotting factor deficiencies,
- with pre-existing coagulopathies,
- on coumarin derivates and at an INR above 3,5,
- using anticoagulants who receive a dose of 16 mg/kg VERSUDEX.

If there is a medical need to give VERSUDEX to these patients the anaesthesiologist needs to decide if the benefits outweigh the possible risk of bleeding complications taking into consideration the patients history of bleeding episodes and type of surgery scheduled.

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), or oedematous state (e.g. severe hepatic impairment) may be associated with longer recovery times.

Recurrence of neuromuscular blockade:

In clinical studies with patients treated with rocuronium or vecuronium, where sugammadex, as contained in VERSUDEX, 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 (see section 4.2 and section 4.8).

Hepatic impairment

VERSUDEX 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 (ICU)

VERSUDEX 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

VERSUDEX should not be used to reverse block induced by non-steroidal NMBAs such as succinylcholine or benzylisoquinolinium compounds.

VERSUDEX should not be used for reversal of neuromuscular blockage induced by **steroidal** NMBAs 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 VERSUDEX in this situation.

VERSUDEX contains 19,4 mg sodium per 2 ml vial, equivalent to 0,97 % 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

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

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 VERSUDEX, theoretically rocuronium or vecuronium could be displaced from VERSUDEX. 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 VERSUDEX administration.

VERSUDEX 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 VERSUDEX 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, as in VERSUDEX 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 VERSUDEX is considered to be equivalent to one missed daily dose of **oral** contraceptive steroids.

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

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

Interference with laboratory tests

VERSUDEX has been shown to interfere with the serum progesterone assay.

This interference was observed in plasma samples spiked with a concentration of VERSUDEX in the same range as obtained for C_{max} after a dose of 16 mg/kg.

Paediatric populations

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

The safety of VERSUDEX in pregnancy and lactation has not been established.

Pregnancy

For sugammadex, as in VERSUDEX, no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development.

Caution should be exercised when administering VERSUDEX to pregnant women.

Breastfeeding

Excretion of sugammadex, as in VERSUDEX, in human milk has not been studied, but can be expected based on the pre-clinical data.

Animal studies have shown excretion of sugammadex, as in VERSUDEX, in breast milk.

Oral absorption of cyclodextrins in general is low and no effect on the suckling child is anticipated following a single dose to the breastfeeding woman.

Fertility

No data available on human fertility. Animal studies to

evaluate fertility did not reveal harmful effects.

4.7. Effects on ability to drive and use machines

VERSUDEX has no known influence on the ability to drive and use machines.

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

4.8. Undesirable effects

a) Summary of the safety profile

VERSUDEX is administered concomitantly with neuromuscular blocking medicines and anaesthetics in surgical patients. The causality of adverse events is therefore difficult to assess.

The most commonly reported adverse reactions in surgical patients were cough, airway complication of anaesthesia, anaesthetic complications, procedural hypotension and procedural complication.

b) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent
Immune system disorders		Medicine hypersensitivity reactions
Nervous system disorders	Dysgeusia	
Respiratory, thoracic and mediastinal disorders	Cough	
Injury, poisoning and procedural complications	Prolonged neuromuscular blockade with suboptimal doses, airway complication of anaesthesia, anaesthetic complication, procedural hypotension, procedural complication	

c) Description of selected adverse reactions

Anaesthetic complications

Anaesthetic complications, indicative of the restoration of neuromuscular function, include movement of a limb or the body or coughing during the anaesthetic procedure or during surgery, grimacing, or sucking on the endotracheal tube, was 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 the database of pooled phase I to III studies with a placebo group, the incidence of recurrence of neuromuscular blockade as measured with neuromuscular monitoring was 2 % after VERSUDEX and 0 % in the placebo group. Virtually all of these cases were from dose-finding studies in which a sub-optimal dose (< 2 mg/kg) was administered. In cases where recurrence of neuromuscular blockade is observed, the patient must be ventilated.

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 VERSUDEX.

Symptoms associated with these reactions can include: Flushing, urticaria, erythematous rash, (severe) hypotension, tachycardia, swelling of 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, as in VERSUDEX. In a study in healthy conscious volunteers, hypersensitivity reactions were reported commonly with sugammadex 16 mg/kg and uncommonly with sugammadex 4 mg/kg or placebo. In this study, dose dependent trends were also observed for dysgeusia, nausea and flushing.

Marked bradycardia

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

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 anaesthetic procedure-related spontaneous breath of patient.

Procedural complication

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

d) Paediatric population

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

e) Other 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.

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

4.9. Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 32.16: Other

Pharmacotherapeutic group: All other therapeutic products, antidotes

ATC code: V03AB35

Mechanism of action

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

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

Absorption

The sugammadex pharmacokinetic parameters were calculated from the total sum of noncomplex-bound and complex-bound concentrations of sugammadex. Pharmacokinetic parameters as clearance and volume of distribution are assumed to be the same for noncomplex-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 bind 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 84 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. 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	48 (22 %)	13,1	3,6 (20 %)
		30	29 (23 %)	13,7	6,1 (21 %)
		10	9 (19 %)	14,2	20,3 (20 %)
Elderly 75 years 75 kg	Normal	80	72 (26 %)	12,4	2,4 (23 %)
	Impaired	50	49 (22 %)	13,1	3,5 (19 %)
		30	29 (22 %)	13,7	6,1 (20 %)
		10	8 (19 %)	14,2	21,0 (23 %)
Adolescent 15 years 56 kg	Normal	95	76 (20 %)	9,3	1,7 (17 %)
	Impaired	48	45 (24 %)	10,1	3,0 (21 %)
		29	26 (22 %)	10,5	5,2 (19 %)
		10	7 (18 %)	10,9	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

1 could be estimated from the model.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Hydrochloric acid and sodium hydroxide (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.

6.3. Shelf life

36 months

After first opening and dilution, chemical and physical in-use stability has been demonstrated for 48 hours at 2 °C to 25 °C. From a microbiological point of view, it 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 ºC.

Do not freeze.

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

For storage conditions of the diluted medicine, see section 6.3.

6.5. Nature and contents of container

Colourless type I glass vial with a bromobutyl rubber stopper and aluminium cap with an orange flip top.

10 vials of 2 ml are packed in an outer carton.

6.6. Special precautions for disposal and other handling

VERSUDEX can be injected into the intravenous line of a running infusion with the following intravenous solutions: Sodium chloride 9 mg/ml (0,9 %), glucose 50 mg/ml (5 %), sodium

chloride 4,5 mg/ml (0,45 %) and glucose 25 mg/ml (2,5 %), Ringer's lactate solution, Ringer's solution, glucose 50 mg/ml (5 %) in sodium chloride 9 mg/ml (0,9 %).
The infusion line should be adequately flushed (e.g. with 0,9 % sodium chloride) between administration of VERSUDEX and other medicines.

For paediatric patients VERSUDEX can be diluted using sodium chloride 9 mg/ml (0,9 %) to a concentration of 10 mg/ml.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

55/34/0103

9. DATE OF FIRST AUTHORISATION

16 May 2023

10. DATE OF REVISION OF TEXT

16 May 2023

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