SAMVEC-4
(Vecuronium Bromide Injection 4mg/Vial) Lyophilized

1.4.1 Prescribing Information

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:
SAMVEC-4 (Vecuronium Bromide for Injection 4mg/vial) Lyophilized

1.1 Strength:
4mg/Vial

1.2 Pharmaceutical form:
Lyophilized Powder Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Batch Size: 20000 Vials

Sr. No.	Name of Ingredient	Specification	mg/vial	Std. Req. Qty.	Uses
1.	Vecuronium Bromide (with 10 % overages)	IH	4.4	88.00 gm (A)*	Active Ingredient
2.	Citric Acid Monohydrate	BP	8.3	166.00 gm	pH adjuster
3.	Disodium hydrogen phosphate	BP	6.5	130.0 gm	Water softening agent
4.	Mannitol Injection grade	BP	38.8	776.00 gm	Diuretic
5.	Citric Acid Monohydrate	BP	q.s pH 4.0	6.0 gm	pH adjuster
6.	Water for Injection	BP	Qs 1.0 ml	q.s 20.0 liter	Vehicle

Note : (A*) : Quantity varies as per potency of raw material.

q. s. : Quantity Sufficient
IH-In-House
BP-British Pharmacopeia

3. PHARMACEUTICAL FORM:
Lyophilized Powder Injection

Visual Description:
White Lyophilized cake.

4. CLINICAL PARTICULARS

4.1. Therapeutic indication(s)

Vecuronium is indicated as an adjunct to general anaesthesia to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery in adults, neonates, infants, children and adolescents.

4.2 Posology and method of administration

Posology

As with other neuromuscular blocking agents, vecuronium should only be administered by, or under supervision of, experienced clinicians who are familiar with the action and use of these drugs.

As with all other neuromuscular blocking agents, the dosage of vecuronium should be individualised in each patient. The anaesthetic method used, the expected duration of surgery, the possible interaction with other drugs that are administered before or during anaesthesia and the condition of the patient should be taken into account when determining the dose.

The use of an appropriate neuromuscular monitoring technique is recommended to monitor neuromuscular block and recovery.

Inhalational anaesthetics potentiate the neuromuscular blocking effects of vecuronium. This potentiation however, becomes clinically relevant in the course of anaesthesia, when the volatile agents have reached the tissue concentrations required for this interaction. Consequently, adjustments with vecuronium should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of vecuronium during long lasting procedures (longer than 1 hour) under inhalational anaesthesia.

Adults

In adult patients the following dosage recommendations may serve as a general guideline for tracheal intubation and muscle relaxation for short to long lasting surgical procedures.

Tracheal intubation

The standard intubating dose during routine anaesthesia is 80 to 100 micrograms vecuronium bromide per kg body weight, after which adequate intubation conditions are established within 90 to 120 seconds in nearly all patients.

Dosages of vecuronium for surgical procedures after intubation with suxamethonium

Recommended doses: 30 to 50 micrograms vecuronium bromide per kg body weight.

If suxamethonium is used for intubation, the administration of vecuronium should be delayed until the patient has clinically recovered from the neuromuscular block induced by suxamethonium.

Maintenance dosing

The recommended maintenance dose is 20 to 30 micrograms vecuronium bromide per kg body weight.

These maintenance doses should best be given when twitch height has recovered to 25% of control twitch height.

Dose requirements for administration of vecuronium by continuous infusion

If vecuronium is administered by continuous infusion, it is recommended to give a loading dose first (see 'Tracheal Intubation') and, when neuromuscular block starts to recover, to start administration of vecuronium by infusion.

The infusion rate should be adjusted to maintain twitch response at 10% of control twitch height or to maintain 1 to 2 responses to train of four stimulation.

In adults, the infusion rate required to maintain neuromuscular block at this level, ranges from 0.8 to 1.4 micrograms vecuronium bromide/kg/min. For neonates and infants see below. Repeat monitoring of neuromuscular block is recommended since infusion rate requirements vary from patient to patient and with the anaesthetic method used.

Elderly patients

The same intubation and maintenance doses as for younger adults (80 – 100 micrograms/kg and 20 -30 micrograms/kg, respectively) can be used. However, the duration of action is prolonged in

elderly compared to younger subjects due to changes in pharmacokinetic mechanisms. The onset time in elderly is similar to younger adults.

Overweight and obese patients

When used in overweight or obese patients (defined as patients with a body weight of 30% or more above ideal body weight), doses should be reduced taking into account an ideal body weight.

Higher doses

Should there be reason for selection of larger doses in individual patients, initial doses ranging from 150 micrograms up to 300 micrograms vecuronium bromide per kg body weight have been administered during surgery both under halothane and neurolept anaesthesia without adverse cardiovascular effects being noted as long as ventilation is properly maintained. The use of these high dosages of vecuronium pharmacodynamically decreases the onset time and increases the duration of action.

In caesarean section and neonatal surgery the dose should not exceed 100 micrograms/kg.

Paediatric population

Adolescents (12-17 years)

Although there is very little information on dosage in adolescents, it is advised to use the same dose as in adults, based on the physiological development at this age.

Children (2-11 years)

Dose requirements in children are higher than for adults and neonates. However, the same intubation and maintenance doses as for adults (80 – 100 micrograms/kg and 20-30 micrograms/kg, respectively) are usually sufficient. Since the duration of action is shorter in children, maintenance doses are required more frequently.

Neonates (0 – 27 days) and infants (28 days - 23 months)

Because of the possible variations of the sensitivity of the neuromuscular junction, especially in neonates and probably in infants up to 4 months of age, an initial test dose of 10 – 20 micrograms vecuronium bromide per kg body weight followed by incremental doses until 90 to 95% depression of twitch response is achieved is recommended. In neonatal surgery the dose should not exceed 100 micrograms/kg.

Dose requirements in older infants (5-23 months) are the same as in adults. However, since the onset time of vecuronium in these patients is considerably shorter than in adults and children, the use of high intubating doses in general is not required for early development of good intubating conditions.

Since the duration of action and recovery time with vecuronium is longer in neonates and infants than in children and adults, maintenance doses are required less frequently.

Preterm newborn infants

There are insufficient data to support dose recommendations for the use of vecuronium bromide in preterm newborn infants.

Continuous infusion in paediatric patients

There are insufficient data concerning continuous infusion of vecuronium in paediatric patients, therefore, no dosing recommendations can be made.

Method of administration

Vecuronium should be administered following reconstitution. Vecuronium is administered intravenously either as a bolus injection or as a continuous infusion.

4.3 Contraindications:

Hypersensitivity to the active substance, to bromide ion or to any of the excipients.

4.4 Special warnings and precautions for use:

Monitoring respiratory function during recovery

Since vecuronium causes paralysis of the respiratory muscles, ventilatory support is mandatory for patients treated with this drug until adequate spontaneous respiration is restored.

Residual neuromuscular blockade

As with other neuromuscular blocking agents, residual neuromuscular blockade has been reported for vecuronium. In order to prevent complications resulting from residual neuromuscular blockade, it is recommended to extubate only after the patient has recovered sufficiently from neuromuscular block. Other factors which could cause residual neuromuscular blockade after extubation in the post-operative phase (such as drug interactions or patient condition) should also be considered. If not used as part of standard clinical practice, the use of a reversal agent should be considered, especially in those cases where residual neuromuscular blockade is more likely to occur.

Drug hypersensitivity reactions

High rates of cross-sensitivity between neuromuscular blocking agents have been reported. Therefore, where possible, before administering vecuronium, hypersensitivity to other neuromuscular blocking agents should be excluded. Vecuronium should only be used when absolutely essential in susceptible patients. Patients who experience a hypersensitivity reaction under general anaesthesia should be tested subsequently for hypersensitivity to other neuromuscular blockers.

Vagal reactions

Since vecuronium has no cardiovascular effects within the clinical dosage range, it does not attenuate bradycardia that may occur due to the use of some types of anaesthetics and opiates or due to vagal reflexes during surgery. Therefore, reassessment of the use and/or dosage of vagolytic drugs such as atropine for premedication or at induction of anaesthesia, may be of value for surgical procedures during which vagal reactions are more likely to occur (e.g. surgical procedures where anaesthetic drugs with known vagal stimulatory effects are used, opthalmic, abdominal or anorectal surgery, etc.).

Use in the intensive care unit (ICU)

In general, following long term use of neuromuscular blocking agents in the ICU, prolonged paralysis and/or skeletal muscle weakness has been noted. In order to help preclude possible prolongation of neuromuscular block and/or overdosage it is strongly recommended that neuromuscular transmission is monitored throughout the use of neuromuscular blocking agents. In addition, patients should receive adequate analgesia and sedation. Furthermore, muscle relaxants should be titrated to effect in the individual patients by or under supervision of experienced clinicians who are familiar with their actions and with appropriate neuromuscular monitoring techniques.

Myopathy after long term administration of non-depolarising neuromuscular blocking agents in the ICU in combination with corticosteroid therapy has been reported frequently. Therefore, for patients receiving both neuromuscular blocking agents and corticosteroids, the period of use of the neuromuscular blocking agent should be limited as much as possible.

The following conditions may influence the pharmacokinetics and/or pharmacodynamics of vecuronium

Hepatic and/or biliary tract disease and renal failure

Because vecuronium is excreted in bile and in urine, vecuronium should be used with caution in patients with clinically significant hepatic and/or biliary diseases and/or renal failure. In these patient groups prolongation of action has been observed, especially when high doses of vecuronium (200 micrograms/kg bodyweight) were administered in patients with hepatic disease.

Prolonged circulation time

Conditions associated with prolonged circulation time such as cardiovascular disease, old age, oedematous state resulting in an increased volume of distribution, may contribute to an increase in the onset time of neuromuscular block. The duration of action may also be prolonged due to a reduced plasma clearance.

Neuromuscular disease

As with other neuromuscular blocking agents, vecuronium should be used with extreme caution in patients with neuromuscular disease or after poliomyelitis since the response to neuromuscular

blocking agents may be considerably altered in these cases. The magnitude and direction of this alteration may vary widely. In patients with myasthenia gravis or the myasthenic (Eaton Lambert) syndrome, small doses of vecuronium may have profound effects and vecuronium should be titrated to the response.

Hypothermia

In operations under hypothermia, the neuromuscular blocking effect of vecuronium is increased and the duration is prolonged.

Obesity

Like other neuromuscular blocking agents, vecuronium may exhibit a prolonged duration and a prolonged spontaneous recovery in obese patients, when the administered doses are calculated on actual body weight.

Burns

Patients with burns are known to develop resistance to non-depolarising agents. It is recommended that the dose is titrated to response.

Other conditions which may increase the effects of vecuronium are

Hypokalaemia (e.g. after severe vomiting, diarrhoea, and diuretic therapy), hypermagnesaemia, hypocalcaemia (after massive transfusions), hypoproteinaemia, dehydration, acidosis, hypercapnoea, cachexia. Severe electrolyte disturbances, altered blood pH or dehydration should therefore be corrected when possible.

Based on preclinical findings, vecuronium may cause a reduction in the partial thromboplastin time and the prothrombin time, like pancuronium bromide, d-tubocurarine or other non-depolarising neuromuscular blocking agents.

4.5 Interaction with other medicinal products and other forms of interaction

The following drugs have been shown to influence the magnitude and/or duration of action of non-depolarising neuromuscular blocking agents:

Effect of other drugs on vecuronium

Increased effect

Halogenated volatile anaesthetics potentiate the neuromuscular block of vecuronium. The effect only becomes apparent with maintenance dosing. Reversal of the block with cholinesterase inhibitors could also be inhibited.

After intubation with suxamethonium.

Long-term concomitant use of corticosteroids and vecuronium in the ICU may result in prolonged duration of neuromuscular block or myopathy.

Other drugs:

- antibiotics: aminoglycoside, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics
- diuretics, quinidine, magnesium salts, calcium channel blocking agents, lithium salts, cimetidine, lidocaine and acute administration of phenytoin or ß-blocking agents.

Recurarisation has been reported after post-operative administration of:

- aminoglycoside, lincosamide, polypeptide and acylamino-penicillin antibiotics, quinidine and magnesium salts.

Decreased effect

- prior chronic administration of phenytoin or carbamazepine
- calcium chloride, potassium chloride.

Variable effect

Administration of other non-depolarising neuromuscular blocking agents in combination with vecuronium may produce attenuation or potentiation of the neuromuscular block, depending on the order of administration and the neuromuscular blocking agent used.

Suxamethonium given after the administration of vecuronium may produce potentiation or attenuation of the neuromuscular blocking effect of vecuronium.

Effect of vecuronium on other drugs

Effect of vecuronium on lidocaine

Vecuronium combined with lidocaine may result in a quicker onset of action of lidocaine.

4.6 Fertility, pregnancy and lactation

Fertility

Animal studies do not indicate an effect on fertility.

Pregnancy

There are insufficient data on the use of vecuronium during animal or human pregnancy to assess potential harm to the foetus. Vecuronium should be given to a pregnant woman only when the attending physician decides that the benefits outweigh the risks.

Note

Reversal of vecuronium-induced neuromuscular block may be inhibited or unsatisfactory in patients receiving magnesium sulphate for toxaemia of pregnancy because magnesium salts enhance neuromuscular block. Therefore, in patients receiving magnesium sulphate, the dosage of vecuronium should be reduced and be carefully titrated to twitch response.

Caesarean section

Studies with vecuronium, administered in doses up to 100 micrograms/kg, have shown its safety for use in caesarean section. In caesarean section the dose should not exceed 100 micrograms/kg.

In several clinical studies vecuronium did not affect Apgar score, foetal muscle tonus or cardiorespiratory adaptation. From umbilical cord blood sampling it is apparent that only very little placental transfer of vecuronium occurs which did not lead to the observation of any clinical adverse effect in the new-born.

Breast-feeding

It is unknown whether vecuronium bromide is excreted in human breast milk. The excretion of vecuronium bromide in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with vecuronium bromide should be made taking into account the benefit of breast-feeding to the child and the benefit of vecuronium bromide therapy to the woman.

4.7 Effects on ability to drive and use machines:

Since vecuronium is used as an adjunct to general anaesthesia, the usual precautionary measures after a general anaesthesia should be taken for ambulatory patients.

4.8 Undesirable effects:

Adverse drug reactions (ADRs) are rare (<1/1000). The most commonly occurring ADRs include changes in vital signs and prolonged neuromuscular block. The most frequently reported ADR during post-marketing surveillance is 'anaphylactic and anaphylactoid reactions' and associated symptoms
(reporting frequency <1/100 000). See also the explanations below the table 1.

Table 1

Adverse reactions are ranked under headings of frequency, the most frequent first, using the following convention: uncommon /rare (<1/100, > 1/10,000), very rare (<1/10,000).

MedDRA SOC	Preferred term[1]	
	Uncommon/rare (<1/100, >1/10 000)	Very rare (<1/10 000)
Immune system disorders		Hypersensitivity
		Anaphylactic reaction

		Anaphylactoid reaction
		Anaphylactic shock
		Anaphylactoid shock
Nervous system disorders		Flaccid paralysis
Cardiac disorders	Tachycardia	
Vascular disorders	Hypotension	Circulatory collapse and shock
		Flushing
Respiratory, thoracic and mediastinal disorders		Bronchospasm
Skin and subcutaneous tissue disorders		Angioneurotic edema
		Urticaria
		Rash
		Erythematous rash
Musculoskeletal and connective tissue disorders		Muscular weakness[2]
		Steroid myopathy[2]
General disorders and administration site conditions	Drug ineffective	Face oedema
	Decreased drug effect/ therapeutic response	Injection site pain
	Increased drug effect/ therapeutic response	Injection site reaction
Injury, poisoning and procedural complications	Prolonged neuromuscular block	Airway complication of anaesthesia
	Delayed recovery from anaesthesia	
MedDRA version 8.0		

[1] Frequencies are estimates derived from post-marketing surveillance reports and data from the general literature.
[2] after long-term use in the ICU

Description of selected adverse reactions

Prolonged Neuromuscular block

The most frequent adverse reaction to non-depolarising blocking agents as a class consists of an extension of the drug's pharmacological action beyond the time period needed. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory insufficiency or apnoea. A few cases of myopathy have been reported after vecuronium was used in the ICU in combination with corticosteroids (see section 4.4).

Anaphylactic reactions

Although very rare, severe anaphylactic reactions to neuromuscular blocking agents, including vecuronium, have been reported. Anaphylactic/anaphylactoid reactions usually comprise of several signs or symptoms e.g. bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse – shock), and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases, been fatal. Due to the possible severity of these reactions, one should always assume they may occur and take the necessary precautions.

Histamine release and histaminoid reactions

Since neuromuscular blocking agents are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reactions at the site of injection and/or generalised histaminoid (anaphylactoid) reactions (see also under anaphylactic reactions above) should always be taken into consideration when administering these drugs.

Experimental studies with intradermal injection of vecuronium have demonstrated that this drug has only a weak capacity for inducing local histamine release. Controlled studies in man failed to demonstrate any significant rise in plasma histamine levels after intravenous administration of vecuronium. Nevertheless, such cases have rarely been reported during large scale use of vecuronium.

4.13 Overdose

In the event of overdosage and prolonged neuromuscular block, the patient should continue to receive ventilatory support and sedation. In this situation there are two options for the reversal of neuromuscular block: (1) sugammadex can be used for reversal of intense (profound) and deep block. The dose of sugammadex to be administered depends on the level of neuromuscular block. The use of sugammadex for the purposes of reversal of vercuronium-induced blockade is recommended for use only in the adult population. (2) An acetylcholinesterase inhibitor (e.g. neostigmine, edrophonium, pyridostigmine) can be used once spontaneous recovery starts and should be administered in adequate doses. When administration of a cholinesterase inhibiting agent fails to reverse the neuromuscular effects of vecuronium, ventilation must be continued until spontaneous breathing is restored. Repeated dosage of a cholinesterase inhibitor can be dangerous.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

ATC Code(s):MO3A C03

Pharmacotherapeutic group: Muscle relaxants, peripherally acting agents

Within the clinical dosage range, vecuronium does not block the sympathetic nicotininic receptors, and thus exerts no ganglion blocking activity. In addition, in this dose range vecuronium does not block the parasympathetic muscarinic receptors, and thus exerts no vagolytic activity.

Tracheal intubation

Within 90 to 120 seconds following intravenous administration of a dose of 80 to 100 micrograms vecuronium bromide per kg body weight, good to excellent conditions for endotracheal intubation occur and within 3 to 4 minutes following administration of these dosages, general muscle paralysis adequate for any type of surgery is established. The duration of action to 25% recovery of control twitch height (clinical duration) with this dose is 24 to 60 minutes. The time to 95% recovery of control twitch height following this dose is approximately 60 to 80 minutes. With higher dosages of vecuronium, onset time to maximal block is shortened and duration of action is prolonged.

Continuous intravenous infusion

When vecuronium is administered by continuous intravenous infusion, a steady state neuromuscular block of 90% can be maintained at a constant rate of drug delivery and without clinically significant prolongation of the recovery time from neuromuscular block at termination of the infusion.

Vecuronium has no cumulative effects if maintenance doses are administered at 25% recovery of control twitch height. Several maintenance doses can therefore be given in succession.

These properties allow the use of vecuronium in short, medium and long lasting surgical procedures.

Reversal of neuromuscular block

Administration of acetylcholinesterase inhibitors, such as neostigmine, pyridostigmine or edrophonium, antagonises the action of vecuronium.

Paediatric patients

Neonates and infants

In neonates and infants the ED_{95} dose of vecuronium bromide under balanced anaesthesia was found to be approximately the same (approx. 47 micrograms/kg body weight) as in adults.

The onset time of vecuronium bromide in neonates and infants is considerably shorter as compared to children and adults, probably due to the shorter circulation time and relative large cardiac output. Also, a greater sensitivity of the neuromuscular junction to the action of neuromuscular blocking agents in these patients may account for a more rapid onset of action.

The duration of action and recovery time with vecuronium bromide is longer in neonates and infants than in adults. Maintenance doses of vecuronium bromide should therefore be less frequently administered.

Children

In children the ED_{95} dose of vecuronium under balanced anaesthesia was found to be higher than in adults (81 vs 43 micrograms/kg bodyweight, respectively). In comparison to adults, the duration of action and recovery time with vecuronium in children are in general approximately 30% and 20-30% shorter respectively.

Similar to adults, cumulative effects with repeat maintenance doses of approximately one quarter of the initial dose and administered at 25% recovery of control twitch height are not observed in paediatric patients.

5.2 Pharmacokinetic properties:

Distribution

After intravenous administration of 100–150 micrograms/kg vecuronium, the distribution half-life of vecuronium amounts to 1.2-1.4 minutes.

Vecuronium is mainly distributed in the extracellular fluid compartment. At steady state, the volume of distribution is 0.18-0.51 $l.kg^{-1}$ in adult patients.

The plasma clearance of vecuronium amounts to 3.0-6.4 $ml.kg^{-1}.min^{-1}$ and its plasma elimination half-life is 36-117 minutes.

Biotransformation

The extent of metabolism of vecuronium is relatively low. In humans, a 3-hydroxy derivative having approximately 50% less neuromuscular blocking potency than vecuronium is formed in the liver. In patients not suffering from renal or hepatic failure, the plasma concentration of this derivative is below detection limit, and does not contribute to the neuromuscular block occurring after administration of vecuronium.

Elimination

Biliary excretion is the main elimination route. It is estimated that within 24 hours after intravenous administration of vecuronium, 40 to 60% of the dose administered is excreted into the bile as monoquaternary compounds. Approximately 95% of these monoquaternary compounds is unchanged vecuronium and less than 5% is 3-hydroxy vecuronium. Prolonged duration of action has been observed in patients with liver disease and/or biliary tract disease, probably as a result of decreased clearance leading to an increased elimination half-life.

Renal elimination is relatively low. The amount of monoquaternary compounds excreted in the urine collected by intravesical catheter for 24 hours following vecuronium administration is 20-30% of the dose administered. In patients with renal failure, the duration of action may be prolonged. This is probably the result of an increased sensitivity to vecuronium, but it could also be the result of a reduced plasma clearance.

Paediatric patients

There are limited pharmacokinetic data for vecuronium in the paediatric population. After intravenous administration, vecuronium plasma clearance is similar across neonates, infants and children (2.8-9.0 $ml.kg^{-1}.min^{-1}$) and not different from the clearance in adults. Volume of distribution at steady state (Vdss) in infants is similar to the one in adult patients (0.29-0.43 l/kg), whereas it is slightly smaller in children (0.13 – 0.32 l/kg).

5.3 Preclinical safety data

Vecuronium bromide showed no genotoxic, embryotoxic or teratogenic potential. Single and repeated dose toxicity studies in rats, dogs and cats revealed no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Citric Acid Monohydrate BP
Disodium hydrogen phosphate BP
Mannitol Inj grade BP
Citric Acid Monohydrate BP
Water for Injection BP

6.2 Incompatibilities:

As is the case for many other drugs, incompatibility has been documented for vecuronium when added to thiopental.

This medicinal product must not be mixed with other medicinal products.

If vecuronium is administered via the same infusion line that is also used for other drugs, it is important that this infusion line is adequately flushed (e.g. with 0.9% sodium chloride) between administration of vecuronium and drugs for which incompatibility with vecuronium has been demonstrated or for which compatibility with vecuronium has not been established.

6.3 Shelf life:

24 months from the date of manufacture.

6.4 Special precautions for storage:

Store at a temperature below 25°C. Do not freeze. Protect from light and moisture.

6.5 Nature and contents of container:

Samvec-4 (lyophilized) 5 vials + 5 ampoules of diluent in a box

6.6 Special precautions for disposal and other handling:

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESS:

Samarth Life Sciences Pvt. Ltd.
Unit II, Plot No. 2, Industrial Area,
Lodhimajra, Baddi, Dist. Solan,
Himachal Pradesh – 173205, India.
Telephone: 09736036973
01795 – 220508

8. MARKETING AUTHORISATION NUMBERS
Not applicable

9. DATE OF FIRST REGISTRATION /RENEWAL OF THE REGISTRATION
Not applicable

10. DATE OF REVISION OF THE TEXT
Not applicable

11. DOSIMETRY (IF APPLICABLE)
Not applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not applicable