Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Genotoxicity:No bacterial mutation assays have been conducted. There are some data to suggest a weak clastogenic effect in mice, but not in patients who had received suxamethonium chloride. Carcinogenicity:Carcinogenicity studies have not been performed. Embryo-foetal Development:Animal reproduction studies have not been conducted with suxamethonium. It is also not known whether suxamethonium can affect reproductive capacity or cause foetal harm when administered to a pregnant woman.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2ml of solution contains Suxamethonium Chloride 100mg (50mg/ml)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection or infusion.
Clear colourless sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Suxamethonium chloride Injection is an ultra-short acting, depolarising, neuromuscular blocking agent. It is used in anaesthesia as a skeletal muscle relaxant to facilitate tracheal intubation and mechanical ventilation in surgical procedures.
Suxamethonium chloride injection is also used to reduce the intensity of muscular contractions associated with pharmacologically or electrically-induced convulsions.

4.2 Posology and method of administration

Posology
Adults: The dose is dependent on body weight, the degree of muscular relaxation required, the route of administration, and the response of individual patients.

To achieve endotracheal intubation, Suxamethonium is usually administered intravenously in a dose of 1mg/kg. This dose will usually produce muscular relaxation in about 30 to 60 seconds and has a duration of action of about 2 to 6 minutes.

Larger doses will produce more prolonged muscular relaxation, but doubling the dose does not necessarily double the duration of relaxation.

Supplementary doses of Suxamethonium of 50% to 100% of the initial dose administered at 5 to 10 minute intervals will maintain muscle relaxation during short surgical procedures performed under general anaesthesia.

For prolonged surgical procedures, Suxamethonium may be given by intravenous infusion as a 0.1% to 0.2% solution, diluted in 5% glucose solution or sterile isotonic saline solution, at a rate of 2.5 to 4 mg per minute. The infusion rate should be adjusted according to the response of individual patients.

The total dose of Suxamethonium given by repeated intravenous injection or continuous infusion should not exceed 500 mg per hour.

Paediatric population
Infants and young children are more resistant to suxamethonium compared with adults.

The recommended intravenous dose of Suxamethonium for neonates and infants is 2 mg/kg. A dose of 1 mg/kg in older children is recommended. (see section 4.4 Special warnings and precautions for use).

When Suxamethonium is given as intravenous infusion in children, the dosage is as for adults with a proportionately lower initial infusion rate based on body weight.

Use by intramuscular bolus dosing:
Suxamethonium may be given intramuscularly to infants at doses up to 4 to 5mg/kg and in older children up to 4 mg/kg. These doses produce muscular relaxation within about 3 minutes. A total dose of 150 mg should not be exceeded.

Elderly: Dosage requirements of suxamethonium in older patients are comparable to those for younger adults.

The elderly may be more susceptible to cardiac arrhythmias, especially if digitalis-like drugs are also being taken. (See section 4.4 'Special warnings and precautions for use.)

Dosage in hepatic impairment*:* Termination of the action of suxamethonium is dependent on plasma cholinesterase, which is synthesised in the liver. Although plasma cholinesterase levels often fall in patients with liver disease, levels are seldom low enough to significantly prolong suxamethonium-induced apnoea (see section 4.4 Special warnings and precautions for use).
Dosage in renal impairment*:* A normal single dose of Suxamethonium chloride Injection may be administered to patients with renal insufficiency in the absence of hyperkalaemia. Multiples or larger doses may cause clinically significant rises in serum potassium and should not be used (see section 4.3 Contraindications, and section 4.4 Special warnings and precautions for use).

Dosage in patient with reduced plasma cholinesterase*:* Patients with reduced plasma cholinesterase activity may experience prolonged and intensified neuromuscular blockade following administration of suxamethonium. In these patients, it may be advisable to administer reduced dosages of Suxamethonium chloride Injection (see section 4.3 Contraindications and section 4.4 Special warnings and precautions for use).

Monitoring advice*:* Monitoring of neuromuscular function is recommended during infusion or if Suxamethonium chloride Injection is to be administered in relatively large cumulative doses over a relatively short period of time in order to individualise dosage requirements (see section 4.4 Special warnings and precautions for use).
Conscious patients (see section 4.3 Contraindications, and section 4.4 Special warnings and precautions for use).

Method of administration
The usual method of Suxamethonium chloride Injection administration is by bolus intravenous injection. It can also be given via intramuscular bolus injection or intravenous infusion

4.3 Contraindications

- Hypersensitivity to suxamethonium or to any of the excipients listed in section 6.1.

- Suxamethonium has no effect on the level of consciousness and should not be administered to a patient who is not fully anaesthetised.

- Suxamethonium is recognised as a potential triggering agent in individuals susceptible to malignant hyperthermia and therefore the use of Suxamethonium chloride Injection is contra-indicated in patients with a personal or family history of this condition. If this condition occurs unexpectedly, all anaesthetic agents known to be associated with its development (including Suxamethonium chloride Injection) must be immediately discontinued, and full supportive measures must be immediately instituted. Intravenous dantrolene sodium is the primary specific therapeutic drug and is recommended as soon as possible after the diagnosis is made.

Suxamethonium should not be used in patients with a history of previous prolonged apnoea after suxamethonium or in those with atypical plasma cholinesterase.

Prolonged and intensified neuromuscular blockade following a Suxamethonium chloride Injection, may occur secondary to reduced plasma cholinesterase in the following states or pathological conditions; end stage hepatic failure, acute or chronic renal failure.

An acute transient rise in serum potassium often occurs following the administration of suxamethonium in normal individuals; the magnitude of this rise is of the order of 0.5mmol/litre. In certain pathological states or conditions, the magnitude of the increase in serum potassium following suxamethonium administration may be excessive and cause serious cardiac arrhythmias and cardiac arrest.

For this reason, the use of suxamethonium is contraindicated in the following patients:

- In patients recovering from major trauma or severe burns; the period of the greatest risk of hyperkalaemia is from 5 to 70 days after the injury and may be further prolonged if there is delayed healing due to persistent infection.
- In patients with neurological deficits involving spinal cord injury, peripheral nerve injury, acute major muscle wasting (upper and/or lower motor neurone lesions); the potential for potassium release occurs within the first six months after the acute onset of the neurological deficit and correlates with the degree and extent of muscle paralysis. Patients who have been immobilised for prolonged periods of time may also be at similar risk.
- In any Patient with pre-existing hyperkalaemia. In the absence of hyperkalaemia and neuropathy, renal failure is not a contraindication to the administration of a normal single dose of suxamethonium, but multiple or large doses may cause clinically significant rises in serum potassium and should not be used.

Suxamethonium causes a significant transient rise in intraocular pressure and should therefore not be used in the presence of open eye injuries or where an increase in intra-ocular pressure is undesirable unless the expected benefit of its use outweighs the potential risk to the eye.

Suxamethonium should be avoided in patients with a personal or family history of congenital myotonic diseases such as myotonia congenita and dystrophia myotonica since its administration may on occasion be associated with severe myotonic spasms and rigidity.

Suxamethonium should not be used in patients with skeletal muscle myopathies e.g. Duchenne muscular dystrophy since its administration may be associated with malignant hyperthermia, ventricular dysrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalaemia.

Since the action of suxamethonium may be prolonged in patients known to have inherited atypical plasma cholinesterase, Suxamethonium chloride Injection should not be used in this group unless the expected benefit of its use outweighs the risk (see section 4.4 Special warnings and precautions for use and section 4.2 Posology and method of administration).

4.4 Special warnings and precautions for use

Suxamethonium paralyses the respiratory muscles as well as other skeletal muscles but has no effect on consciousness. Suxamethonium chloride Injection should be administered only with adequate general anaesthesia and only by or under the close supervision of an experienced anaesthetist with adequate facilities available for immediate tracheal intubation and artificial ventilation.

Cross-sensitivity

As there is a higher rate of cross-sensitivity with other neuromuscular blocking (both depolarising and non-depolarising) drugs, caution is advised where there is a history of sensitivity to neuromuscular blocking drugs.

Suxamethonium 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.

During prolonged administration of suxamethonium, it is recommended that the patient is fully monitored with a peripheral nerve stimulator in order to avoid overdosage.

Hyperkalaemia
Suxamethonium increases serum potassium by 0.5mmol/L in normal individuals. This may be significant with pre-existing elevated serum potassium. Patients with burns or certain neurological conditions may develop severe hyperkalaemia (see

section 4.3 Special warnings and precautions for use). In severe sepsis, the potential for hyperkalaemia may be related to the severity and duration of the infection.

Bradycardia and other cardiac dysrhythmias
In healthy adults, suxamethonium occasionally causes a mild transient slowing of the heart rate on initial administration. Bradycardias are more commonly observedin children or if repeated doses are given (both adults and children). Pre-treatment with intravenous atropine or glycopyrrolate can significantly reduce the incidence and/or severityof suxamethonium-related bradycardia.

Suxamethonium can induce cardiac dysrhythmias and arrest. In the absence of hyperkalaemia, ventricular dysrhythmias are rare although patients on cardiac glycosides are at increased risk (see section 4.5 Interactions). The action of suxamethonium on the heart may cause changes in cardiac rhythm including cardiac arrest.

Raised intra-ocular pressure (IOP)
Suxamethonium causes a transient increase in intraocular pressure and should not be used in the presence of penetrating eye injury except where the potential benefits outweigh the injury to the eye.

Cholinesterase deficiency
Suxamethonium is rapidly hydrolysed by plasma cholinesterase which thereby limits the intensity and duration of the neuromuscular blockade.

Individuals with decreased plasma cholinesterase activity exhibit a prolonged response to suxamethonium. Approximately 0.05% of the population has an inherited cause of reduced cholinesterase activity.

Prolonged and intensified neuromuscular blockade following Suxamethonium Injection may occur secondary to reduced plasma cholinesterase activity in the following states or pathological conditions:

- physiological variation as in pregnancy and the purpurium. (see section 4.6)
- genetically determined abnormal plasma cholinesterase (see section 4.3)
- severe generalized tetanus, tuberculosis, other severe or chronic infections
- following severe burns (see section 4.3)
- chronic debilitating disease, malignancy, chronic anaemia and malnutrition
- end stage hepatic failure, acute or chronic renal failure (see section 4.2)
- auto-immune diseases:myxoedema, collagen diseases;
- iatrogenic: following plasma exchange, plasmapheresis, cardiopulmonary bypass, and as a result of concomitant drug therapy (see section 4.5).

Paediatric population

Caution should be exercised when using suxamethonium in children since paediatric patients more likely to have undiagnosed myopathies or pre-disposition to malignant hyperthermia and rhabdomyolysis, which places them at increased risk of serious adverse events following suxamethonium (see section 4.3 and section 4.8).Susceptible to bradycardia (see above).

Muscle pains

Muscle pains are frequently experienced after administration of suxamethonium and most commonly occur in ambulatory patients undergoing short surgical procedures under general anaesthesia. There appears to be no direct connection between the degree of visible muscle fasciculation after Suxamethonium administration and the incidence or severity of pain. The use of small doses of non-depolarising muscle relaxants given minutes before suxamethonium administration has been advocated for the reduction of incidence and severity of suxamethonium-associated muscle pains. This technique may require the use of doses of suxamethonium in excess of 1mg/kg to achieve satisfactory conditions for endotracheal intubation.

Myasthenia gravis

It is inadvisable to administer suxamethonium to patients with advanced myasthenia gravis. Although thesepatients are

resistant to suxamethonium they develop a state of atypical phase II block which can result in delayed recovery.

Myasthenic Eaton-Lambert syndrome

Patients with the myasthenic Eaton-Lambert syndrome are more sensitive than normal to suxamethonium and the dose should be reduced in these patients. Patients in remission from myasthenic Eaton-Lambert syndrome may however demonstrate a normal response to suxamethonium.

Prolonged use

If Suxamethonium is given over a prolonged period, the characteristic depolarizing neuromuscular (or Phase I) block may change to one with characteristics of a non-depolarising (or Phase II) block. Although the characteristics of a developing Phase II block resemble those of a true non-depolarising block, the former cannot always be fully or permanently reversed by anticholinesterase agents. When a Phase II block is fully established, its effects will then usually be fully reversible with standard doses of neostigmine accompanied by an anticholinergic agent.

Tachyphylaxis occurs after repeated doses.

Use in other conditions

This agent should be used with caution in ill and cachectic patients, in patients with acid-base disturbances or electrolyte imbalance, parenchymatous liver disease, obstructive jaundice, carcinomatosis, in those in contact with certain insecticides, e.g. organophosphorous compounds and in those receiving therapeutic radiation.

Suxamethonium should be used with caution in patients with fractures or muscle spasms because the initial muscle fasciculations may cause additional trauma.

Muscarinic effects of this compound e.g. increased bronchial and salivary secretions may be prevented by atropine.

When this agent is given as an infusion, this should be monitored with care to avoid overdose.

Suxamethonium has no direct effect on the myocardium, but by stimulation of both autonomic ganglia and muscarinic receptors suxamethonium may cause changes in cardiac rhythm, including cardiac arrest.

Use with other solutions

Suxamethonium should not be mixed with any other agent in the same syringe (particularly thiopentone/thiopental). Suxamethonium chloride Injection is acidic and should not be mixed with highly alkaline solutions, e.g. barbiturates.

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

4.5 Interaction with other medicinal products and other forms of interaction

Certain drugs or chemicals are known to reduce normal plasma cholinesterase activity and may therefore prolong the neuromuscular blocking effects of suxamethonium chloride injection. These include:
Antibacterials

Enhanced effects of suxamethonium with

- Aminoglycosides
- Clindamycin, polymyxins and vancomycin
- Piperacillin

Antimalarials

- Quinine and chloroquine - effects of suxamethonium possibly enhanced

Antipsychotics

Enhanced effects of suxamethonium with

- Promazine
- Promethazine
- Chlorpromazine
- Phenelzine
- Lithium carbonate

Generalanaesthetic agents

- Propofol – increased risk of myocardial depression and bradycardia
- Volatile liquid s Generalanaesthetic: halothane, enflurane, desflurane, isoflurane, diethylether and methoxyflurane have little effect on the phase I block of Suxamethonium injection but will accelerate the onset and enhance the intensity of a Phase II suxamethonium-induced block.
- Ketamine and propanidid – possible prolonged block

Analgesics

Enhanced effects of suxamethonium with

- Morphine, morphine antagonists, pethidine, pancuronium, propanidid

Anti-arrhythmics

- Lidocaine (lignocaine) – enhanced and prolonged neuromuscular blockade
- Quinidine, procainamide and verapamil
- Beta-blockers – enhanced and prolonged neuromuscular blockade

Local anaesthetics

Enhanced effects of suxamethonium with

- Procaine
- Cocaine
- Chloroprocaine
- Lidocaine (see above)

Cardiac glycosides

- Possible increased risk of bradycardia and other dysrhythmias, including ventricular dysrhythmias and cardiac arrest (also see sections 4.4 and 4.8).

- More susceptible to the effects of suxamethonium exacerbated by hyperkalaemia

Cytotoxics

Enhanced effects of suxamethonium with

- Cyclophosphamide
- Thiotepa
- Other alkylating agents (chlorethamine: tretamine)
- Triethylene-melamine

Immunomodulators

- Azathioprine – prolonged neuromuscular blockade

Magnesium

- Parenteral magnesium – enhanced neuromuscular blockade

Metoclopramide

- Enhanced effects of suxamethonium

Parasympathetics

Enhanced effects of suxamethonium with

- Donepezil
- Edrophonium, galantamine, neostigmine, pyridostigmine, physostigmine and rivastigmine
- Tacrine hydrochloride

Sympathomimetics (beta agonists)

- Bambuterol and terbutaline – enhanced effects of suxamethonium

Anti-histamines

- Diphenhydramine – enhanced effects of suxamethonium

Drugs known to reduce normal plasma cholinesterase

In addition to the drugs listed above, certain other drugs and chemicals are known to reduce normal plasma cholinesterase activity and therefore may prolong the neuromuscular effect of suxamethonium. These include

- Organophosphorous insecticides and metriphonate
- Ecothiopate eye drops (prolonged apnoea after suxamethonium has occurred)
- TrimetaphanSelective serotonin reuptake inhibitors (SSRI).

The following have potentially adverse effects on plasma cholinesterase activity

- Aprotinin
- Oestrogens and oral contraceptives
- Oxytocin
- High-dose steroids

Liver disease, cancer, pregnancy, dehydration, electrolyte imbalances and overdosage (due to excessive production of succinylmonocholine) may also prolong the action of suxamethonium.

4.6 Fertility, pregnancy and lactation

Pregnancy
Suxamethonium has no direct action on the uterus or other smooth muscle structures. In normal therapeutic doses it does not cross the placental barrier in sufficient amounts to affect the respiration of the infant.

Suxamethonium chloride injection should nevertheless not be administered to pregnant women unless the expected benefit of its use outweighs possible risks to the foetus.

Plasma cholinesterase levels may fall during the first trimester of pregnancy to about 70-80% of their pre-pregnancy values; a further fall to about 60-70% of the pre-pregnancy levels occurs within 2-4 days after delivery. Plasma cholinesterase levels then increase to reach normal over the next 6 weeks. Consequently, a high proportion of pregnancy and puerperal patients may exhibit mildly prolonged neuromuscular blockade following Suxamethonium chloride injection (see section 4.4 Special warnings and precautions for use).

Breast-feeding

It is not known whether suxamethonium or its metabolites are excreted in human milk.
therefore, caution should be exercised following administration of suxamethonium to nursing mothers.

Fertility
No studies of the effect of suxamethonium on female fertility or pregnancy have been performed.

4.7 Effects on ability to drive and use machines

This precaution is not relevant to the use of Suxamethonium chloride injection. Suxamethonium will always be used in combination with a general anaesthetic and therefore, the usual precautions relating to performance of tasks following general anaesthesia apply.

4.8 Undesirable effects

There is limitedclinical documentation that can be used as support for determining thefrequency of adverse reactions.
The frequency categories assigned to the adverse reactions are estimates. For most reactions, the frequency was determined from published data and the background incidence was not considered when determining the frequency groups.

Adverse reactions are listed below by system organ class and frequency. Estimated frequencies were determined from published data. Frequenciesare defined as follows: Very common (≥1/10); Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000).

System organ class	Frequency	Undesirable effects
Immune system disorders	Very Rare	Anaphylactic reactions
Eye disorders	Common	Increased intraocular pressure
Cardiac disorders	Common	Bradycardia, tachycardia

	Rare	Arrhythmias (including ventricular arrhythmias), cardiac arrest[1]
Vascular disorders	Common	Skin flushing Hypertension and hypotension have also been reported.
Respiratory, thoracic and mediastinal disorders	Rare	Bronchospasm, prolonged respiratory depression[2], apnoea.
Gastrointestinal disorders	Very Common	Increased intragastric pressure Excessive salivation has also been reported
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorder	Very common Common Rare	Muscle fasciculation, post-operative muscle pains (please refer to section 4.4) Myoglobinaemia[3], myoglobinuria[3] Trismus
General disorders and administration site conditions	Vary rare	Malignant hyperthermia (please refer section 4.4)
Investigations	Common	Transient blood potassium increase

[1]There are case reports of hyperkalaemia-related cardiac arrests following the administration of suxamethonium to patients with congenital cerebral palsy, tetanus, Duchenne muscular dystrophy, and closed head injury. Such events have also been reported rarely in children with hitherto undiagnosed muscular disorders.

[2]Individuals with decreased plasma cholinesterase activity exhibit a prolonged response to suxamethonium. Approximately 0.05% of the population has an inherited cause of reduced cholinesterase activity. Please refer to section 4.4 Special Warnings and Precautions for Use.

[3]Rhabdomyolysis has also been reported (see section 4.3 and section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Website: www.hpra.ie

4.9 Overdose

Symptoms:
Apnoea and prolonged muscle paralysis are the main and serious effects of overdosage.

Management:
It is essential to maintain a patent airway together with assisted ventilation until spontaneous respiration returns.

The decision to use neostigmine to reverse a phase II suxamethonium-induced block depends on the judgement of the clinician in the individual case. Valuable information in regard to this decision will be gained by monitoring neuromuscular function. If neostigmine is used, its administration should be accompanied by appropriate dose of an anticholinergic drug such as atropine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peripherally acting muscle relaxants, choline derivatives, ATC code M03AB01

Mechanism of action:

Suxamethonium is an ultra-short acting, depolarising, neuromuscular blocking agent.

Pharmacodynamic effects:

Suxamethonium, an analogue of acetylcholine, inhibits neuromuscular transmission by depolarising the motor end plates in skeletal muscle. The depolarisation may be observed as fasciculation. Subsequent neuromuscular transmission is inhibited as long as an adequate concentration of suxamethonium remains at the receptor site. Onset of flaccid paralysis occurs within 30-60 seconds of intravenous injection and with single administration persists for 2-6 minutes.

The paralysis following administration of suxamethonium is progressive, with differing sensitivities of different muscles. This initially involves consecutively the levator muscles of the face, muscles of the glottis and finally the intercostals and the diaphragm and all other skeletal muscles.

The short duration of suxamethonium is considered to be due to its rapid metabolism in the blood. Suxamethonium is rapidly hydrolysed by plasma cholinesterase to succinylcholine (which possesses clinically insignificant depolarising muscle relaxant properties) and then more slowly to succinic acid and choline.

5.2 Pharmacokinetic properties

Absorption:
The pharmacokinetics of a bolus dose of suxamethonium have been studied in anaesthetised adult patients using a high performance liquid chromatographic assay.

Distribution:
The pharmacokinetic parameters for suxamethonium 1mg/kg and 2mg/kg respectively are: apparent volume of distribution 16.4 ± 14.7ml/kg and 5.6 ± 6.8ml/kg; area under the plasma concentration-time curve 124.3 ± 163.2 and 695 ±1008.9 minutes/microgram/ml.

The arterial blood suxamethonium concentration at 30 and 120 seconds following injection of suxamethonium 1mg/kg are 79.5 ± 108.4 and 3.3 ± 6.7 micrograms/ml, and following injection of 2mg/kg suxamethonium are 336.2 ± 512.5 and 7.2 ±13.0 micrograms/ml, respectively.

Elimination:
The pharmacokinetic parameters for suxamethonium 1mg/kg and 2mg/kg respectively are: total body clearance 40.5 ± 38.7 and 15.0 ± 14.8 litre/min and elimination half-life 16.6 ± 4.8 and 11.7 ± 4.5 seconds.

Suxamethonium was not detectable 150 seconds after administration of either 1mg/kg or 2mg/kg suxamethonium.

5.3 Preclinical safety data

Genotoxicity:
No bacterial mutation assays have been conducted.
There are some data to suggest a weak clastogenic effect in mice, but not in patients who had received suxamethonium chloride.
Carcinogenicity:
Carcinogenicity studies have not been performed.
Embryo-foetal Development:
Animal reproduction studies have not been conducted with suxamethonium. It is also not known whether suxamethonium can affect reproductive capacity or cause foetal harm when administered to a pregnant woman.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Acetate
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

18 months.
For single use only, any unused solution should be discarded.

6.4 Special precautions for storage

Store in a refrigerator (2^{o}C to 8^{o}C).
Do not freeze.
Keep the ampoules in the outer carton.

6.5 Nature and contents of container

2 ml, clear glass ampoules, type I Ph. Eur. borosilicate glass packed in cardboard cartons to contain 10 x 2 ml ampoules.

6.6 Special precautions for disposal and other handling

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

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals (Ireland) Ltd
4045 Kingswood Road
Citywest Business Park
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0073/110/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 December 1988
Date of last renewal: 20 December 2008

10 DATE OF REVISION OF THE TEXT

September 2022