Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

UKPAR

Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion

Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion

(Cisatracurium besilate)

UK Licence Number: PL 43801/0055-0056

Sciecure Pharma Limited

LAY SUMMARY

Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion
Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion
(Cisatracurium besilate)

This is a summary of the Public Assessment Report (PAR) for Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion (PL 43801/0055) and Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion (PL 43801/0056). It explains how Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion and Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion and Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion.

The product will collectively be referred to as 'Cisatracurium besilate Sciecure' throughout the remainder of this public assessment report (PAR) for ease of reading.

For practical information about using Cisatracurium besilate Sciecure, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cisatracurium besilate Sciecure and what is it used for?
Cisatracurium besilate Sciecure is a 'generic medicine'. This means that Cisatracurium besilate Sciecure is similar to a 'reference medicine' already authorised in the European Union (EU) called Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland; PL 39699/0092-0093).

Cisatracurium besilate Sciecure is used:

- To relax muscles during operations on adults and children over 1 month of age, including heart surgery
- To help insert a tube into the windpipe (tracheal intubation), if a person needs help to breathe
- To relax the muscles of adults in intensive care.

The patient should speak to their doctor if they would like more explanation about this medicine.

How does Cisatracurium besilate Sciecure work?
This medicine contains an active ingredient called cisatracurium besilate. This belongs to a group of medicines called muscle relaxants. This active substance works by blocking communication between the nervous system and muscles. The active substance is termed an intermediate-duration, non-depolarising, neuromuscular, blocking agent.

How is Cisatracurium besilate Sciecure used?
The pharmaceutical form of this medicine is a solution for injection/infusion. The route of administration of this medicine is:

- as a single injection into the vein (intravenous bolus injection);
- as a continuous infusion into the vein. This is where the medicine is slowly given over a long period of time.

This medicine will only be administered to the patient by a person who is qualified to do so.

The doctor will decide the way the patient is given the medicine and the dose they will receive. It will depend on:

- the patient's body weight;
- the amount and duration of muscle relaxation required;
- the patient's expected response to the medicine.

Children less than 1 month old should not have this medicine.

Please read section 3 of the package leaflet for detailed dosing recommendations, the route of administration, and the duration of treatment.

For further information on how Cisatracurium besilate Sciecure is used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

What benefits of Cisatracurium besilate Sciecure have been shown in studies?
No additional studies were needed as Cisatracurium besilate Sciecure is a generic medicine and an aqueous solution that is given by injection or infusion and contains the same active substance as the reference medicine, Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland; PL 39699/0092-0093).

What are the possible side effects of Cisatracurium besilate Sciecure?
Because Cisatracurium besilate Sciecure is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicines Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland; PL 39699/0092-0093).

For the full list of all side effects and restrictions reported with Cisatracurium besilate Sciecure, see section 4 of the package leaflet available on the MHRA website.

Why was Cisatracurium besilate Sciecure approved?
It was concluded that, in accordance with EU requirements, Cisatracurium besilate Sciecure has been shown to be comparable to Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland; PL 39699/0092-0093); the benefits are greater than the risks and it is recommended that Cisatracurium besilate Sciecure can be approved for use.

What measures are being taken to ensure the safe and effective use of Cisatracurium besilate Sciecure?
A risk management plan (RMP) has been developed to ensure that Cisatracurium besilate Sciecure is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for **Cisatracurium besilate Sciecure** including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

Other information about Cisatracurium besilate Sciecure
A Marketing Authorisation was granted in the UK for Cisatracurium besilate Sciecure on 28 September 2018.

The full PAR for Cisatracurium besilate Sciecure follows this summary.
For more information about treatment with Cisatracurium besilate Sciecure , read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in November 2018.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Sciecure Pharma Limited, a Marketing Authorisation for the medicinal products Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion (PL 43801/0055) and Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion (PL 43801/0056)These products are prescription-only medicine (POM).

Cisatracurium besilate Sciecure is an intermediate-duration, non-depolarising neuromuscular blocking agent for intravenous administration and is indicated for use during surgical and other procedures in adults and children aged 1 month and over. Cisatracurium besilate Sciecure is also indicated for use in adults requiring intensive care. Cisatracurium besilate Sciecure can be used as an adjunct to general anesthesia, or sedation in the Intensive Care Unit (ICU) to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation.

These applications were submitted under Article 10 (1) of Directive 2001/83/EC, as amended, as generic applications. The originator reference medicinal products for these applications are Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion, originally authorised to the Marketing Authorisation holder; The Wellcome Foundation Limited (PL 00003/0364) on 07 August 1995. A subsequent change of ownership procedure took place to the current Marketing Authorisation holder; Aspen Pharma Trading Limited, Ireland (PL 39699/0092 and PL 39699/0093) on 27 June 2017.

The active substance of Cisatracurium Sciecure is cisatracurium (as besilate). Cisatracurium is an intermediate-duration, non-depolarising benzylisoquinolinium skeletal muscle relaxant.

Cisatracurium undergoes degradation in the body at physiological pH and temperature by Hofmann elimination (a chemical process) to form laudanosine and the monoquaternary acrylate metabolite. The monoquaternary acrylate undergoes hydrolysis by non-specific plasma esterases to form the monoquaternary alcohol metabolite. Elimination of cisatracurium is largely organ independent but the liver and kidneys are primary pathways for the clearance of its metabolites. These metabolites do not possess neuromuscular blocking activity.

No new non-clinical studies were submitted, which is acceptable given that these applications were based on being generic medicinal products of reference products that have been in clinical use for over 10 years.

No new clinical data have been submitted and none are required for applications of this type. As it is an aqueous solution for intravenous administration a bioequivalence study is not required for these generic applications in line with current CHMP Bioequivalence Guideline (CPMP/EWP/QWP/1401/98 rev 1/corr **). The applications concern generic versions of Cisatracurium besilate Sciecure, with the same active substance and same excipients therefore with essential similarity to the reference products; Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland, PL 39699/0092-0093).

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product type at all sites responsible for the manufacture, assembly and batch release of these products.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards

of GMP are in place at those non-Community sites.

II QUALITY ASPECTS

II.1 Introduction

Each ampoule contains cisatracurium 2 mg, as cisatracurium besilate 2.68 mg per 1 ml
One ampoule of 2.5 ml contains 5 mg of cisatracurium
One ampoule of 5 ml contains 10 mg of cisatracurium
One ampoule of 10 ml contains 20 mg of cisatracurium

Each vial contains cisatracurium 5 mg as cisatracurium besilate 6.69 mg per 1 ml and one vial of 30 ml contains 150 mg of cisatracurium.

Other ingredients consist of the pharmaceutical excipients benzene sulfonic acid and water for injections.

Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion is packed into 2.5 ml, 5 ml and or 10 ml, Type I, transparent, glass ampoules. Cisatracurium besilate Sciecure 2 mg/ml Solution for Injection / Infusion is available in a box containing 1 and 5 ampoules.

Cisatracurium besilate Sciecure 5 mg/ml Solution for Injection / Infusion is packed into 30 ml, Type I, clear, glass vials sealed with a rubber stopper and an aluminium flip-cap. Each box contains 1 vial.

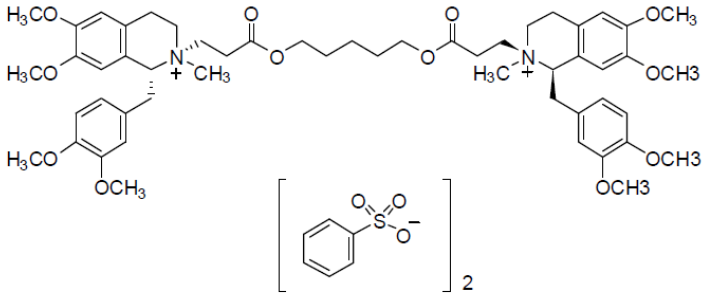
Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

II.2 Drug Substance

INN:	cisatracurium besilate
Chemical name:	(1R,1'R,2R,2'R)-2,2'-(3,11-dioxo-4,10-dioxatridecamethylene)bis(1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-1-veratrylisoquinolinium) dibenzenesulfonate Structure:

Structure:



Molecular formula:	$C_{65}H_{82}N_2O_{18}S_2$
Molecular weight:	1243.5 g/mol
Description:	White to yellowish powder, slightly hygroscopic
Solubility:	Freely soluble in alcohol, soluble in water, practically insoluble in diethylether and 1-octanol

The drug substance is the subject of an active substance master file (ASMF).

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analyses data are provided that comply with the proposed specification.
Satisfactory Certificates of Analysis have been provided for all working standards used.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate a safe, efficacious solution for injection/infusion containg 2 mg or 5 mg cisatracurium (as besilate) per each ml of solution that is comparable to the originator reference medicinal product; Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland, PL 39699/0092-0093.

A satisfactory account of the pharmaceutical development has been provided.

Comparative impurity profiles have been provided for the proposed and reference products.

All excipients comply with their respective monographs. Water for injection complies within the European Pharmacopoeia monograph and benzenesulfonic acid conforms to its in-house specifications.

None of the excipients used contain material of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the product, together with an appropriate account of the manufacturing process. Process validation data on commercial scale batches have been provided. The results are satisfactory.

Finished Product Specification

The finished product specification proposed is acceptable. Test methods have been described that have been adequately validated. Batch data complying with the release specification have been provided. Certificates of Analysis have been provided for all working standards used.

Stability of the Product

Finished product stability studies were performed in accordance with current guidelines on batches of the finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 15 months for the undiluted product with the storage conditions ‘Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package in order to protect from light’. For storage conditions after dilution of the medicinal product, see section 6.3 of the SmPC.

Shelf life after reconstitution:
Chemical and physical in-use stability has been demonstrated for 24 hours at 5°C and 25°C (see section 6.6).

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

Suitable post approval stability commitments to continue stability testing on batches of finished product have been provided.

II.4 Discussion on chemical, pharmaceutical and biological aspects
There are no objections to the approval of these applications from a pharmaceutical viewpoint.

III NON-CLINICAL ASPECTS
III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of cisatracurium besilate are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology
Not applicable for these product types. Refer to section 'III.1; Introduction' detailed above.

III.3 Pharmacokinetics
Not applicable for these product types. Refer to section 'III.1; Introduction' detailed above.

III.4 Toxicology
Not applicable for these product types. Refer to section 'III.1; Introduction' detailed above.

III.5 Ecotoxicity/environmental risk assessment (ERA)
Since Cisatracurium besilate Sciecure is intended for generic substitution, this will not lead to an increase of the environmental exposure. An environmental risk assessment is therefore not deemed necessary**.**

III.6 Discussion on the non-clinical aspects
There are no objections to the approval of these applications from a non-clinical viewpoint.

IV CLINICAL ASPECTS
IV.1 Introduction
According to the regulatory requirements of CHMP Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**) a bioequivalence study is not required for parenteral aqueous solutions and the applicant has not submitted any.

No new efficacy or safety studies have been performed and none are required for these types of applications. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of cisatracurium besilate.

IV.2 Pharmacokinetics
The proposed product, Cisatracurium besilate Sciecure is an aqueous intravenous solution that contains the same qualitative and quantitative composition in terms of active substance (cisatracurium besilate) and the same pharmaceutical form (solution for injection/infusion) as the reference product;

Nimbex 2mg/ml Solution for Injection/Infusion and Nimbex Forte 5 mg/ml, solution for injection/infusion (Aspen Pharma Trading Limited, Ireland; PL 39699/0092-0093).

In line with the guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**), the test product is to be administered as a parenteral aqueous solution containing the same qualitative and quantitative composition in terms of active substance and excipients and is of the same pharmaceutical form as the currently approved product. No bioequivalence study has been submitted with these applications and none is required.

IV.3 Pharmacodynamics

No new pharmacodynamic data were submitted and none were required for applications of this type.

IV.4 Clinical efficacy

No new efficacy data were submitted, and none were required for applications of this type.

IV.5 Clinical safety

No new safety data were submitted and none are required.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance System

The Marketing Authorisation holder (MAH) has submitted a risk management plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to colchicine.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:

Summary of safety concerns	
Important identified risks	• Cross-sensitivity between neuromuscular blocking agents • Anaphylactic reactions • Hypotension in ICU patients • Myopathy • Increased sensitivity in patients with myasthenia gravis and other forms of neuromuscular diseases • Sensitivity in patient with severe acid-base and/or serum electrolyte abnormalities
Important potential risks	• Seizures in ICU patients • Bradycardia
Missing information	• Use in neonates aged less than 1 month and in paediatric population • Use in pregnancy and lactation • Patients undergoing surgery with induced hypothermia • Patients with burns • Patients with a history of malignant hyperthermia

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

IV.7 Discussion on the clinical aspects

The grant of a Marketing Authorisation is recommended for these applications from a clinical viewpoint.

V User consultation

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of these products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with cisatracurium besilate is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The following approved labelling text for these products can be found below:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX CARTON

1. NAME OF THE MEDICINAL PRODUCT

Cisatracurium besilate Sciecure 2 mg/mL Solution for Injection/Infusion

Cisatracurium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each mL contains cisatracurium 2 mg as cisatracurium besilate 2.68 mg.

3. LIST OF EXCIPIENTS

Benzene sulfonic acid, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection/ infusion

1 ampoule of 2.5 mL
5 ampoules of 2.5 mL
1 ampoule of 5 mL
5 ampoules of 5 mL
1 ampoule of 10 mL
5 ampoules of 10 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous administration.
Administered by a qualified person as an intravenous bolus injection or a continuous infusion into vein.
Read the package leaflet before use.
Use as directed by a doctor.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

If diluted, store the infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sciecure Pharma Limited

3000 Cathedral Hill, Guildford, Surrey, England, GU2 7YB

12. MARKETING AUTHORISATION NUMBER(S)

PL 43801/0055

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Cisatracurium besilate Sciecure 2 mg/mL Solution for Injection/Infusion

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE/2.5mL – 5mL – 10mL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Cisatracurium besilate Sciecure 2 mg/mL solution for Injection/Infusion

Cisatracurium
Intravenous administration.

2. METHOD OF ADMINISTRATIONI

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2.5 mL
5 mL
10 mL

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX CARTON

1. NAME OF THE MEDICINAL PRODUCT

Cisatracurium besilate Sciecure 5 mg/mL solution for Injection/Infusion

Cisatracurium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each mL contains cisatracurium 5 mg as cisatracurium besilate 6.69 mg.

3. LIST OF EXCIPIENTS

Benzene sulfonic acid, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection/ infusion

1 vial of 30 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous administration.
Administered by a qualified person as an intravenous bolus injection or a continuous infusion into vein.
Read the package leaflet before use.
Use as directed by a doctor.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

If diluted, store the infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sciecure Pharma Limited

3000 Cathedral Hill, Guildford, Surrey, England, GU2 7YB

12. MARKETING AUTHORISATION NUMBER(S)

PL 43801/0056

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Cisatracurium besilate Sciecure 5 mg/mL Solution for Iinjection/Infusion

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

VIAL LABEL

1. NAME OF THE MEDICINAL PRODUCT

Cisatracurium besilate Sciecure 5 mg/mL solution for Injection/Infusion

Cisatracurium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each mL contains cisatracurium 5 mg as cisatracurium besilate 6.69 mg.

3. LIST OF EXCIPIENTS

Benzene sulfonic acid, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection/ infusion

1 vial of 30 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous administration.
Administered by a qualified person as an intravenous bolus injection or a continuous infusion into vein.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

If diluted, store the infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sciecure Pharma Limited
3000 Cathedral Hill, Guildford, Surrey, GU2 7YB, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 43801/0056

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Cisatracurium besilate Sciecure 5 mg/mL solution for Injection/Infusion

Annex 1

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)