

Applicant: Dr Reddy's Laboratories
Product Name: ERIBULIN DRL
Dosage form and strength: Eribulin 1 mg/2 mL, Solution for injection.

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

ERIBULIN DRL (Solution for Injection)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 mL solution contains 1 mg of Eribulin mesylate equivalent to 0,88 mg of eribulin.

Inactive ingredients:

Contains 5 % (v/v) dehydrated alcohol.

Sugar free.

3. PHARMACEUTICAL FORM

Solution for Injection.

Clear colourless solution free from visible particulate matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ERIBULIN DRL is indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease (see section 5.1).

Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.

ERIBULIN DRL is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease (see section 5.1).

4.2 Posology and method of administration

ERIBULIN DRL should be administered in units specialised in the administration of cytotoxic chemotherapy and only under the supervision of a qualified medical practitioner experienced in the appropriate use of cytotoxic medicines.

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Posology

The recommended dose of ERIBULIN DRL as ready-to-use solution is 1,23 mg/m² which should be administered intravenously over 2 to 5 minutes on Day 1 and 8 of every 21-day cycle.

IMPORTANT:

PLEASE NOTE:

The recommended dose refers to the base of the active substance (eribulin).

Calculation of the individual dose to be administered to a patient must be based on the strength of the ready-to-use solution that contains 0,44 mg/mL eribulin and the dose recommendation of 1,23 mg/m². The dose reduction recommendation shown below are also shown as the dose of eribulin to be administered based on the strength of the ready-to-use solution.

In the pivotal studies, the corresponding publications and in some other regions e.g., the US and Switzerland, the recommended dose is based on the salt form (eribulin mesylate).

Patients may experience nausea or vomiting. Anti-emetic prophylaxis including corticosteroids should be considered.

Dose delays during therapy

The administration of ERIBULIN DRL should be delayed on Day 1 or Day 8 for any of the following:

- Absolute neutrophil count (ANC) < 1 x 10⁹/L
- Platelets < 75 x 10⁹/L
- Grade 3 or 4 non-haematological toxicities.

Dose reduction during therapy

Dose reduction recommendations for retreatment are shown in the following table.

Dose reduction recommendations

Adverse reaction after previous ERIBULIN DRL administration	Recommended dose of ERIBULIN DRL
Haematological	
ANC < 0,5 x 10 ⁹ /L lasting more than 7 days	0,97 mg/m ²
ANC < 1 x 10 ⁹ /L neutropenia complicated by fever or infection	
Platelets < 25 x 10 ⁹ /L thrombocytopenia	
Platelets < 50 x 10 ⁹ /L thrombocytopenia complicated by	

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haemorrhage or requiring blood or platelet transfusion	
Non-haematological	
Any Grade 3 or 4 in the previous cycle	
Reoccurrence of any haematological or non-haematological adverse reactions as specified above	
Despite reduction to 0,97 mg/m ²	0,62 mg/m ²
Despite reduction to 0,62 mg/m ²	Consider discontinuation

Do not re-escalate the ERIBULIN DRL dose after it has been reduced.

Special populations

Patients with hepatic impairment

Impaired liver function due to metastases

The recommended dose of ERIBULIN DRL in patients with mild hepatic impairment (Child-Pugh A) is 0,97 mg/m² administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.

The recommended dose of ERIBULIN DRL in patients with moderate hepatic impairment (Child-Pugh B) is 0,62 mg/m² administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.

Severe hepatic impairment (Child-Pugh C) has not been studied but it is expected that a more marked dose reduction is needed if ERIBULIN DRL is used in these patients.

Impaired liver function due to cirrhosis

This patient group has not been studied. The doses given above may be used in mild and moderate impairment but close monitoring is advised as the doses may need readjustment.

Patients with renal impairment

Patients with moderately or severely impaired renal function (creatinine clearance < 50 mL/min) will have increased ERIBULIN DRL exposure.

The recommended dose of ERIBULIN DRL in patients with moderate renal impairment (creatinine clearance (CLcr) 30 to 50 mL/min) is 1,1 mg/m² administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.

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The safety of ERIBULIN DRL was not studied in patients with severe renal impairment (CrCl < 30 mL/min).

For all patients with renal impairment, caution and close safety monitoring is advised (see section 5.2).

Elderly patients

No specific dose adjustments are recommended based on the age of the patient.

Paediatric population

There is no relevant use of ERIBULIN DRL in children and adolescents in the indication of breast cancer.

The safety and efficacy of ERIBULIN DRL in children from birth to 18 years of age have not been established in soft tissue sarcoma. No data are available.

Method of administration:

ERIBULIN DRL is for intravenous use. ERIBULIN DRL should be administered intravenously over 2 – 5 minutes.

The dose may be diluted in up to 100 mL of sodium chloride 9 mg/mL (0,9 % NaCl) solution for injection (see section 6.6). It should not be diluted in glucose 5 % infusion solution.

Good peripheral venous access or a patent central line should be ensured prior to administration.

There is no evidence that ERIBULIN DRL is a vesicant or an irritant. In the event of extravasation, treatment should be symptomatic.

For information relevant to the handling of cytotoxic medicines see section 6.6.

4.3 Contraindications

- Hypersensitivity to eribulin or to any of the excipients of ERIBULIN DRL.
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

Haematology

Myelosuppression is dose dependent and primarily manifested as neutropenia (see section 4.8).

Monitoring of complete blood counts should be performed on all patients prior to each dose of

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ERIBULIN DRL. Treatment with ERIBULIN DRL should only be initiated in patients with Absolute Neutrophil Count values $\geq 1,5 \times 10^9/L$ and platelets $> 100 \times 10^9/L$.

Febrile neutropenia occurred in $< 5 \%$ of patients treated with eribulin. Patients experiencing febrile neutropenia, severe neutropenia or thrombocytopenia, should be treated according to the recommendations (see section 4.2).

Patients with alanine aminotransferase (ALT) or aspartate aminotransferase (AST) $> 3 \times$ upper limit of normal (ULN) experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia. Although data are limited, patients with bilirubin $> 1,5 \times$ ULN also have a higher incidence of Grade 4 neutropenia and febrile neutropenia.

Fatal cases of febrile neutropenia, neutropenic sepsis, sepsis and septic shock have been reported.

Severe neutropenia may be managed by the use of granulocyte colony-stimulating factor (G-CSF) or equivalent at the physician's discretion in accordance with relevant guidelines (see section 5.1).

Peripheral neuropathy

Patients should be closely monitored for signs of peripheral motor and sensory neuropathy. The development of severe peripheral neurotoxicity requires a delay or reduction of dose (see section 4.2).

In clinical studies, patients with pre-existing neuropathy greater than Grade 2 were excluded. However, patients with pre-existing neuropathy Grade 1 or 2 were no more likely to develop new or worsening symptoms than those who entered the study without the condition.

QT prolongation

In an uncontrolled open-label ECG study in 26 patients, QT prolongation was observed on Day 8, independent of eribulin concentration, with no QT prolongation observed on Day 1. ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradyarrhythmia's or concomitant treatment with medicines known to prolong the QT interval, including Class Ia and III

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antiarrhythmics, and electrolyte abnormalities. Hypokalaemia, hypocalcaemia or hypomagnesaemia should be corrected prior to initiating ERIBULIN DRL and these electrolytes should be monitored periodically during therapy. ERIBULIN DRL should be avoided in patients with congenital long QT syndrome.

Excipients

This medicine contains small amounts of dehydrated alcohol (alcohol), less than 100 mg per dose.

4.5 Interaction with other medicines and other forms of interaction

Eribulin is mainly (up to 70 %) eliminated through biliary excretion. The transport protein involved in this process is unknown. Eribulin is not a substrate of breast cancer resistance protein (BCRP), organic anion (OAT1, OAT3, OATP1B1, OATP1B3), multi-drug resistance-associated protein (MRP2, MRP4) and bile salt export pump (BSEP) transporters.

No drug-drug interactions are expected with CYP3A4 inhibitors and inducers. Eribulin exposure (AUC and C_{max}) was unaffected by ketoconazole, a CYP3A4 and P glycoprotein (Pgp) inhibitor, and rifampicin, a CYP3A4 inducer.

Effects of eribulin on the pharmacokinetics of other medicines

In vitro data indicate that eribulin is a mild inhibitor of the important medicine metabolising enzyme CYP3A4. No *in vivo* data are available. Caution and monitoring for adverse events are recommended with concomitant use of substances that have a narrow therapeutic window and that are eliminated mainly via CYP3A4-mediated metabolism (eg., alfentanil, cyclosporine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus).

Eribulin does not inhibit the CYP enzymes CYP1A2, 2B6, 2C8, 2C9, 2C19, 2D6 or 2E1 at relevant clinical concentrations.

At relevant clinical concentrations, eribulin did not inhibit BCRP, OCT1, OCT2, OAT1, OAT3, OATP1B1 and OATP1B3 transporter-mediated activity.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential / Contraception in males and females

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Women of childbearing potential must be advised to avoid becoming pregnant whilst they or their male partner are receiving ERIBULIN DRL and have to use effective contraception during and up to 3 months after treatment.

Pregnancy

ERIBULIN DRL is contraindicated in pregnancy and lactation. There are no data from the use of ERIBULIN DRL in pregnant women.

ERIBULIN DRL is embryotoxic, foetotoxic, and teratogenic in rats.

ERIBULIN DRL should not be used during pregnancy (see section 4.3).

Breastfeeding

There is no information on the excretion of ERIBULIN DRL or its metabolites in human or animal breast milk.

Mothers on ERIBULIN DRL must not breastfeed their infants (see section 4.3).

Fertility

Testicular toxicity has been observed in rats and dogs.

Male patients should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with ERIBULIN DRL.

4.7 Effects on ability to drive and use machines

ERIBULIN DRL may cause adverse reactions such as tiredness and dizziness which may lead to minor or moderate influence on the ability to drive or use machines. Patients should be advised not to drive or use machines if they feel tired or dizzy.

4.8 Undesirable effects

Summary of safety Profile

The most commonly reported adverse reactions related to ERIBULIN DRL, are bone marrow suppression manifested as neutropenia, leucopenia, anaemia and thrombocytopenia with associated infections. New onset or worsening of pre-existing peripheral neuropathy has also been reported. Gastrointestinal toxicities, manifested as anorexia, nausea, vomiting, diarrhoea, constipation, and stomatitis are among reported undesirable effects. Other undesirable effects include fatigue, alopecia, increased liver enzymes, sepsis and musculoskeletal pain syndrome.

Tabulated list of adverse reactions

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Adverse reactions listed below are classified according to frequency and system organ class (SOC).

System Organ Class	Frequent	Less frequent	Frequency unknown
Infections and infestations	Urinary tract infection, Pneumonia, Oral candidiasis, Oral herpes, Upper respiratory tract infection, Nasopharyngitis Rhinitis, Herpes zoster	Sepsis, Neutropenic sepsis, Septic Shock	
Blood and lymphatic system disorders	Neutropenia, Leukopenia, Anaemia, Lymphopenia, Febrile neutropenia, Thrombocytopenia	*Disseminated intravascular coagulation	
Metabolism and nutrition disorders	Decreased appetite, Hypokalaemia, Hypomagnesaemia, Dehydration, Hyperglycaemia, Hypophosphataemia		
Psychiatric disorders	Insomnia, Depression		
Nervous system disorders	Peripheral neuropathy ^a , Headache, Dysgeusia, Dizziness, Hypoaesthesia, Lethargy, Neurotoxicity		
Eye disorders	Lacrimation increased, Conjunctivitis		
Ear and labyrinth	Vertigo, Tinnitus		

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disorders			
Cardiac disorders	Tachycardia		
Vascular disorders	Hot flush, Pulmonary embolism	Deep vein thrombosis	
Respiratory, thoracic and mediastinal disorders	Dyspnoea, Cough, Oropharyngeal pain, Epistaxis, Rhinorrhoea	Interstitial lung disease	
Gastrointestinal disorders	Nausea, Constipation, Diarrhoea, Vomiting, Abdominal pain, Stomatitis, Dry mouth, Dyspepsia, Gastroesophageal reflux disease, Abdominal distension	Mouth ulceration, Pancreatitis	
Hepatobiliary disorders	Aspartate aminotransferase increased, Alanine aminotransferase increased, Gamma glutamyl transferase increased, Hyperbilirubinaemia	Hepatotoxicity	
Skin and subcutaneous tissue disorders	Alopecia, Rash, Pruritus, Nail disorder, Night sweats, Dry skin, Erythema, Hyperhidrosis, Palmar plantar erythrodysesthesia	Angioedema	Stevens-Johnson syndrome/ Toxic epidermal necrolysis
Musculoskeletal	Arthralgia and myalgia,		

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and connective tissue disorders	Back pain, Pain in extremity, Bone pain, Muscle spasms, Musculoskeletal pain, Musculoskeletal chest pain, Muscular weakness		
Renal and urinary disorders	Dysuria	Haematuria, Proteinuria _a , Renal failure	
General disorders and administration site conditions	Fatigue/Asthenia, Pyrexia, Mucosal Inflammation, Peripheral oedema, Pain, Chills, Chest pain, Influenza like illness		
Investigations	Weight decreased		

^a Includes preferred terms of peripheral neuropathy, peripheral motor neuropathy, polyneuropathy, paraesthesia, peripheral sensory neuropathy, peripheral sensorimotor neuropathy and demyelinating polyneuropathy

* Rare

Overall, the safety profiles in the breast cancer and soft tissue sarcoma patient populations were similar.

Description of selected adverse reactions

Neutropenia

The neutropenia observed was reversible and not cumulative.

Neutrophil counts of $< 0,5 \times 10^9/L$ that lasted for more than 7 days may occur.

Neutropenia was reported as a Treatment Emergent Adverse Event (TEAE) in the sarcoma population and in the breast cancer population.

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Fatal cases of febrile neutropenia, neutropenic sepsis, sepsis and septic shock have been reported.

Severe neutropenia may be managed by the use of G-CSF or equivalent at the physician's discretion in accordance with relevant guidelines.

Neutropenia resulted in discontinuation less frequently in patients receiving eribulin.

Disseminated intravascular coagulation

Cases of disseminated intravascular coagulation have been reported, typically in association with neutropenia and/or sepsis.

Peripheral neuropathy

In breast cancer patients the most frequent adverse reaction resulting in discontinuation of treatment with eribulin was peripheral neuropathy.

In studies, patients with pre-existing neuropathy were as likely to develop new or worsening symptoms as those who entered the study without the condition.

Hepatotoxicity

In some patients with normal/abnormal liver enzymes prior treatment with eribulin, increased levels of liver enzymes have been reported with initiation of eribulin treatment. Such elevations appeared to have occurred early with eribulin treatment in cycle 1 - 2 for the majority of these patients and whilst thought likely to be a phenomenon of adaptation to eribulin treatment by the liver and not a sign of significant liver toxicity in most patients, hepatotoxicity has also been reported.

Special populations

Elderly population

The safety profile of eribulin in elderly patients (≥ 65 years of age) was similar to that of patients < 65 years of age except for asthenia/fatigue which showed an increasing trend with age. No dose adjustments are recommended for the elderly population.

Patients with hepatic impairment

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Patients with ALT or AST > 3 x ULN experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia. Although data are limited, patients with bilirubin > 1,5 x ULN also have a higher incidence of Grade 4 neutropenia and febrile neutropenia (see also "sections 4.2 and 5.2").

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

4.9 Overdose

Symptoms of over-dosage reported were hypersensitivity reactions and neutropenia.

There is no known antidote for ERIBULIN DRL overdose. In the event of an overdose, the patient should be closely monitored. Management of overdose should include supportive medical interventions to treat the presenting clinical manifestations.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agents, other antineoplastic agents,

ATC code: L01XX41

Pharmacological classification - A.26 Cytostatic agents

Mechanism of action

Eribulin mesylate is a synthetic analogue of halichondrin B, a natural medicine isolated from the marine sponge *Halichondria okadai* that inhibits tubulin formation and mitotic spindle function, leading to phase G₂/M cell-cycle arrest.

Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into non-productive aggregates. Eribulin exerts its effects via a tubulin-based antimetabolic mechanism leading to G₂/M cell cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged and irreversible mitotic blockage.

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5.2 Pharmacokinetic properties

Distribution

Eribulin is rapidly and widely distributed, hence has a large volume of distribution of 43 to 114 l/m².

The plasma protein binding of eribulin (100 to 1000 ng/mL) ranged from 49 % to 65 % in human plasma.

Biotransformation

Unchanged eribulin was the major circulating species in plasma following administration of ¹⁴C-eribulin to patients.

Metabolite concentrations represented < 0,6 % of parent compound, confirming that there are no major human metabolites of eribulin.

Elimination

Eribulin has a low clearance of 1,16 to 2,42 l/h/m² with a terminal half-life of approximately 40 h. No significant accumulation of eribulin was observed on weekly administration. The pharmacokinetic properties are not dose or time dependent in the range of eribulin doses of 0,22 to 3,53 mg/m².

Eribulin is eliminated primarily by biliary excretion.

After administration of ¹⁴C-eribulin to patients, approximately 82 % of the dose was eliminated in faeces and only 9 % in urine indicating that renal clearance is not a significant route of eribulin elimination.

Unchanged eribulin represented most of the total radioactivity in faeces and urine.

Hepatic impairment

A study evaluated the pharmacokinetics of eribulin in patients with mild (Child-Pugh A; n=7) and moderate (Child-Pugh B; n=4) hepatic impairment due to liver metastases. Compared to patients with normal hepatic function (n=6), eribulin exposure increased 1,8-fold and 3-fold in patients with mild and moderate hepatic impairment, respectively.

Administration of eribulin at a dose of 0,97 mg/m² to patients with mild hepatic impairment and 0,62 mg/m² to patients with moderate hepatic impairment resulted in a somewhat higher exposure than after a dose of 1,23 mg/m² to patients with normal hepatic function. Eribulin was not studied in patients with severe hepatic impairment (Child-Pugh C).

There is no study in patients with hepatic impairment due to cirrhosis (see section 4.2).

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Renal impairment

Increased ERIBULIN DRL exposure was seen in patients with moderately or severely impaired renal function, with high between-subject variability. The pharmacokinetics of eribulin were evaluated in a Phase 1 study in patients with normal renal function (Creatinine clearance: ≥ 80 mL/min; n=6), moderate (30 to 50 mL/min; n=7) or severe (15 to <30 mL/min; n=6) renal impairment. Creatinine clearance was estimated with the Cockcroft-Gault formula. A 1,5-fold (90 % CI: 0,9 to 2,5) higher dose-normalised AUC(0-inf) was observed in patients with moderate and severe renal impairment. See section 4.2 for treatment recommendations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dehydrated Alcohol

Hydrochloric Acid

Sodium Hydroxide

Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened vial

24 months

In-use instructions

From a microbiological point of view unless the method of opening precludes the risk of microbial contamination the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

If not used immediately ERIBULIN DRL as the undiluted solution in a syringe should not normally be stored longer than 48 hours at 25 °C, or 72 hours at 2 °C to 8 °C.

Diluted solutions of ERIBULIN DRL in sodium chloride 9 mg/ml (0,9 %) solution for injection should not be stored longer than 48 hours at 25 °C, or 72 hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

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Store at or below 25 °C. Excursions above 25 °C are not permitted.

Do not freeze. Store the vials in the original cartons.

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

ERIBULIN DRL is supplied in tubular (sulphur treated Type-I, 5 mL clear glass vials stoppered with 13 mm rubber stoppers and sealed with 13 mm aluminum flip-off seals.

The pack sizes are cartons of 1 or 6 vials.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

ERIBULIN DRL is a cytotoxic anticancer medicine and, as with other toxic compounds, caution should be exercised in its handling. The use of gloves, goggles, and protective clothing is recommended. If the skin comes into contact with the ERIBULIN DRL solution, the skin should be washed immediately and thoroughly with soap and water. If the ERIBULIN DRL solution contacts mucous membranes, the membranes should be flushed thoroughly with water. ERIBULIN DRL should only be prepared and administered by personnel appropriately trained in handling of cytotoxic medicines.

Pregnant staff should not handle ERIBULIN DRL.

The dose may be diluted in up to 100 mL of sodium chloride 9 mg/mL (0,9 % NaCl) solution for injection.

Following administration, it is recommended that the intravenous line be flushed with sodium chloride 9 mg/mL (0,9 % NaCl) solution for injection to ensure administration of the complete dose.

In the absence of compatibility studies ERIBULIN DRL must not be mixed with other medicines except sodium chloride 9 mg/mL (0,9 % NaCl) solution for injection.

It should not be diluted in glucose 5 % infusion solution.

Discard any unused portion of the vial.

Any unused medicine should be returned to the pharmacy to be correctly disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Dr. Reddy's Laboratories (Pty) Ltd.

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Block C, Woodmead North Office Park,

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2191

South Africa

8. REGISTRATION NUMBER

57/26/0539

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03 June 2025

10. DATE OF REVISION OF TEXT

To be allocated