

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fetroja 1 g powder for concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains cefiderocol sulfate tosylate equivalent to 1 g of cefiderocol.

Excipient with known effect

Each vial contains 7.64 mmol of sodium (approximately 176 mg).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for concentrate for solution for infusion (powder for concentrate).

White to off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fetroja is indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options (see sections 4.2, 4.4 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

It is recommended that Fetcroja should be used to treat patients that have limited treatment options only after consultation with a physician with appropriate experience in the management of infectious diseases.

Posology

Table 1 Recommended dose of Fetcroja¹ for patients with a creatinine clearance (CrCL) ≥ 90 mL/min²

Renal function	Dose	Frequency	Duration of treatment
Normal renal function (CrCL ≥ 90 to < 120 mL/min)	2 g	Every 8 hours	Duration in accordance with the site of infection ³
Augmented renal clearance (CrCL ≥ 120 mL/min)	2 g	Every 6 hours	Duration in accordance with the site of infection ³

¹To be used in combination with antibacterial agents active against anaerobic pathogens and/or Gram-positive pathogens when these are known or suspected to be contributing to the infectious process.

²As calculated using the Cockcroft-Gault formula.

³e.g. for complicated urinary tract infections including pyelonephritis and complicated intra-abdominal infections the recommended treatment duration is 5 to 10 days. For hospital-acquired pneumonia including ventilator-associated pneumonia the recommended treatment duration is 7 to 14 days. Treatment up to 21 days may be required.

Special populations

Renal impairment

Table 2 Recommended dose of Fetcroja for patients with a CrCl < 90 mL/min¹

Renal function	Dose	Frequency
Mild renal impairment (CrCL ≥ 60 to < 90 mL/min)	2 g	Every 8 hours
Moderate renal impairment (CrCL ≥ 30 to < 60 mL/min)	1.5 g	Every 8 hours
Severe renal impairment	1 g	Every 8 hours

(CrCL ≥ 15 to < 30 mL/min)		
End stage renal disease (CrCL < 15 mL/min)	0.75 g	Every 12 hours
Patient with intermittent haemodialysis ²	0.75 g	Every 12 hours

¹As calculated using the Cockcroft-Gault formula.

²As cefiderocol is removed by haemodialysis, administer cefiderocol at the earliest possible time after completion of haemodialysis on haemodialysis days.

Hepatic impairment

No dose adjustment is required in patients with hepatic impairment (see section 5.2).

Elderly population

No dosage adjustment is required (see section 5.2).

Paediatric population

The safety and efficacy of Fetcroja in children below 18 years of age has not yet been established. No data are available.

Method of administration

Intravenous use.

Fetcroja is administered by intravenous infusion over 3 hours.

For instructions on reconstitution and dilution of the medicinal product before administration, see section 6.6.

If treatment with a combination of another medicinal product and Fetcroja is unavoidable, administration should not occur in the same syringe or in the same infusion solution. It is recommended to adequately flush intravenous lines between administration of different medicinal products.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Hypersensitivity to any cephalosporin antibacterial medicinal product.

Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins, monobactams or carbapenems).

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Hypersensitivity has been reported with cefiderocol (see sections 4.3 and 4.8).

Patients who have a history of hypersensitivity to carbapenems, penicillins or other beta-lactam antibacterial medicinal products may also be hypersensitive to cefiderocol. Before initiating therapy with Fetcroja, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics (see section 4.3).

If a severe allergic reaction occurs, treatment with Fetcroja must be discontinued immediately and adequate emergency measures must be initiated.

Clostridioides difficile-associated diarrhoea

Clostridioides difficile-associated diarrhoea (CDAD) has been reported with cefiderocol (see section 4.8). The condition can range in severity from mild diarrhoea to fatal colitis and should be considered in patients who present with diarrhoea during or subsequent to the administration of cefiderocol. Discontinuation of therapy with cefiderocol and the use of supportive measures together with the administration of specific treatment for *Clostridioides difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Seizure

Cephalosporins have been implicated in triggering seizures. Patients with known seizure disorders should continue anticonvulsant therapy. Patients who develop focal tremors, myoclonus, or seizures should be evaluated neurologically and placed on anticonvulsant therapy if not already instituted. If necessary, the dose of cefiderocol should be adjusted based on renal function (see section 4.2). Alternatively, cefiderocol should be discontinued.

Limitations of the clinical data

In clinical trials, cefiderocol has only been used to treat patients with the following types of infection: complicated urinary tract infections (cUTI); hospital-acquired pneumonia (HAP), ventilator-associated pneumonia (VAP), healthcare-associated pneumonia (HCAP); sepsis and patients with bacteraemia (some with no identified primary focus of infection).

The use of cefiderocol to treat patients with infections due to Gram-negative aerobic pathogens who have limited treatment options is based on pharmacokinetic-pharmacodynamic analyses for cefiderocol and on limited clinical data from a randomized clinical trial in which 80 patients were treated with cefiderocol and 38 patients were treated with best available therapy for infections caused by carbapenem-resistant organisms.

All-cause mortality in patients with infections due to carbapenem-resistant Gram-negative bacteria

A higher all-cause mortality rate was observed in patients treated with cefiderocol as compared to best available therapy (BAT) in a randomised, open-label trial in critically-ill patients with infections known or suspected to be due to carbapenem-resistant Gram-negative bacteria. The higher day 28 all-cause mortality rate with cefiderocol occurred in patients treated for nosocomial pneumonia, bacteraemia and/or sepsis [25/101 (24.8%) vs. 9/49 (18.4%) with BAT; treatment difference 6.4%, 95% CI (-8.6, 19.2)]. All-cause mortality remained higher in patients treated with cefiderocol through end-of-study [34/101 (33.7%) vs. 9/49 (18.4%) with BAT;

treatment difference 15.3%, 95% CI (-0.2, 28.6)]. The cause of the increase in mortality has not been established. In the cefiderocol group there was an association between mortality and infection with *Acinetobacter spp.*, which accounted for the majority of infections due to non-fermenters. In contrast, mortality was not higher in cefiderocol vs. BAT patients with infections due to other non-fermenters.

Spectrum of activity of cefiderocol

Cefiderocol has little or no activity against the majority of Gram-positive organisms and anaerobes (see section 5.1). Additional antibacterial medicinal products should be used when these pathogens are known or suspected to be contributing to the infectious process.

Non-susceptible organisms

The use of cefiderocol may result in the overgrowth of non-susceptible organisms, which may require interruption of treatment or other appropriate measures.

Renal function monitoring

Renal function should be monitored regularly as dose adjustment may be needed during the course of therapy.

Drug/laboratory test interactions

Cefiderocol may result in false-positive results in urine dipstick tests (urine protein, ketones, or occult blood). Alternative methods of testing should be used by the clinical laboratories to confirm positive tests.

Antiglobulin test (Coombs test) seroconversion

A positive direct or indirect Coombs test may develop during treatment with cefiderocol.

Controlled sodium diet

Each 1 g vial contains 7.64 mmol of sodium (approximately 176 mg).

Each 2 g dose of cefiderocol, when reconstituted with 100 mL of 0.9% sodium chloride injection, provides 30.67 mmol (705 mg) of sodium and is approximately 35% of the WHO adult recommended maximum daily dietary intake. The total daily dose (2 g administered 3 times a day) of sodium from cefiderocol therapy is 2.1 g, just greater than the WHO recommend daily maximum of 2 g sodium for an adult.

When reconstituted in 100 mL of 5% dextrose injection each 2 g dose of cefiderocol provides 15.28 mmol (352 mg) of sodium. The total daily sodium dose (2 g administered 3 times a day) from cefiderocol reconstituted in 5% dextrose injection is 1056 mg which is approximately 53% of the WHO adult recommended maximum daily dietary intake of 2 g sodium.

4.5 Interaction with other medicinal products and other forms of interaction

Based on in vitro studies and two phase 1 clinical studies no significant drug-drug interactions are anticipated between cefiderocol and substrates, inhibitors or inducers of cytochrome P450 enzymes (CYPs) or transporters (see section 5.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of cefiderocol sodium in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Fetroja during pregnancy.

Breast-feeding

It is unknown whether Fetroja/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Fetroja therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

The effect of cefiderocol on fertility in humans has not been studied. Based on preclinical data, from a study with sub-clinical exposure, there is no evidence that Fetroja has an effect on male or female fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Fetroja has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most common adverse reactions were diarrhoea (8.2%), vomiting (3.6%), nausea (3.3%) and cough (2%).

Tabulated list of adverse reactions

The following adverse reactions have been reported with cefiderocol during clinical studies (Table 3). Adverse reactions are classified according to frequency and System Organ Class (SOC). Frequency categories are defined as: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10000$ to $< 1/1000$); very rare ($< 1/10000$); not known (cannot be estimated from the available

data). Within each System Organ Class, undesirable effects are presented in order of decreasing seriousness.

Table 3 Tabulated list of adverse reactions

System organ class	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Not known
<i>Infections and infestations</i>	Candidiasis including oral candidiasis, vulvovaginal candidiasis, candiduria and candida infection, <i>Clostridioides difficile</i> colitis including pseudomembranous colitis and <i>Clostridioides difficile</i> infection		
<i>Blood and lymphatic system disorders</i>			Neutropenia
<i>Immune System Disorders</i>		Hypersensitivity including skin reactions and Pruritus	
<i>Respiratory, thoracic and mediastinal disorders</i>	Cough		
<i>Gastrointestinal disorders</i>	Diarrhoea, Nausea, Vomiting		
<i>Skin and subcutaneous tissue disorders</i>	Rash including rash macular, rash maculo-papular, rash erythematous and drug eruption		
<i>Renal and urinary disorders:</i>			Chromaturia
<i>General disorders and administration site conditions</i>	Infusion site reaction including infusion site pain, injection site pain, infusion site erythema and injection site phlebitis		
<i>Investigations</i>	Alanine aminotransferase increased, Gamma-glutamyltransferase increased, Aspartate aminotransferase increased, Hepatic function abnormal including liver function test increased, hepatic enzyme increased,	Blood urea increased	

System organ class	Common ($\geq 1/100$ to $< 1/10$)	Uncommon ($\geq 1/1000$ to $< 1/100$)	Not known
	transaminases increased and liver function test abnormal, Blood creatinine increased		

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 the Yellow Card Scheme, website: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There is no information on clinical signs and symptoms associated with an overdose of cefiderocol.

In the event of overdose, patients should be monitored and treatment discontinuation and general supportive treatment should be considered.

Approximately 60% of cefiderocol is removed by a 3- to 4-hour haemodialysis session.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, other beta-lactam antibacterials. ATC code: J01DI04

Mechanism of action

Cefiderocol is a siderophore cephalosporin. In addition to passive diffusion through outer membrane porin channels, cefiderocol is able to bind to extracellular free iron via its siderophore side chain, allowing active transport into the periplasmic space of Gram-negative bacteria through siderophore uptake systems. Cefiderocol subsequently binds to penicillin binding proteins (PBPs), inhibiting bacterial peptidoglycan cell wall synthesis which leads to cell lysis and death.

Resistance

Mechanisms of bacterial resistance that may lead to resistance to cefiderocol include mutant or acquired PBPs; beta-lactamase enzymes with ability to hydrolyse cefiderocol; mutations affecting regulation of bacterial iron uptake; mutations in siderophore transport proteins; overexpression of native bacterial siderophores

The *in vitro* antibacterial activity effect of cefiderocol against normally susceptible species is not affected by the majority of beta-lactamases, including metallo-enzymes. Due to the siderophore-mediated mode of cell entry, the *in vitro* activity of cefiderocol activity is generally less affected by porin loss or efflux-mediated resistance compared to many other beta-lactam agents.

Cefiderocol has little or no activity against Gram-positive or anaerobic bacteria due to intrinsic resistance.

Antibacterial activity in combination with other antibacterial agents

In vitro studies demonstrated no antagonism between cefiderocol and amikacin, ceftazidime/avibactam, ceftolozane/tazobactam, ciprofloxacin, clindamycin, colistin, daptomycin, linezolid, meropenem, metronidazole, tigecycline, or vancomycin.

Susceptibility testing breakpoints

MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for cefiderocol and are listed here:

https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx

Pharmacokinetic/pharmacodynamic relationship

The time that unbound plasma concentrations of cefiderocol exceeds the minimum inhibitory concentration ($\%fT_{>MIC}$) against the infecting organism has been shown to best correlate with efficacy.

Antibacterial activity against specific pathogens

In-vitro studies suggest that the following pathogens would be susceptible to cefiderocol in the absence of acquired mechanisms of resistance:

Aerobic Gram-negative organisms

Achromobacter spp.
Acinetobacter baumannii complex
Burkholderia cepacia complex
Citrobacter freundii complex
Citrobacter koseri
Escherichia coli
Enterobacter cloacae complex
Klebsiella (Enterobacter) aerogenes
Klebsiella pneumoniae
Klebsiella oxytoca
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Serratia spp.
Pseudomonas aeruginosa
Serratia marcescens
Stenotrophomonas maltophilia

In vitro studies indicate that the following species are not susceptible to cefiderocol:

Aerobic Gram-positive organisms

Anaerobic organisms

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Fectroja in one or more subsets of the paediatric population in the treatment of infections due to aerobic Gram-negative bacteria (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

After multiple dose administration of cefiderocol, there is no accumulation of cefiderocol administered every 8 hours in healthy adult subjects with normal renal function.

Distribution

The binding of cefiderocol to human plasma proteins, primarily albumin, is in the range of 40 to 60%, the geometric mean (CV%) volume of distribution during the terminal phase of cefiderocol in healthy adult subjects (n = 43) after intravenous administration of a single 2 g dose of cefiderocol was 18.0 L (18.1%), similar to extracellular fluid volume.

Biotransformation

After administration of a single 1 g dose of [¹⁴C]-labelled cefiderocol infused over 1 hour, cefiderocol accounted for 92.3% of the plasma AUC for total radioactivity. The most predominant metabolite, pyrrolidine chlorobenzamide (PCBA, which is a degradation product of cefiderocol), accounted for 4.7% of the plasma AUC for total radioactivity, while other more minor metabolites each accounted for < 2% of the plasma AUC for total radioactivity.

Interaction with other medicinal products.

Co-administration with 2 g doses of cefiderocol given every 8 hours did not affect the pharmacokinetics of midazolam (a CYP3A substrate), furosemide (a OAT1 and OAT3 substrate) or metformin (a OCT1, OCT2, and MATE2-K substrate). Co-administration with 2 g doses of cefiderocol given every 8 hours increased rosuvastatin (a OATP1B3 substrate) AUC by 21%, which was considered not to be clinically meaningful.

Elimination

The terminal elimination half-life in healthy adult subjects was 2 to 3 hours. The geometric mean (%CV) of clearance of cefiderocol in healthy subjects is estimated to be 5.18 (17.2%) L/hr. Cefiderocol is primarily eliminated by the kidneys. After administration of a single 1 g dose of [¹⁴C]-labelled cefiderocol infused over 1 hour, the amount of total radioactivity excreted in urine was 98.6% of the administered dose, with 2.8% of the administered dose excreted in faeces. The amount of unchanged cefiderocol excreted in urine was 90.6% of the administered dose.

Linearity/non-linearity

Cefiderocol exhibits linear pharmacokinetics within the dose range of 100 mg to 4000 mg.

Special populations

In a population pharmacokinetic analysis, no clinically relevant effect on the pharmacokinetics of cefiderocol was observed with respect to age, gender or race.

Paediatric population

Pharmacokinetic studies have not been performed with cefiderocol in infants and children under 18 years of age (see section 4.2).

Renal impairment

The pharmacokinetics of cefiderocol after administration of a single 1 g dose was assessed in subjects with mild renal impairment (n=8, estimated glomerular filtration rate [eGFR] of 60 to < 90 mL/min/1.73 m²), moderate renal impairment (n=7, eGFR 30 to < 60 mL/min/1.73 m²), severe renal impairment (n=6, eGFR less than 30 mL/min/1.73 m²), end-stage renal disease (ESRD) requiring haemodialysis (n=8), and healthy subjects with normal renal function (n=8, estimated creatinine clearance of at least 90 mL/min). The geometric mean ratios (GMR; mild, moderate, severe or ESRD without haemodialysis/normal renal function) and 90% confidence intervals (CI) for the AUC of cefiderocol were 1.0 (0.8, 1.3), 1.5 (1.2, 1.9), 2.5 (2.0, 3.3) and 4.1 (3.3, 5.2), respectively. Approximately 60% of Fetcroja was removed by a 3- to 4-hour haemodialysis session.

The recommended dose adjustments in subjects with varying degrees of renal impairment are expected to provide comparable exposures to subjects with normal renal function or mild renal impairment (see section 4.2).

Patients with augmented renal clearance

Simulations using the population PK model demonstrated that the recommended dose adjustment for ARC provide exposures, including %T>MIC, of Fetcroja comparable to those in patients with normal renal function.

Hepatic impairment

Hepatic impairment is not expected to alter the elimination of Fetcroja as hepatic metabolism/excretion represent a minor pathway of elimination of Fetcroja.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety

pharmacology, or genotoxicity. Carcinogenicity studies with cefiderocol have not been conducted.

Cefiderocol was negative for mutagenicity in an *in vitro* reverse mutation test with bacteria and in the *in vitro* HPRT gene mutation assay in human cells. Positive findings were seen in an *in vitro* chromosomal aberration test in cultured TK6 cells and an *in vitro* mouse lymphoma assay (MLA). There was no evidence of *in vivo* genotoxicity (rat micronucleus assay and comet assay in rats).

Cefiderocol had no impairment of fertility and early embryonic development in rats treated with cefiderocol intravenously up to 1000 mg/kg/day corresponding to a margin to clinical exposure of 0.8. There was no evidence of teratogenicity or

embryotoxicity in rats or mice that received 1000 mg/kg/day or 2000 mg/kg/day respectively corresponding to margins to clinical exposure of 0.9 and 1.3

Cefiderocol had no adverse effects on growth and development, including neurobehavioural function in juvenile rats that received 1000 mg/kg/day subcutaneously during postnatal day (PND)7 to PND27, or 600 mg/kg/day intravenously from PND28 to PND48.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Sodium chloride

Sodium hydroxide (pH adjustment)

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

If treatment with a combination of another medicinal product and Fetroja is unavoidable, administration should not occur in the same syringe or in the same infusion solution. It is recommended to adequately flush intravenous lines between administration of different medicinal products.

6.3 Shelf life

Powder

3 years.

Stability of reconstituted solution in the vial

Chemical and physical in-use stability after reconstitution has been demonstrated for 1 hour at 25°C.

From a microbiological point of view, unless the method of opening/reconstitution precludes the risk of microbial contamination, the reconstituted product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and should not be more than 1 hour at 25°C.

Stability of the diluted solution in the infusion bag

Chemical, microbiological and physical in-use stability after dilution has been demonstrated for 6 hours at 25°C and for 24 hours at 2 to 8°C protected from light, followed by 6 hours at 25°C.

From a microbiological point of view, diluted products should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 6 hours at 25°C or 24 hours at 2 to 8°C protected from light, followed by 6 hours at 25°C, unless dilution has taken place in controlled and validated aseptic conditions. The 6-hour period at 25°C should be inclusive of the product administration period of 3 hours (see section 4.2). If storing the infusion solution in the refrigerator, the infusion bag should be removed and allowed to reach room temperature prior to use.

For preparation of solution for administration, see Section 6.6.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C)

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

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

6.5 Nature and contents of container

14 mL vial (Type I clear glass vial), chlorobutyl elastomeric stopper, and aluminum seal with a plastic flip-off cap. The vials are packed in a cardboard carton.

Pack size of 10 vials.

6.6 Special precautions for disposal

Each vial is for single use only.

The powder should be reconstituted with 10 mL of either sodium chloride 9 mg/ml (0.9%) solution for injection or 5% dextrose injection taken from the 100 mL bags that will be used to prepare the final infusion solution and should be gently shaken to dissolve. The vial(s) should be allowed to stand until the foaming generated on the surface has disappeared (typically within 2 minutes). The final volume of the reconstituted solution in the vial will be approximately 11.2 mL (caution: the reconstituted solution is not for direct injection).

To prepare the required doses, the appropriate volume of reconstituted solution should be withdrawn from the vial according to Table 4. Add the withdrawn volume to the infusion bag containing the remainder of the 100 mL of sodium chloride 9 mg/ml (0.9%) solution for injection, or 5% dextrose injection, inspect the resulting diluted drug product solution in the infusion bag visually for particulate matter and discoloration prior to use. Do not use discoloured solutions or solutions with visible particles.

Table 4 Preparation of cefiderocol doses

Cefiderocol dose	Number of 1 g cefiderocol vials to be reconstituted	Volume to withdraw from reconstituted vial(s)	Total volume of cefiderocol solution required for further dilution in at least 100 mL of 0.9% sodium chloride injection or 5% dextrose injection
2 g	2 vials	11.2 mL (entire contents) from both vials	22.4 mL
1.5 g	2 vials	11.2 mL (entire contents) from first vial AND 5.6 mL from second vial	16.8 mL
1 g	1 vial	11.2 mL (entire contents)	11.2 mL
0.75 g	1 vial	8.4 mL	8.4 mL

Standard aseptic techniques should be used for solution preparation and administration.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PLGB 50999/0009

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

13/01/2025

10 DATE OF REVISION OF THE TEXT

13/01/2025