SUMMARY OF RPODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Colistat, 3,000,000 IU, 4,500,000 IU, powder for solution for intravenous administration.
International nonproprietary name: Colistin.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Colistimethate sodium
One vial contains:
Active substance:
Colistimethate sodium –3,000,000 IU or 4,500,000 IU.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for intravenous administration 3,000,000 IU, 4,500,000 IU.
White or off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Colistat *by intravenous administration* is indicated for the treatment of severe infections caused by susceptible Gram-negative aerobic microorganisms in adults and children, including neonates, when other therapies are not applicable (see sections 4.2, 4.4, 4.8 and 5.1).
Official recommendations for the appropriate use of antibacterial agents shall be taken into account.

4.2 Posology and method of administration

Posology

The dosage regimen and duration of therapy are established taking into account the severity of the infection and the clinical response to therapy. Therapeutic recommendations shall be followed.
The dose is expressed in international units (IU) of colistimethate sodium. A table for converting IU to milligrams (mg) of colistimethate sodium and to mg of the active base (colistin) is given at the end of this section.
The following dosage recommendations are based on limited population pharmacokinetic data in critically ill patients (see section 4.4).
Adults and adolescents
The recommended daily maintenance dose is 9,000,000 IU in 2-3 divided doses.
For critically ill patients, the loading dose shall be 9,000,000 IU. The optimal time interval before administration of the first maintenance dose has not been established.
Simulation suggests that loading and maintenance doses of up to 12,000,000 IU may be required in some cases for patients with good renal function. However, clinical experience with such doses is extremely limited and safety has not been established.
The loading dose is used in patients with normal renal function as well as in patients with renal failure, including those on renal replacement therapy.

Special populations

Renal impairment
Dose adjustments are necessary in renal failure, but pharmacokinetic data in patients with impaired renal function are very limited.

Patients with impaired renal function (creatinine clearance < 50 ml/min) are recommended to reduce the dose. The recommended frequency of administration of the medicinal product is 2 times daily.

Creatinine clearance (ml/min)	Daily dose
< 50-30	5,500,000 – 7,500,000 IU
< 30-10	4,500,000 – 5,500,000 IU
< 10	3,500,000 IU

Hemodialysis and continuous hemo(dia)filtration
Colistin is able to penetrate the semipermeable membrane of conventional hemodialysis and continuous venovenous hemofiltration or hemodiafiltration (CVVHF or CVVHDF). Population pharmacokinetic data in patients receiving renal replacement therapy are very limited. There are no clear recommendations for the dosing regimen.
For patients on hemodialysis, the following dosing regimen is recommended:
- days without hemodialysis: 2,250,000 IU per day (2,200,000 - 2,300,000 IU/day);
- days of hemodialysis: 3,000,000 IU per day - the medicinal product shall be administered after hemodialysis. The daily dose shall be divided into 2 administrations.
For CVVHF or CVVHDF, the dosing regimen corresponds to the dosing regimen in patients with normal renal function. The daily dose shall be divided into 3 doses.
Hepatic impairment
Colistimethate sodium shall be administered with caution to patients with impaired liver function, as there are no data on the use of colistimethate sodium in such patients.
Elderly
No dosage adjustment is required for *elderly patients* with normal renal function.
Pediatric population
There are limited data on dosing in children. Renal maturity shall be taken into account when choosing a dosing regimen in children. The dose shall be based on lean body mass.
Children weighing ≤ 40 kg are given 75,000-150,000 IU/kg per day; the daily dose shall be divided into 3 doses.
The dosing regimen in children weighing > 40 kg is the same as in adults.
Doses exceeding 150,000 IU/kg per day have been reported in children with cystic fibrosis.
There are no data on the use of a loading dose or its amount in critically ill children.
Dosing recommendations are not established in children with *renal impairment*.
Method of administration
Colistat is administered intravenously as a slow infusion over 30-60 minutes.
Patients with a totally implantable venous access device can tolerate a bolus injection of up to 2 million units in 10 ml over at least 5 minutes (see section 6.6).
Colistimethate sodium is hydrolyzed to the active substance colistin in aqueous solution.
For dose preparation, particularly when multiple vials are required, reconstitution of the required dose shall be performed using strict aseptic technique (see section 6.6).
Dose conversion table
The dose of colistimethate sodium shall be prescribed and administered in IU only. The number of IU per vial is indicated on the medicinal product label. There have been reports of administration errors due to doses being expressed in different units.

The conversion table is provided for reference only; the values given therein shall be considered approximate.

Content of active substance		≈ mass of colistimethate sodium (mg)*
IU of colistimethate sodium	≈ mg of colistin base	

12,500	0.4	1
150,000	5	12
1,000,000	34	80
4,500,000	150	360
I,000,000	300	720

* Nominal activity of the active substance = 12,500 IU/mg.

4.3 Contraindications

Hypersusceptibility to colistimethate sodium, colistin or polymyxin B.

4.4 Special warnings and precautions for use

If necessary, co-administration of intravenous colistimethate sodium with other antibacterial agents shall be considered taking into account the susceptibility of the pathogens and to prevent resistance. Since the development of resistance to intravenous colistin has been reported when it is used as monotherapy, co-administration of Colistat with other antibacterial agents shall be considered to prevent resistance. Clinical data on the efficacy and safety of intravenous colistimethate sodium are limited. The recommended doses for all subpopulations are based on limited data (clinical and pharmacokinetic/pharmacodynamic data). In particular, there are limited safety data for high doses (> 6,000,000 IU/day), loading doses, and use in special populations (patients with renal impairment and children). Colistat shall be used only in cases where commonly used antibacterial agents are ineffective or cannot be used.

In case of an *allergic reaction*, treatment with colistimethate sodium shall be discontinued and appropriate measures shall be taken.

Renal impairment

Renal function shall be monitored at the start of treatment and regularly during therapy in all patients. The dose of colistimethate sodium shall be adjusted according to creatinine clearance (see section 4.2). Patients with hypovolemia or receiving other potentially nephrotoxic medicinal products are at increased risk of colistin-induced nephrotoxicity (see sections 4.5 and 4.8).

A correlation of nephrotoxicity with the cumulative dose and duration of treatment has been reported. The benefit of prolonged therapy shall outweigh the risk of potential nephrotoxicity.

Colistimethate sodium shall be administered with caution to children under 1 year of age, since this group of patients is characterized by insufficient renal functional maturity. Also, the influence of immature renal and metabolic activity on the conversion of colistimethate sodium to colistin has not been established.

Neurotoxicity

High serum concentrations of colistimethate sodium after intravenous or intramuscular administration may be caused by overdose or failure to reduce the dose in patients with impaired renal function and may result in neurotoxicity.

Concomitant administration of non-depolarizing muscle relaxants or antibiotics with similar neurotoxic effects also causes neurotoxicity. Reducing the dose of colistimethate sodium may improve symptoms. Neurotoxic adverse reactions reported include dizziness, transient facial paraesthesia, speech disorders, vasomotor instability, visual disturbances, confusion, psychosis, and apnea. Perioral paraesthesia and paraesthesia of the extremities shall be monitored as they are symptoms of overdose (see section 4.9).

Particular caution shall be exercised when administering the medicinal product to patients with *porphyria*.

Since colistimethate sodium reduces the release of acetylcholine, colistat shall be used in patients with *myasthenia gravis* with caution and only if clearly needed.

A case of respiratory arrest has been reported following *intramuscular administration* of colistimethate sodium. Impaired renal function increases the likelihood of apnea and neuromuscular block following colistimethate sodium administration.
Antibiotic-associated and pseudomembranous *colitis*, which may occur with all antibacterial medicinal products, may also occur with colistimethate sodium. Their severity may range from mild to life-threatening. If diarrhea occurs during the use of colistimethate sodium (see section 4.8), therapy shall be discontinued and medicinal products for the treatment of *Clostridium difficile* shall be prescribed. Medicinal products that inhibit peristalsis shall not be prescribed.
During treatment with colistimethate sodium, the emergence of strains of resistant microorganisms is possible. Restoration of the efficacy of the medicinal product is possible after discontinuation and/or modification of therapy.
Sodium
Colistat contains less than 1 mmol of sodium (23 mg) per vial, making it virtually sodium-free.

4.5 Interaction with other medicinal products and other forms of interaction
Particular caution shall be exercised when colistat is administered concomitantly with potentially neurotoxic and/or nephrotoxic medicinal products.
Caution shall be exercised when co-administering colistimethate sodium in different dosage forms, as information on potential net toxicity is limited.
In vivo data on the interaction of colistimethate sodium with other medicinal products and its mechanism of elimination are limited. *In vitro* studies of human hepatocytes showed that colistimethate sodium or colistin did not induce the activity of any of the P450 (CYP) enzymes tested (CYP1A2, 2B6, 2C8, 2C9, 2C19, and 3A4/5). Potential medicinal product interactions shall be considered when colistimethate sodium is co-administered with medicinal products that inhibit or induce enzymes that metabolize the medicinal product, or with medicinal products that are substrates for renal transport mechanisms.
Since colistin affects acetylcholine release, non-depolarizing muscle relaxants shall be used with caution in patients receiving colistimethate sodium, as it may prolong the effect of muscle relaxants (see section 4.4).
Concomitant use of colistimethate sodium and macrolides such as azithromycin and clarithromycin, or fluoroquinolones such as norfloxacin or ciprofloxacin shall be administered with caution in patients with myasthenia gravis (see section 4.4).
Colistat shall not be used concomitantly with medicinal products with neurotoxic and/or nephrotoxic action, such as aminoglycosides (gentamicin, amikacin, netilmicin and tobramycin). When used concomitantly with cephalosporins, the risk of nephrotoxicity may increase.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are insufficient data on the use of colistimethate sodium during pregnancy. According to a single-dose study, colistimethate sodium can cross the placental barrier, and repeated doses may cause embryotoxicity. Animal studies on the effects of colistimethate sodium on reproductive function and development of offspring are insufficient (see section 5.3). However, it has been demonstrated that colistimethate sodium crosses the placenta and, therefore, at a therapeutic dose for pregnant women, there is a risk of toxicity to the fetus. The medicinal product shall not be used during pregnancy unless the potential benefit from its use justifies the possible risk to the fetus. *In each case, the medicinal product shall be used under medical supervision!*
Lactation

Colistimethate sodium can be excreted in breast milk, therefore, if it is necessary to use colistimethate sodium *during lactation*, the discontinuation of breastfeeding shall be considered (see section 5.3).
Fertility
There are no data on the possible effects of colistimethate sodium on human fertility. Animal studies have not shown any effects on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines
Colistimethate sodium may affect the ability to drive to drive and use machines. Neurotoxic effects such as dizziness, confusion, or blurred vision are possible during parenteral administration of colistimethate sodium. Patients shall refrain from these activities if these adverse effects occur.

4.8 Adverse reactions
The likelihood of developing adverse reactions may be related to age, renal function and general condition of the patient.
Adverse reactions are presented in accordance with the system-organ classification and frequency of occurrence. When indicating the frequency, the following categories were used: very common (≥1/10), common (≥1/100, but <1/10), uncommon (≥1/1000, but <1/100), rare (≥1/10000, but <1/1000), very rare (<1/10000), frequency unknown (based on the available data, the frequency of occurrence cannot be estimated).
Immune system disorders: frequency unknown - skin rash, anaphylactic reactions, drug-induced fever. If such reactions occur, colistimethate sodium shall be discontinued.
Nervous system disorders: very common - neurotoxicity (may be associated with overdose, poorly selected dose in patients with renal failure and concomitant use of neuromuscular blockers or other medicinal products with similar neurological effects; dose reduction may help reduce these symptoms); rare - vasomotor instability, slurred speech, visual impairment, confusion or psychosis; frequency unknown - respiratory arrest, transient sensory disturbances (facial paresthesia, dizziness), drowsiness, ataxia. Patients with cystic fibrosis may experience moderate neurological reactions (in 27% of patients), which resolve spontaneously during treatment or after its discontinuation.
Gastrointestinal disorders: frequency unknown - gastrointestinal disorders.
Skin and subcutaneous tissue disorders: very common - generalized itching, urticaria.
Renal and urinary disorders: very common – renal dysfunction; rare – renal failure. Renal dysfunction usually occurs after the use of doses exceeding those recommended in patients with normal renal function, or due to an insufficiently reduced dose of the medicinal product in patients with renal failure, or due to the concomitant use of other nephrotoxic medicinal products. These adverse reactions are usually reversible and disappear after discontinuation of therapy. In patients with cystic fibrosis using recommended doses of the medicinal product, nephrotoxicity reactions occur rarely (less than 1% of cases). Signs of nephrotoxicity may occur in seriously ill hospitalized patients without a diagnosis of cystic fibrosis (about 20%).
General disorders and administration site conditions: frequency unknown - injection site irritation.

Reporting suspected adverse reactions
It is important to report suspected adverse reactions after registration of the medicinal product in order to ensure continuous monitoring of the benefit-risk ratio of the medicinal product. Healthcare professionals are encouraged to report any suspected adverse reactions of the medicinal product through the national adverse reaction reporting system:
Republic of Belarus
220037, Minsk, Tovarishchesky lane, 2a
Center for Examinations and Tests in Health Service UE

Telephone of the Pharmacovigilance Department: +375 (17) 242 00 29; fax: +375 (17) 242 00 29
E-mail: rcpl@rceth.by, rceth@rceth.by
http://www.rceth.by

4.9 Overdose

Symptoms

Overdose of colistimethate sodium may cause neuromuscular blockade, which in turn may lead to muscle weakness, dyspnea and possible respiratory arrest. Overdose may also cause acute renal failure characterized by decreased urine output and elevated serum urea and creatinine concentrations.

Treatment

There is no specific antidote for overdose of colistimethate sodium. Maintenance therapy is recommended. Forced diuresis with mannitol, prolonged hemodialysis, or peritoneal dialysis may be used to increase the rate of medicinal product elimination, but their efficacy has not been proven. In case of accidental ingestion of the medicinal product, the development of toxic effects is unlikely, since colistimethate sodium is insignificantly absorbed from the gastrointestinal tract.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group Antibacterials for systemic use. Other antibacterials. Polymyxins.

ATC code J01XB01.

Mechanism of action

Colistin is a cyclic polypeptide antibacterial agent belonging to the group of polymyxins. Polymyxins act by damaging the cell membrane, and the resulting physiological effects are lethal to the bacteria. Polymyxins are selective for aerobic gram-negative bacteria that have a hydrophobic outer membrane.

Resistance

Resistant bacteria are characterized by modification of the phosphate groups of lipopolysaccharide, which are replaced by ethanolamine or aminoarabinose. In resistant gram-negative bacteria, such as *Proteus mirabilis* and *Burkholderia cepacia*, a complete replacement of the lipid phosphate by ethanolamine or aminoarabinose is found. Cross-resistance is expected between colistin (polymyxin E) and polymyxin B. Since the mechanism of action of polymyxins differs from that of other antibacterial agents, resistance to colistin and polymyxin by the above mechanism alone cannot be expected to lead to resistance to other classes of medicinal products.

Pharmacokinetic/pharmacodynamic relationship

Polymyxins has a concentration-dependent bactericidal effect on susceptible bacteria. fAUC/MIC (minimum inhibitory concentration) is considered to correlate with clinical efficacy.

Table 1. Cutoff values for the interpretation of MIC values (EUCAST*, version 12.0, dated 01.01.2022)

Microorganisms	MIC cutoff values ***	
	Sensitive	Resistant**
Acinetobacter	≤ 2 mg/l	> 2 mg/l
Enterobacteriaceae	≤ 2 mg/l	> 2 mg/l
Pseudomonas spp.	≤ 4 mg/l	> 4 mg/l

*EUCAST – European Committee on Antimicrobial Susceptibility Testing, http://www.eucast.org.

** Cutoff values apply to the dosing regimen: 2,000,000 – 3,000,000 IU 3 times daily. A loading dose of up to 9,000,000 IU may be used.
***Colistin MIC determination shall be performed using broth microdilutions. Quality control shall be performed with both the susceptible QC strain (E. coli ATCC 25922 or P. aeruginosa ATCC 27853) and the colistin-resistant E. coli NCTC 13846 (mcr-1 positive).
For information on how to use the cutoff values, please see http://www.eucast.org/eucastguidancedocuments/.

Susceptibility

The prevalence of acquired resistance may vary geographically and over time for individual species, and local information on resistance is desirable, particularly when treating severe infections. When necessary, specialist advice shall be sought when the local prevalence of resistance is such that the usefulness of the agent in at least some types of infections is questionable.

Acinetobacter baumannii, Haemophilus influenzae, Klebsiella spp., Pseudomonas aeruginosa are usually sensitive to colistimethate sodium.

Acquired resistance may vary geographically and over time in relation to selected bacterial species.

Acquired resistance is possible for *Stenotrophomonas maltophilia, Achromobacter xylosoxidans* (formerly *Alcaligenes xylosoxidans*). Resistant Gram-negative bacteria include *Proteus spp., Providencia spp., Serratia spp., Burkholderia cepacia* and related species.

Cross-resistance between colistimethate sodium and polymyxin B is possible. Since the mechanism of action of polymyxins differs from that of other antibiotics, resistance to colistimethate sodium and polymyxin B by the above mechanism does not imply resistance to other groups of medicinal products.

5.2 Pharmacokinetic properties

Absorption

Limited data are available on the pharmacokinetics of colistimethate sodium and colistin. Pharmacokinetics in critically ill patients have been shown to differ from those in less severely ill patients and healthy volunteers.

Following intravenous administration, higher serum levels were obtained in 10 minutes. Serum concentrations declined with a half-life of 2-3 hours after intravenous or intramuscular administration in adults and in children, including premature infants.

Following infusion, inactive colistimethate sodium (prodrug) is converted to active colistin. Peak plasma colistin concentrations have been shown to occur with a delay of up to 7 hours after colistimethate sodium administration to critically ill patients.

Gastrointestinal absorption in healthy individuals is insignificant.

Distribution

The volume of distribution of colistin in healthy subjects is small and approximately corresponds to the volume of extracellular fluid. The volume of distribution is significantly increased in critically ill patients. Protein binding is moderate and decreases at higher concentrations.

The pharmacokinetics of both colistimethate sodium and colistin are linear over the clinically relevant dose range.

Colistimethate sodium accumulates in the liver, kidneys, brain, heart, and muscle.

In the absence of meningitis, penetration into the cerebrospinal fluid is minimal, but increases in the presence of meningeal inflammation.

The medicinal product is able to penetrate the placenta.

Metabolism and elimination

About 30% of colistimethate sodium is converted to colistin in healthy subjects, its clearance depends on creatinine clearance, and when renal function decreases, most of the colistimethate sodium is converted to colistin. In patients with severe renal impairment (creatinine clearance < 30 ml/min), the conversion rate can reach 60-70%. Colistimethate

sodium is excreted mainly through the kidneys by glomerular filtration. In healthy subjects, 60-70% of colistimethate sodium is excreted unchanged in the urine within 24 hours.
The elimination of active colistin has not been fully characterized. Colistin undergoes significant renal tubular reabsorption and may be eliminated without renal involvement or undergo renal metabolism with the potential for renal accumulation. Colistin clearance is reduced in renal impairment, possibly due to increased conversion of colistimethate sodium.
Mean urinary levels ranged from about 270 mcg/mL in 2 hours to about 15 mcg/mL in 8 hours after intravenous administration and from 200 mcg/mL to about 25 mcg/mL over a similar period after intramuscular administration.
After intravenous administration, the elimination half-life of colistimethate sodium in healthy subjects and those with cystic fibrosis is about 3 hours and 4 hours, respectively, with a total clearance of about 3 L/h. In critically ill patients, the half-life increases to 9-18 hours.
Pharmacokinetics in particular medical cases
In case of *renal impairment*, the dose of colistimethate sodium shall be reduced to prevent accumulation of the medicinal product in the body.
Clinical studies of colistimethate sodium did not include sufficient numbers of *elderly patients* (65 years and older) to determine specific pharmacokinetic parameters. Clinical experience has not revealed differences between elderly and younger patients. In general, dose selection for the elderly shall be cautious, usually starting at the lower end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and concomitant disease or other medicinal product therapy. This medicinal product is known to be eliminated largely by the kidneys, and the risk of toxic reactions may be greater in patients with impaired renal function. As elderly patients are likely to have decreased renal function, caution shall be exercised in dose selection, and renal function monitoring may be useful.
There are limited data on the use of the medicinal product in *infants*. In this population, the possibility of higher maximum plasma concentrations and a longer half-life shall be taken into account, and serum levels of the active substance shall be monitored.

5.3 Preclinical safety data
Data on potential genotoxicity are limited, and there are no data on carcinogenicity for colistimethate sodium. Colistimethate sodium has been shown to induce chromosomal aberrations in human lymphocytes *in vitro*, possibly related to a decrease in the mitotic index. No teratogenicity was observed in reproductive toxicity studies on rats and mice. However, intramuscular administration of colistimethate sodium to rabbits during organogenesis at a dose of 4.15 and 9.3 mg/kg resulted in the development of varus deformity of the foot in 2.6 and 2.9% of the fetuses, respectively. These doses are 0.5 and 1.2 times higher than the maximum daily human dose. Administration at a dose of 9.3 mg/kg caused increased bone resorption. There are no other significant preclinical safety data to supplement the information obtained as a result of administration in patients.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Colistat does not contain any excipients.

6.2 Incompatibilities
This medicinal product shall not be used concomitantly with other medicinal products except those mentioned in section 6.6.

6.3 Expiry date (Shelf life)
2 years
Reconstituted/diluted solutions:

Colistimethate hydrolysis increases significantly upon reconstitution and dilution below its critical micelle concentration of approximately 80,000 IU per ml.
Solution for intravenous infusion shall be used immediately after preparation.
Freshly prepared solutions for intravenous bolus injection in the manufacturer's vials retain their physical and chemical stability for 24 hours when stored protected from light at a temperature of 2-8 °C (refrigerator).
From a microbiological point of view, the medicinal product shall be used immediately, otherwise the responsibility for the storage time and conditions during use lies with the consumer.
Diluted solutions for infusion with a concentration of <80,000 IU/ml shall be used immediately.

6.4 Special precautions for storage
Store at a temperature below 25 °C.
For storage conditions after reconstitution and dilution of the medicinal product, see subsection 6.3 of this section.

6.5 Nature and contents of container
3,000,000 IU or 4,500,000 IU in 10 ml vials. Vials are sealed with rubber stoppers and rolled with aluminum caps with a plastic lid labeled "FLIP OFF" or without labeling. 5 vials with a leaflet in a boxboard pack or 36 vials with a leaflet in a boxboard pack (for hospitals).

6.6 Special precautions for disposal of used medicinal product or waste obtained after use of the medicinal product and other medicinal product handling
The medicinal product does not contain preservatives, therefore, when preparing solutions, it is necessary to observe standard aseptic rules.
To prepare a solution for *intravenous bolus injection*, the contents of the Colistat vial are dissolved in 10 ml of water for injection or 0.9% sodium chloride solution. The solvent shall be injected into the vial slowly, gently shaking the vial until a clear solution is formed, avoiding the appearance of foam. The reconstituted solution is clear and colorless.
For *intravenous infusion*, the solution obtained after reconstituting the contents of the vial as for bolus injection can be diluted in 50-200 ml of 0.9% sodium chloride solution. The prepared solution is clear and colorless.
The unused remainder of the medicinal product solution is subject to disposal.
To avoid administering a dose less than required, the medicinal product shall be completely dissolved. The prepared solution shall be carefully removed from the vial!
Any unused amount of medicinal product solution shall be disposed of.
For the shelf life of prepared solutions, see subsection 6.3.
All remaining medicinal product and waste shall be destroyed in accordance with the established procedure.

6.7 Prescription status
On prescription.

7. MARKETING AUTHORISATION HOLDER
TriplePharm JLLC, Minskaya st., 2B, 223141, Logoysk, Minsk region, Republic of Belarus, tel./fax: (+375) 1774 43 181,
e-mail: triplepharm@gmail.com

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28.08.2014
Date of latest renewal: 25.09.2019

10. DATE OF REVISION OF THE TEXT

Summary of product characteristics of the medicinal product Colistat are available on the official website of the authorized state body on the Internet at http://www.rceth.by.