

<u>MA (EU) number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/19/1374/001	Esperoct	500 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 500 IU; Solvent: 4 ml (125 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/002	Esperoct	1000 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 1000 IU; Solvent 4 ml (250 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/003	Esperoct	1500 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 1500 IU; Solvent: 4 ml (375 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/004	Esperoct	2000 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 2000 IU; Solvent 4 ml (500 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/005	Esperoct	3000 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 3000 IU; Solvent: 4 ml (750 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/006	Esperoct	4000 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 4000 IU; Solvent: 4 ml (1000 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter
EU/1/19/1374/007	Esperoct	5000 IU	Powder and solvent for solution for injection	Intravenous use	Powder: vial (glass); Solvent: pre-filled syringe (glass)	Powder: 5000 IU; Solvent: 4 ml (1250 IU/ml)	1 vial + 1 pre-filled syringe + 1 plunger rod + 1 vial adapter