

<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/1/99/103/001	ReFacto AF	250 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass), solvent: pre-filled syringe	powder: 250 IU; solvent 4 ml (62.5 IU/ml)	1 vial + 1 pre-filled syringe + 1 vial adapter + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze
EU/1/99/103/002	ReFacto AF	500 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass), solvent: pre-filled syringe	powder: 500 IU; solvent 4 ml (125 IU/ml)	1 vial + 1 pre-filled syringe + 1 vial adapter + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze
EU/1/99/103/003	ReFacto AF	1000 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass), solvent: pre-filled syringe	powder: 1000 IU; solvent 4 ml (250 IU/ml)	1 vial + 1 pre-filled syringe + 1 vial adapter + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze
EU/1/99/103/004	ReFacto AF	2000 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass), solvent: pre-filled syringe	powder: 2000 IU; solvent 4 ml (500 IU/ml)	1 vial + 1 pre-filled syringe + 1 vial adapter + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze
EU/1/99/103/005	ReFacto AF	3000 IU	Powder and solvent for solution for injection in pre-filled syringe	Intravenous use	1 pre filled syringe	Powder 3000 IU; solvent 4 ml (750 IU/ml)	1 pre filled syringe + 1 plunger rod + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze + 1 vented sterile cap
EU/1/99/103/006	ReFacto AF	500 IU	Powder and solvent for solution for injection in pre-filled syringe	Intravenous use	1 pre filled syringe	powder: 500 IU; solvent 4 ml (125 IU/ml)	1 pre filled syringe + 1 plunger rod + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze + 1 vented sterile cap
EU/1/99/103/007	ReFacto AF	1000 IU	Powder and solvent for solution for injection in pre-filled syringe	Intravenous use	1 pre filled syringe	powder: 1000 IU; solvent 4 ml (250 IU/ml)	1 pre filled syringe + 1 plunger rod + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze + 1 vented sterile cap

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EU/1/99/103/008	ReFacto AF	2000 IU	Powder and solvent for solution for injection in pre-filled syringe	Intravenous use	1 pre filled syringe	powder: 2000 IU; solvent 4 ml (500 IU/ml)	1 pre filled syringe + 1 plunger rod + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze + 1 vented sterile cap
EU/1/99/103/009	ReFacto AF	250 IU	Powder and solvent for solution for injection in pre-filled syringe	Intravenous use	1 pre filled syringe	powder: 250 IU; solvent 4 ml (62.5 IU/ml)	1 pre filled syringe + 1 plunger rod + 1 sterile infusion set + 2 alcohol swabs + 1 plaster + 1 gauze + 1 vented sterile cap