

| MA (EU) number | (Invented) name | Strength | Pharmaceutical form | Route of administration | Immediate Packaging | Content (concentration) | Pack size |
|-----------------------|----------------------------|-----------------|--|------------------------------------|---|---|---|
| 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 |