

| <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/1/17/1247/001 | ADYNOVI | 250 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 250 IU; solvent: 2 ml (125 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/002 | ADYNOVI | 250 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 250 IU; solvent: 2 ml (125 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/003 | ADYNOVI | 250 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 250 IU; solvent: 5 ml (50 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/004 | ADYNOVI | 250 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 250 IU; solvent: 5 ml (50 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/005 | ADYNOVI | 500 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 500 IU; solvent: 2 ml (250 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/006 | ADYNOVI | 500 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 500 IU; solvent: 2 ml (250 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/007 | ADYNOVI | 500 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 500 IU; solvent: 5 ml (100 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/008 | ADYNOVI | 500 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 500 IU; solvent: 5 ml (100 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/009 | ADYNOVI | 1000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 1000 IU; solvent: 2 ml (500 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/010 | ADYNOVI | 1000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 1000 IU; solvent: 2 ml (500 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/011 | ADYNOVI | 1000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 1000 IU; solvent: 5 ml (200 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/012 | ADYNOVI | 1000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 1000 IU; solvent: 5 ml (200 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/013 | ADYNOVI | 2000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 2000 IU; solvent: 5 ml (400 IU/ml) | 1 vial + 1 vial + reconstitution device |

| <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/1/17/1247/014 | ADYNOVI | 2000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 2000 IU; solvent: 5 ml (400 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |
| EU/1/17/1247/015 | ADYNOVI | 3000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 3000 IU; solvent: 5 ml (600 IU/ml) | 1 vial + 1 vial + reconstitution device |
| EU/1/17/1247/016 | ADYNOVI | 3000 IU | Powder and solvent for solution for injection | Intravenous use | powder: vial (glass); solvent: vial (glass) | powder: 3000 IU; solvent: 5 ml (600 IU/ml) | 1 vial + 1 vial, preassembled with reconstitution device |