

| <b><u>MA (EU) number</u></b> | <b><u>(Invented) name</u></b> | <b><u>Strength</u></b> | <b><u>Pharmaceutical form</u></b>             | <b><u>Route of administration</u></b> | <b><u>Immediate Packaging</u></b>                            | <b><u>Content (concentration)</u></b> | <b><u>Pack size</u></b>   |
|------------------------------|-------------------------------|------------------------|---|---------------------------------------|--|---------------------------------------|---|
| EU/1/95/003/005              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 15 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                     |
| EU/1/95/003/006              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 5 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                      |
| EU/1/95/003/007              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 3 x 15 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                 |
| EU/1/95/003/008              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 12 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)<br>(Titration pack) |
| EU/1/95/003/009              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 14 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                     |
| EU/1/95/003/010              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 3 x 14 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                 |
| EU/1/95/003/011              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 12 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                     |
| EU/1/95/003/012              | Betaferon                     | 0.25 mg/ml             | Powder and solvent for solution for injection | Subcutaneous use                      | powder: vial (glass);<br>solvent: pre-filled syringe (glass) | powder:0.3 mg<br>solvent: 1.2 ml      | 2x 14 x (1 vial + 1 pre-filled syringe + 1 vial adapter with needle + 2 alcohol wipes)                  |