

| <b><u>MA (EU) number</u></b> | <b><u>(Invented)<br/>name</u></b> | <b><u>Strength</u></b>                                 | <b><u>Pharmaceutical<br/>form</u></b> | <b><u>Route of<br/>administration</u></b> | <b><u>Immediate<br/>Packaging</u></b> | <b><u>Pack size</u></b>                                                                                                       |
|------------------------------|-----------------------------------|--------------------------------------------------------|---------------------------------------|-------------------------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| EU/1/25/1956/001             | Austedo                           | 12 mg + 24 mg<br>+ 30 mg +<br>36 mg + 42 mg<br>+ 48 mg | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | Initiation pack: 42<br>tablets (7 x 12 mg + 7<br>x 24 mg + 7 x 30 mg<br>+ 7 x 36 mg + 7 x<br>42 mg + 7 x 48 mg)<br>28 tablets |
| EU/1/25/1956/002             | Austedo                           | 24 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 28 tablets                                                                                                                    |
| EU/1/25/1956/003             | Austedo                           | 24 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 84 tablets                                                                                                                    |
| EU/1/25/1956/004             | Austedo                           | 30 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 28 tablets                                                                                                                    |
| EU/1/25/1956/005             | Austedo                           | 30 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 84 tablets                                                                                                                    |
| EU/1/25/1956/006             | Austedo                           | 36 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 28 tablets                                                                                                                    |
| EU/1/25/1956/007             | Austedo                           | 36 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 84 tablets                                                                                                                    |
| EU/1/25/1956/008             | Austedo                           | 42 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 28 tablets                                                                                                                    |
| EU/1/25/1956/009             | Austedo                           | 42 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 84 tablets                                                                                                                    |
| EU/1/25/1956/010             | Austedo                           | 48 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 28 tablets                                                                                                                    |
| EU/1/25/1956/011             | Austedo                           | 48 mg                                                  | Prolonged-<br>release tablet          | Oral use                                  | blister<br>(PVC/PCTFE/PVC/alu)        | 84 tablets                                                                                                                    |