

| <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</u></b>                     | <b><u>Pack size</u></b>   |
|------------------------------|-----------------------------|------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|---|---|
| EU/1/17/1181/001             | Spherox                     | 10–70<br>spheroids/cm <sup>2</sup> | Implantation<br>suspension        | Intraarticular use                    | Applicator (PU)                   | 1 to 60 spheroids<br>in up to 200 µl      | 1 to 10 sterile<br>tubes with up to 2<br>applicators each<br>+ 1 syringe per<br>applicator  |
| EU/1/17/1181/002             | Spherox                     | 10–70<br>spheroids/cm <sup>2</sup> | Implantation<br>suspension        | Intraarticular use                    | Pre-filled syringe<br>(PP)        | 1 to 100<br>spheroids in up to<br>1000 µl | 1 to 10 sterile<br>tubes with 1 pre-<br>filled syringe each<br>+ 1 indwelling<br>cannula or 1 filter<br>stem per pre-<br>filled syringe |