



# Medi-MAA

(<sup>99m</sup>Tc-HSA macroaggregated human albumin)

TC-MR-18

|  |  |
|--|--|
| <b>Active substance</b>                                      | Each vial contains 2.5 mg macroaggregated human albumin (macrosalb).   |
| <b>Particle size</b>   | The number of macroaggregates per vial ranges between $3 \times 10^6$ and $8 \times 10^6$ . In the labelled product, the particle size distribution is as follows: more than 90% of the particles are between 10 and 100 micrometres.      |
| <b>Indications</b>   | After radiolabelling with sodium pertechnetate ( <sup>99m</sup> Tc) solution, the solution obtained is indicated for: <ul style="list-style-type: none"><li>→ Pulmonary perfusion scintigraphy</li><li>→ Radionuclide venography</li></ul> |
| <b>Excipients</b>  | Human serum albumin<br>Stannous chloride dihydrate (E512)<br>Sodium chloride   |
| <b>Dose for adults</b>                                       | Planar pulmonary perfusion scintigraphy: 40-150 MBq (1.08-4.05 mCi)<br>SPECT pulmonary perfusion scintigraphy: maximum 200 MBq (5.4 mCi)   |
| <b>Labelling activity</b>                                    | Maximum 6.85 GBq (185 mCi)   |
| <b>Labelling volume</b>                                      | 3-10 ml/vial   |
| <b>Storage conditions</b>                                    | Store the kit in a refrigerator (2°C - 8°C)  |
| <b>Shelf life</b>  | 18 months  |
| <b>Shelf-life and storage conditions after radiolabeling</b> | 9.5 hours<br>Store below 25°C.   |
| <b>Pack size</b>   | 6 vials  |
| <b>Authorized countries</b>                                  | The Netherlands, Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Luxemburg, Malta, Norway, Poland, Spain, Sweden  |
| <b>Marketing Authorization Holder</b>                        | Medi-Radiopharma Ltd.<br>2030 Érd, Szamos u. 10-12., Hungary   |