

## **Annex I**

### **List of medicinal products and presentations**

| <b>Member State<br/>EU/EEA</b> | <b>Applicant</b>   | <b>Invented Name</b> | <b>Strength</b> | <b>Pharmaceutical form</b> | <b>Route of<br/>administration</b> |
|--------------------------------|--|----------------------|-----------------|----------------------------|------------------------------------|
| Germany                        | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 0,25 mg         | nebuliser suspension       | Inhalation use                     |
| Germany                        | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 0,5 mg          | nebuliser suspension       | Inhalation use                     |
| Germany                        | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 1 mg            | nebuliser suspension       | Inhalation use                     |
| Italy                          | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 0,125 mg/ml     | nebuliser suspension       | Inhalation use                     |
| Italy                          | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 0,25 mg/ml      | nebuliser suspension       | Inhalation use                     |

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|--------------------------------|--|----------------------|---------------------|----------------------------|------------------------------------|
| Italy                          | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 0,5 mg/ml           | nebuliser suspension       | Inhalation use                     |
| The Netherlands                | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 250 microgram/2 ml  | nebuliser suspension       | Inhalation use                     |
| The Netherlands                | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 500 microgram /2 ml | nebuliser suspension       | Inhalation use                     |
| The Netherlands                | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide SUN       | 1000 microgram/2 ml | nebuliser suspension       | Inhalation use                     |
| Poland                         | Sun Pharmaceutical Industries<br>Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budezonid SUN        | 0,125 mg/ml         | nebuliser suspension       | Inhalation use                     |

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|----------------------------|---|----------------------|-----------------|----------------------------|--------------------------------|
| Poland                     | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budezonid SUN        | 0,25 mg/ml      | nebuliser suspension       | Inhalation use                 |
| Poland                     | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budezonid SUN        | 0,5 mg/ml       | nebuliser suspension       | Inhalation use                 |
| Spain                      | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesónida SUN       | 0,25 mg/ml      | nebuliser suspension       | Inhalation use                 |
| Spain                      | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesónida SUN       | 0,5 mg/ml       | nebuliser suspension       | Inhalation use                 |
| Sweden                     | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 0,125 mg/ml     | nebuliser suspension       | Inhalation use                 |

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|----------------------------|---|----------------------|-----------------|----------------------------|--------------------------------|
| Sweden                     | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 0,25 mg/ml      | nebuliser suspension       | Inhalation use                 |
| Sweden                     | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonid SUN        | 0,5 mg/ml       | nebuliser suspension       | Inhalation use                 |
| United Kingdom             | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide           | 0,125 mg/ml     | nebuliser suspension       | Inhalation use                 |
| United Kingdom             | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide           | 0,25 mg/ml      | nebuliser suspension       | Inhalation use                 |
| United Kingdom             | Sun Pharmaceutical Industries Europe B.V.<br>Polarisavenue 87<br>2132 JH Hoofddorp<br>The Netherlands | Budesonide           | 0,5 mg/ml       | nebuliser suspension       | Inhalation use                 |