

## **Dodatak I**

**Popis naziva, farmaceutskog oblika, jačina lijekova, puta primjene,  
podnositelja zahtjeva i nositelja odobrenja u državama članicama**

| <b>Država članica (EGP)</b> | <b>Podnositelj zahtjeva</b>                                                                 | <b>Nositelj odobrenja</b>                                                                                           | <b>INN</b>                    | <b>Naziv</b>                                           | <b>Jačina</b> | <b>Farmaceutski oblik</b> | <b>Put primjene</b> |
|-----------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------------------------|---------------|---------------------------|---------------------|
| Belgija                     |                                                                                             | Astellas Pharma BV,<br>Erasmus Park,<br>Square Marie Curie<br>50, Building 5, 1st floor<br>1070 Brussels<br>Belgium | Nicardipine hydrochloride     | Rydene                                                 | 1 mg/ml       | otopina za injekciju      | u venu              |
| Belgija                     | Magenta Pharma Consulting<br>Ericapark 38<br>2403 EG Alphen aan den Rijn<br>The Netherlands |                                                                                                                     | Nicardipine hydrochloride     | Nicardipine Aguetant                                   | 10 mg/10 ml   | otopina za injekciju      | u venu              |
| Francuska                   |                                                                                             | NOVARTIS PHARMA SAS<br>2-4, rue Lionel Terray<br>92500 Rueil-Malmaison<br>FRANCE                                    | nicardipine (chlorhydrate de) | LOXEN 10 mg/10 ml, solution injectable (I.V.)          | 10 mg/10 ml   | otopina za injekciju      | u venu              |
| Francuska                   |                                                                                             | LABORATOIRE AGUETTANT<br>1, rue Alexander Fleming<br>69007 Lyon<br>FRANCE                                           | nicardipine (chlorhydrate de) | NICARDIPINE AGUETTANT 10 mg/10 ml, solution injectable | 10 mg/10 ml   | otopina za injekciju      | u venu              |
| Francuska                   |                                                                                             | ARROW GENERIQUES<br>26, avenue Tony Garnier<br>69007 Lyon<br>FRANCE                                                 | nicardipine (chlorhydrate de) | NICARDIPINE ARROW 10 mg/10 ml, solution injectable     | 10 mg/10 ml   | otopina za injekciju      | u venu              |

| <b>Država članica (EGP)</b> | <b>Podnositelj zahtjeva</b>                                                                                                           | <b>Nositelj odobrenja</b>                                                                                      | <b>INN</b>                   | <b>Naziv</b>                                          | <b>Jačina</b>  | <b>Farmaceutski oblik</b>            | <b>Put primjene</b> |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------------|-------------------------------------------------------|----------------|--------------------------------------|---------------------|
| Luksemburg                  |                                                                                                                                       | ASTELLAS PHARMA<br>Square Marie Curie<br>50 1<br>Building 5<br>1070 Brussels<br>Belgium                        | Nicardipine                  | Rydene                                                | 1 mg/ml (5 ml) | otopina za injekciju                 | u venu              |
| Španjolska                  |                                                                                                                                       | ASTELLAS PHARMA,<br>S.A.<br>Paseo del Club<br>Deportivo,1<br>bloque 14<br>28223 Pozuelo de<br>Alarcón (Madrid) | Nicardipine<br>hydrochloride | VASONASE<br>1 mg/ml solución<br>para perfusión        | 1 mg/ml        | otopina za infuziju                  | u venu              |
| Nizozemska                  |                                                                                                                                       | Astellas Pharma B.V.<br>Sylviusweg 62<br>2333 BE Leiden<br>The Netherlands                                     | nicardipine                  | Cardene IV                                            | 5 mg/5 ml      | koncentrat za<br>otopinu za infuziju | u venu              |
| Ujedinjeno Kraljevstvo      | Mercury<br>Pharmaceuticals<br>Limited<br>No. 1 Croydon,<br>12-16<br>Addiscombe<br>Road, Croydon,<br>Surrey CR0 0XT,<br>United Kingdom |                                                                                                                | Nicardipine<br>hydrochloride | Nicardipine<br>10mg/10ml<br>solution for<br>injection | 1 mg/1 ml      | otopina za injekciju                 | u venu              |