



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2024  
EMA/16501/2024  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): irinotecan (except for liposomal formulations)

Procedure No. PSUSA/00001783/202305



| <b>Product Name (in authorisation country)</b>                                        | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|---------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/001                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/002                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/003                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/004                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/005                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/006                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/007                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/008                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/009                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |

| <b>Product Name (in authorisation country)</b>                                        | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|---------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/010                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/011                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/012                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/013                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/014                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/015                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |
| Irinotekanijev klorid<br>Mylan 20 mg/ml<br>koncentrat za raztopino<br>za infundiranje | FR/H/0334/001                       | H/09/00804/016                       | MYLAN PHARMACEUTICALS<br>LIMITED          | SI                                              |