

## **Bilag I**

*Fortegnelse over lægemidlernes navne, lægemiddelform(er), styrke(r), indgivelsesvej(e), ansøger(e), indehaver(e) af markedsføringstilladelse(r) i medlemsstaterne*

| Medlemsstat EU/EAA | Ansøger  | Navn  | Styrke | Lægemiddelform     | Indgivelsesvej      |
|--------------------|--|---|--------|--------------------|---------------------|
| Frankrig           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | DIDANOSINE AUROBINDO 200mg,<br>gélule gastro-résistante       | 200mg  | Enterokapsel, hård | Oral<br>anvendelse. |
| Frankrig           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | DIDANOSINE AUROBINDO 250mg,<br>gélule gastro-résistante       | 250mg  | Enterokapsel       | Oral<br>anvendelse. |
| Frankrig           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | DIDANOSINE AUROBINDO 400mg,<br>gélule gastro-résistante       | 400mg  | Enterokapsel       | Oral<br>anvendelse. |
| Tyskland           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosin Aurobindo 200mg<br>magensaftresistente Hartkapseln  | 200mg  | Enterokapsel       | Oral<br>anvendelse. |
| Tyskland           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosin Aurobindo 250mg<br>magensaftresistente Hartkapseln  | 250mg  | Enterokapsel       | Oral<br>anvendelse. |
| Tyskland           | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosin Aurobindo 400mg<br>magensaftresistente Hartkapseln  | 400mg  | Enterokapsel       | Oral<br>anvendelse. |
| Italien            | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosina Aurobindo 200mg capsule<br>rigide gastroresistenti | 200mg  | Enterokapsel       | Oral<br>anvendelse. |

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|----------|--|---|-------|--------------|---------------------|
| Italien  | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosina Aurobindo 250mg capsule<br>rigide gastroresistenti     | 250mg | Enterokapsel | Oral<br>anvendelse. |
| Italien  | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosina Aurobindo 400mg capsule<br>rigide gastroresistenti     | 400mg | Enterokapsel | Oral<br>anvendelse. |
| Holland  | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine Aurobindo 250mg<br>maagsapersistentente capsules, hard | 250mg | Enterokapsel | Oral<br>anvendelse. |
| Holland  | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine Aurobindo 400mg<br>maagsapersistentente capsules, hard | 400mg | Enterokapsel | Oral<br>anvendelse. |
| Portugal | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosina Aurobindo  | 250mg | Enterokapsel | Oral<br>anvendelse. |
| Portugal | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosina Aurobindo  | 400mg | Enterokapsel | Oral<br>anvendelse. |
| Rumænien | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine Aurobindo 250mg capsule<br>gastrorezistente            | 250mg | Enterokapsel | Oral<br>anvendelse. |

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|----------------|--|---|-------|--------------------|---------------------|
| Rumænien       | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine Aurobindo 400mg capsule<br>gastrorezistente          | 400mg | Enterokapsel       | Oral<br>anvendelse. |
| Spanien        | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | DIDANOSINA AUROBINDO 250mg<br>cápsulas duras gastrorresistentes | 250mg | Enterokapsel, hård | Oral<br>anvendelse. |
| Spanien        | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | DIDANOSINA AUROBINDO 400mg<br>cápsulas duras gastrorresistentes | 400mg | Enterokapsel       | Oral<br>anvendelse. |
| Storbritannien | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine 200mg gastro-resistant<br>capsules, hard             | 200mg | Enterokapsel       | Oral<br>anvendelse. |
| Storbritannien | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine 250mg gastro-resistant<br>capsules, hard             | 250mg | Enterokapsel       | Oral<br>anvendelse. |
| Storbritannien | Aurobindo Pharma (Malta) Limited<br>Vault 14, Level 2, Valletta Waterfront<br>Floriana FRN 1913<br>Malta | Didanosine 400mg gastro-resistant<br>capsules, hard             | 400mg | Enterokapsel       | Oral<br>anvendelse. |