

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2013 to 30 November 2013

(decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive 2001/82/EC ⁽²⁾)

(2013/C 380/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
20.11.2013	Didanosine Art 29	See Annex I	See Annex I	22.11.2013

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S), ROUTE(S) OF ADMINISTRATION, APPLICANT(S) IN THE MEMBER STATES

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
France	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	DIDANOSINE AUROBINDO 200 mg, gélule gastro-résistante	200 mg	Gastro-resistant capsule, hard	Oral use
France	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	DIDANOSINE AUROBINDO 250 mg, gélule gastro-résistante	250 mg	Gastro-resistant capsule, hard	Oral use
France	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	DIDANOSINE AUROBINDO 400 mg, gélule gastro-résistante	400 mg	Gastro-resistant capsule, hard	Oral use
Germany	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosin Aurobindo 200 mg magensaftresistente Hartkapseln	200 mg	Gastro-resistant capsule, hard	Oral use
Germany	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosin Aurobindo 250 mg magensaftresistente Hartkapseln	250 mg	Gastro-resistant capsule, hard	Oral use
Germany	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosin Aurobindo 400 mg magensaftresistente Hartkapseln	400 mg	Gastro-resistant capsule, hard	Oral use
Italy	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosina Aurobindo 200 mg capsule rigide gastroresistenti	200 mg	Gastro-resistant capsule, hard	Oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosina Aurobindo 250 mg capsule rigide gastroresistenti	250 mg	Gastro-resistant capsule, hard	Oral use
Italy	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosina Aurobindo 400 mg capsule rigide gastroresistenti	400 mg	Gastro-resistant capsule, hard	Oral use
Netherlands	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosine Aurobindo 250 mg maagsapersistentente capsules, hard	250 mg	Gastro-resistant capsule, hard	Oral use
Netherlands	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosine Aurobindo 400 mg maagsapersistentente capsules, hard	400 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosina Aurobindo	250 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosina Aurobindo	400 mg	Gastro-resistant capsule, hard	Oral use
Romania	Aurobindo Pharma (Malta) Limited Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913 Malta	Didanosine Aurobindo 250 mg capsule gastrorezistente	250 mg	Gastro-resistant capsule, hard	Oral use
Romania	Aurobindo Pharma (Malta) Limited Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913 Malta	Didanosine Aurobindo 400 mg capsule gastrorezistente	400 mg	Gastro-resistant capsule, hard	Oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Spain	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	DIDANOSINA AUROBINDO 250 mg cápsulas duras gastrorresistentes	250 mg	Gastro-resistant capsule, hard	Oral use
Spain	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	DIDANOSINA AUROBINDO 400 mg cápsulas duras gastrorresistentes	400 mg	Gastro-resistant capsule, hard	Oral use
United Kingdom	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosine 200 mg gastro-resistant capsules, hard	200 mg	Gastro-resistant capsule, hard	Oral use
United Kingdom	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosine 250 mg gastro-resistant capsules, hard	250 mg	Gastro-resistant capsule, hard	Oral use
United Kingdom	Aurobindo Pharma (Malta) Limited, Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913, Malta	Didanosine 400 mg gastro-resistant capsules, hard	400 mg	Gastro-resistant capsule, hard	Oral use