EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 December 2011
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Press Office

Medicines granted a Community marketing authorisation under the centralised procedure

Since the CHMP meeting 14-17 November 2011

Invented name	Desloratadine Teva
INN	desloratadine
Marketing Authorisation Holder	Teva Pharma B.V.
Proposed ATC code	R06A X27
Indication	Relief of symptoms associated with: - allergic - urticaria
CHMP opinion date	22/09/2011
Marketing authorisation date	24/11/2011

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Invented name	Komboglyze
INN	saxagliptin and metformin hydrochloride
Marketing Authorisation Holder	Bristol-Myers Squibb/AstraZeneca EEIG
Proposed ATC code	A10BD10
Indication	As an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets.
CHMP opinion date	22/09/2011
Marketing authorisation date	24/11/2011

Invented name	Onduarp
INN	telmisartan and amlodipine
Marketing Authorisation Holder	Boehringer Ingelheim International GmbH
Proposed ATC code	C09DB04
Indication	Treatment of essential hypertension in adults
CHMP opinion date	22/09/2011
Marketing authorisation date	24/11/2011

Invented name	Dasselta
INN	desloratadine
Marketing Authorisation Holder	KRKA, d.d., Novo mesto
Proposed ATC code	R06AX27
Indication	Relief of symptoms associated with: - allergic - urticaria
CHMP opinion date	22/09/2011
Marketing authorisation date	28/11/2011

Invented name	Edurant
INN	rilpivirine
Marketing Authorisation Holder	Janssen-Cilag International NV
Proposed ATC code	J05AG05
Indication	In combination with other antiretroviral medicinal products, indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml
CHMP opinion date	22/09/2011
Marketing authorisation date	28/11/2011

Invented name	Eviplera
INN	emtricitabine / rilpivirine / tenofovir disoproxil
Marketing Authorisation Holder	Gilead Sciences International Limited
Proposed ATC code	J05AR08
Indication	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml
CHMP opinion date	22/09/2011
Marketing authorisation date	28/11/2011

Invented name	Dificlir
INN	fidaxomicin
Marketing Authorisation Holder	FGK Representative Service GmbH.
Proposed ATC code	not yet assigned
Indication	Treatment of *Clostridium difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD) in adults
CHMP opinion date	22/09/2011
Marketing authorisation date	05/12/2011

Invented name	Levetiracetam Actavis Group
INN	levetiracetam
Marketing Authorisation Holder	Actavis Group PTC ehf.
Proposed ATC code	N03AX14
Indication	As monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. As adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults, children and infants from 1 month of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.
CHMP opinion date	22/09/2011
Marketing authorisation date	05/12/2011

Invented name	Edarbi
INN	azilsartan medoxomil
Marketing Authorisation Holder	Takeda Global Research and Development Centre (Europe) Ltd
Proposed ATC code	C09CA09
Indication	Treatment of essential hypertension in adults
CHMP opinion date	22/09/2011
Marketing authorisation date	07/12/2011

Invented name	Ipreziv
INN	azilsartan medoxomil
Marketing Authorisation Holder	Takeda Global Research and Development Centre (Europe) Ltd
Proposed ATC code	C09CA09
Indication	Treatment of essential hypertension in adults
CHMP opinion date	22/09/2011
Marketing authorisation date	07/12/2011