



27 September 2011  
EMA/788369/2011  
Press Office

## Medicines granted a Community marketing authorisation under the centralised procedure

Since the CHMP meeting 18-21 July 2011

Invented name	Ibandronic acid Sandoz
INN	ibandronic acid
Marketing Authorisation Holder	Sandoz Pharmaceuticals GmbH
Proposed ATC code	M05B A 06
Indication	Prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases
CHMP opinion date	17/02/2011
Marketing authorisation date	26/07/2011

Invented name	Zoely
INN	nomegestrol acetate and estradiol
Marketing Authorisation Holder	Merck Serono Europe Limited
Proposed ATC code	G03AA14
Indication	Oral contraception
CHMP opinion date	22/03/2011
Marketing authorisation date	27/07/2011

Invented name	Entacapone Orion
INN	entacapone
Marketing Authorisation Holder	Orion Corporation
Proposed ATC code	N04BX02
Indication	As an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in adult patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on those combinations.



Invented name	Entacapone Orion
CHMP opinion date	23/06/2011
Marketing authorisation date	18/08/2011

Invented name	Levetiracetam Teva
INN	levetiracetam
Marketing Authorisation Holder	Teva Pharma B.V.
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.
CHMP opinion date	19/05/2011
Marketing authorisation date	19/08/2011

Invented name	Levodopa/Carbidopa/Entacapone Orion
INN	levodopa, carbidopa and entacapone
Marketing Authorisation Holder	Orion Corporation
Proposed ATC code	N04BA03
Indication	Treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase (DDC) inhibitor treatment.
CHMP opinion date	23/06/2011
Marketing authorisation date	24/08/2011

Invented name	Trajenta
INN	linagliptin
Marketing Authorisation Holder	Boehringer Ingelheim International GmbH
Proposed ATC code	A10BH05
Indication	<p>Treatment of type 2 diabetes mellitus to improve glycaemic control in adults:</p> <p>as monotherapy</p> <ul style="list-style-type: none"> <li>in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.</li> </ul> <p>as combination therapy</p> <ul style="list-style-type: none"> <li>in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.</li> <li>in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate</li> </ul>

Invented name	Trajenta
	glycaemic control.
CHMP opinion date	23/06/2011
Marketing authorisation date	24/08/2011

Invented name	Levetiracetam ratiopharm
INN	levetiracetam
Marketing Authorisation Holder	ratiopharm GmbH
Proposed ATC code	N03AX14
Indication	<p>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.</p> <p>As adjunctive therapy:</p> <ul style="list-style-type: none"> <li>• in the treatment of partial onset seizures with or without secondary generalisation in adults, children and infants from 1 month of age with epilepsy.</li> <li>• in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.</li> <li>• in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.</li> </ul>
CHMP opinion date	19/05/2011
Marketing authorisation date	26/08/2011

Invented name	VIBATIV
INN	telavancin
Marketing Authorisation Holder	Astellas Pharma Europe B.V.
Proposed ATC code	J01XA03
Indication	Treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).
CHMP opinion date	19/05/2011
Marketing authorisation date	02/09/2011

Invented name	Votubia
INN	everolimus
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	L01XE10
Indication	Treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA)

Invented name	Votubia
	associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.
CHMP opinion date	23/06/2011
Marketing authorisation date	02/09/2011

Invented name	ZYTIGA
INN	abiraterone acetate
Marketing Authorisation Holder	Janssen-Cilag International NV
Proposed ATC code	L02BX03
Indication	With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.
CHMP opinion date	21/07/2011
Marketing authorisation date	05/09/2011

Invented name	Dexdor
INN	dexmedetomidine
Marketing Authorisation Holder	Orion Corporation
Proposed ATC code	N05CM18
Indication	For sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).
CHMP opinion date	21/07/2011
Marketing authorisation date	16/09/2011

Invented name	INCIVO
INN	telaprevir
Marketing Authorisation Holder	Janssen Cilag International NV
Proposed ATC code	Not yet assigned
Indication	In combination with peginterferon alfa and ribavirin, indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis): <ul style="list-style-type: none"> <li>• who are treatment-naïve;</li> <li>• who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.</li> </ul>
CHMP opinion date	21/07/2011
Marketing authorisation date	19/09/2011

