



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 October 2011
EMA/852421/2011
Press Office

Medicines granted a Community marketing authorisation under the centralised procedure

Since the CHMP meeting 19-22 September 2011

Invented name	Pramipexole Accord
INN	pramipexole
Marketing Authorisation Holder	Accord Healthcare Limited
Proposed ATC code	N04BC05
Indication	<p>Indicated in adults for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations).</p> <p>Indicated in adults for symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in doses up to 0.54 mg of base</p>
CHMP opinion date	21/07/2011
Marketing authorisation date	30/09/2010

Invented name	Levetiracetam Accord
INN	levetiracetam
Marketing Authorisation Holder	Accord Healthcare Limited
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">in the treatment of partial onset seizures with or without secondary generalisation in adults, children and infants from 1 month of age with epilepsy.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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Invented name	Levetiracetam Accord
	<ul style="list-style-type: none"> 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	21/07/2011
Marketing authorisation date	03/10/2011

Invented name	Levetiracetam Actavis
INN	levetiracetam
Marketing Authorisation Holder	Actavis Group PTC ehf.
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"> 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	21/07/2011
Marketing authorisation date	03/10/2011

Invented name	Matever
INN	levetiracetam
Marketing Authorisation Holder	Pharmathen S.A.
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"> 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.

Invented name	Matever
	<ul style="list-style-type: none"> 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	21/07/2011
Marketing authorisation date	03/10/2011

Invented name	Telmisartan Teva Pharma
INN	telmisartan
Marketing Authorisation Holder	Teva Pharma B.V.
Proposed ATC code	C09CA07
Indication	Treatment of essential hypertension in adults
CHMP opinion date	21/07/2011
Marketing authorisation date	03/10/2011