



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 November 2011  
EMA/914235/2011  
Press Office

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

Since the CHMP meeting 17-19 October 2011

Invented name	IoA
INN	nomegestrol acetate and estradiol (as hemihydrate)
Marketing Authorisation Holder	N.V. Organon
Proposed ATC code	G03AA14
Indication	Oral contraception
CHMP opinion date	22/03/2011
Marketing authorisation date	16/11/2010

Invented name	Plenadren
INN	hydrocortisone
Marketing Authorisation Holder	DuoCort Pharma AB
Proposed ATC code	H02AB09
Indication	Treatment of adrenal insufficiency in adults
CHMP opinion date	21/07/2011
Marketing authorisation date	03/11/2011



Invented name	Vyndaqel
INN	tafamidis
Marketing Authorisation Holder	Pfizer Specialty UK Limited
Proposed ATC code	N07XX08
Indication	treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment
CHMP opinion date	21/07/2011
Marketing authorisation date	16/11/2011