



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/461586/2016  
Procedure Management and Committees Support Division

## Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for Paracetamol modified release containing medicinal products Alvedon and associated names

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1445



Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Glaxosmithkline Consumer Healthcare S.A/N.V.	Panadol Retard 8 Heures	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Belgium	Glaxosmithkline Consumer Healthcare S.A/N.V.	Panadol Retard 8 Stunden	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Belgium	Glaxosmithkline Consumer Healthcare S.A/N.V.	Panadol Retard 8 Ur	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Bulgaria	Krka, D.D., Novo Mesto	дорета Sr	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Czech Republic	Krka, D.D., Novo Mesto	Doreta Prolong	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Denmark	Actavis Group Hf.	Pinex Retard	Paracetamol	Paracetamol 500mg Tablet	Prolonged-Release Tablet	Oral Use
Denmark	Glaxosmithkline Consumer Healthcare A/S	Panodil	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Denmark	Glaxosmithkline Consumer Healthcare A/S	Panodil Retard	Paracetamol	Paracetamol 500mg Tablet	Prolonged-Release Tablet	Oral Use
Estonia	Krka, D.D., Novo Mesto	Doreta	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Glaxosmithkline Consumer Healthcare A/S	Panadol Extend	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Greece	Glaxosmithkline Consumer Healthcare Hellas Sa	Panadol Extend	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Hungary	Krka, D.D., Novo Mesto	Doreta Sr	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Iceland	Actavis Hf.	Paratabs Retard	Paracetamol	Paracetamol 500mg Tablet	Prolonged-Release Tablet	Oral Use
Iceland	Gebro Pharma Gmbh	Diliban Retard	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Iceland	Glaxosmithkline Consumer Healthcare A/S	Panodil Extend	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Latvia	Krka, D.D., Novo Mesto	Doreta	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Lithuania	Krka, D.D., Novo Mesto	Doreta	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Luxembourg	Glaxosmithkline Consumer Healthcare S.A/N.V.	Panadol Retard 8 Heures	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use

<b>Member State in EEA</b>	<b>Marketing authorisation holder</b>	<b>Product name</b>	<b>INN</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Luxembourg	Glaxosmithkline Consumer Healthcare S.A/N.V.	Panadol Retard 8 Stunden	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Netherlands	Glaxosmithkline Consumer Healthcare B.V	Panadol Extend	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use
Poland	Krka, D.D., Novo Mesto	Doreta	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Portugal	Glaxosmithkline Consumer Healthcare, Produtos Para A Saúde E Higiene, Lda	Panadol Prolong	Paracetamol	Paracetamol 665mg Tablet	Prolonged-Release Tablet	Oral Use
Portugal	Jaba Recordati, S.A.	Diliban Retard	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Portugal	Krka, D.D., Novo Mesto	Tramadol + Paracetamol Krka	Paracetamol, Tramadol	Paracetamol 650mg Tablet, Tramadol 75mg Tablet	Prolonged-Release Tablet	Oral Use
Portugal	Krka, D.D., Novo Mesto	Tramadol + Paracetamol Krka	Paracetamol, Tramadol	Paracetamol 650mg Tablet, Tramadol 75mg% Tablet	Prolonged-Release Tablet	Oral Use
Portugal	Krka, D.D., Novo Mesto	Tramadol + Paracetamol Krka	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	Glaxosmithkline Consumer Healthcare, Glaxosmithkline Export Ltd	Panadol Artro	Paracetamol	Paracetamol 665mg Tablet	Prolonged-Release Tablet	Oral Use
Romania	Krka, D.D., Novo Mesto	Doreta Ep	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Slovakia	Krka, D.D., Novo Mesto	Doreta Sr	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Slovenia	Krka, D.D., Novo Mesto	Doreta Sr	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Spain	Laboratorios Gebro Pharma, S.A.	Diliban Retard	Tramadol Hydrochloride, Paracetamol	Tramadol Hydrochloride 75mg Tablet, Paracetamol 650mg Tablet	Prolonged-Release Tablet	Oral Use
Sweden	Glaxosmithkline Consumer Healthcare A/S	Alvedon	Paracetamol	Paracetamol 665mg Tablet	Modified-Release Tablet	Oral Use