



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines 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 hydroxyprogesterone-containing medicinal products

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1528

Please note that this draft Annex I may be updated during the procedure to reflect any amended information on concerned products/MAHs.

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Member State in EU/EEA	Marketing authorisation holder	Product name	INN/ active substance + strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH	Proluton Depot	Hydroxyprogesterone caproate 250 mg/ml	Solution for injection	Intramuscular use
France	Bayer Healthcare	Progesterone Retard Pharon Bayer Healthcare	Hydroxyprogesterone caproate 500 mg/2 ml	Solution for injection	Intramuscular use
Italy	Ibsa Farmaceutici Italia	Lentogest	Hydroxyprogesterone caproate 341 mg/2 ml	Solution for injection	Intramuscular use

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