

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 December 2018 to 31 December 2018**

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC⁽¹⁾ or Article 38 of Directive 2001/82/EC⁽²⁾)

(2019/C 32/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
18.12.2018	Perlinring and associated names -	etonogestrel/ ethinylestradiol	See annex	See annex	19.12.2018

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

ANNEX

List of medicinal products and presentations

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg pro 24 Stunden — Vaginalring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Belgium	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg par 24 heures, système de diffusion vaginal / Perlinring 0,120 mg/0,015 mg per 24 uur; hulpmiddel voor vaginaal gebruik	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Croatia	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg tijekom 24 sata, sustav za isporuku u rodnici	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Czech Republic	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Denmark	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Estonia	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use

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Finland	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg per 24 h depotlää- kevalmiste, emättimeen	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
France	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 15 microgrammes/120 mi- crogrammes/24 heures, système de dif- fusion vaginal	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Germany	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Hungary	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg/24 óra hüvelyben alkalmazott gyógyszerleadó rendszer	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Iceland	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Ireland	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Italy	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Latvia	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 120/15 mikrogramu 24 stundās vaginālās ievadišanas sistēma	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Lithuania	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Ongavia 120/15 mikrogramų/24 valan- das vartojimo į makšį sistema	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
The Nether- lands	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg per 24 uur; hulpmiddel voor vaginaal gebruik	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Norway	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Poland	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Portugal	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Romania	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,120 mg/0,015 mg/24 ore sistem cu cedare vaginală	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Slovak Republic	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use

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Slovenia	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Etonogestrel/etinilestradiol Actavis 0,120 mg/0,015 mg na 24 ur vaginalni dostavni sistem	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Spain	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Pirlinring 0,120 mg/0,015 mg for cada 24 horas, sistema de liberación vaginal	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
Sweden	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use
United Kingdom	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður, Iceland	Perlinring 0,015 mg/0,12 mg/ 24 hours Vaginal Delivery System	0,120 mg/0,015 mg per 24 hours	Vaginal Delivery System	Vaginal use