

**Viðauki I: Listi yfir markaðsleyfishafa, umboðsaðila á Íslandi, virkt innihaldsefni, sérheiti, styrkleika og lyfjaform**

| <b>Markaðsleyfishafi</b>  | <b>Umboðsaðili á Íslandi</b>                                | <b>INN</b>   | <b>Sérheiti</b> | <b>Styrkleiki</b>     | <b>Lyfjaform</b> |
|---|---|--|-----------------|-----------------------|------------------|
| Bayer Pharma AG<br>Müllerstraße 178<br>D-13353 Berlin<br>Germany              | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>betadex-clatrat<br>Drospirenon | Yasminelle      | 0,02mg 3 mg           | Filmuhúðuð tafla |
| Bayer Pharma AG<br>Müllerstraße 178<br>D-13353 Berlin<br>Germany              | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>betadex-clatrat<br>Drospirenon | YAZ             | 0,02mg 3 mg           | Filmuhúðuð tafla |
| N.V. Organon<br>Kloosterstraat 6<br>5349 AB, Oss<br>The Netherlands           | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | Ethinylestradiol<br>Deogestrel                     | Gracial         | 0.030mg 0.123<br>mg   | Tafla            |
| N.V. Organon Kloosterstraat 6<br>5349 AB, Oss<br>The Netherlands              | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | Ethinylestradiol<br>Deogestrel                     | Marvelon        | 0.030mg 0.150<br>mg   | Tafla            |
| N.V. Organon<br>Kloosterstraat 6<br>5349 AB, Oss<br>The Netherlands           | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | Ethinylestradiol<br>Deogestrel                     | Mercilon        | 0.020mg + 0.150<br>mg | Tafla            |
| Bayer AB<br>Postbox 606 Gustav III's Boulevard 56<br>SE-16926 Solna<br>Sweden | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>Drospirenon                    | Eloine          | 0,02mg 3 mg           | Filmuhúðuð tafla |
| Bayer AB<br>Postbox 606 Gustav III's Boulevard 56<br>SE-16926 Solna<br>Sweden | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>Drospirenon                    | Palandra        | 0,03mg 3 mg           | Filmuhúðuð tafla |
| Bayer Pharma AG<br>Müllerstraße 178<br>D-13353 Berlin<br>Germany              | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>Drospirenon                    | Yasmin          | 0,03mg 3 mg           | Filmuhúðuð tafla |
| Bayer Pharma AG<br>Müllerstraße 178<br>D-13353 Berlin<br>Germany              | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>Drospirenon                    | Yasmin 28       | 0,03mg 3 mg           | Filmuhúðuð tafla |
| Pfizer ApS,<br>Lautrupvang 8,<br>DK-2750 Ballerup,<br>Denmark                 | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Ethinylestradiol<br>gestoden                       | Harmonet        | 0.020mg + 0.075<br>mg | Tafla            |

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| <b>Markaðsleyfishafi</b>  | <b>Umboðsaðili á Íslandi</b>                                | <b>INN</b>  | <b>Sérheiti</b> | <b>Styrkleiki</b>                        | <b>Lyfjaform</b> |
|---|---|---|-----------------|--|------------------|
| Actavis Group PTC ehf<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                |   | Desogestrel/<br>ethinylestradiol                    | Benidette       | 0,15 mg 0,02 mg                          | Tafla            |
| Actavis Group PTC ehf<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                |   | Desogestrel/<br>ethinylestradiol                    | Benifema        | 0,15 m 0,03 mg                           | Tafla            |
| Bayer AB<br>Postbox 606 Gustav III's Boulevard 56<br>SE-16926 Solna<br>Sweden                 | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Dropsirenone/<br>ethinylestradiol                   | Flexyess        | 3mg 0,02 mg                              | Filmuhúðuð tafla |
| N.V. Organon<br>Kloosterstraat 6<br>5349 AB, Oss<br>The Netherlands                           | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | etonogestrelum<br>Ethinylestradiolu<br>m            | NuvaRing        | 11,7 mg 2,7 mg                           | Skeiðarinnlegg   |
| Bayer AB<br>Postbox 606 Gustav III's Boulevard 56<br>SE-16926 Solna<br>Sweden                 | Icepharma<br>Lynghálsi 13<br>110 Reykjavík<br>Sími 540 8000 | Dienogestum<br>Ethinylestradiolu<br>m               | Qlaira          | 0/3mg - 2mg/2<br>mg - 3mg/2mg -<br>0/1mg | Filmuhúðuð tafla |
| Janssen-Cilag International NV,<br>Turnhoutseweg, 30,<br>B-2340 Beerse,<br>Belgía             | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | Norelgestromin/<br>etinylestradiol                  | Evra            | 6 mg,600 µg                              | Forðaplástur     |
| Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon<br>Hertfordshire EN11 9BU<br>Bretland | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | nomegestrol<br>acetat/ estradiol<br>(as hemihydrat) | Zoely           | 1.5 mg,2.5 mg                            | Filmuhúðuð tafla |
| Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon<br>Hertfordshire EN11 9BU<br>Bretland | Vistor hf.<br>Hörgatúni 2,<br>210 Garðabæ<br>Sími 535 7000  | nomegestrol<br>acetat/ estradiol<br>(as hemihydrat) | Ioa             | 1.5 mg,2.5 mg                            | Filmuhúðuð tafla |
| ratiopharm GmbH<br>Graf-Arco-Str. 3<br>89079 Ulm<br>Germany                                   | LYFIS<br>Grensásvegi 22<br>108 Reykjavík<br>Sími 534 3500   | Desogestrel/<br>ethinylestradiol                    | Denise          | 0,15 mg 0,02 mg                          | Tafla            |