



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2016
EMA/346191/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ethinylestradiol / gestodene (transdermal application)

Procedure no.: PSUSA/00010145/201508



| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|-------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| apleek 60 mikrog/24 tuntia + 13 mikrog/24 tuntia depotlaastari | FR/H/0547/001 | 31074 | BAYER OY | FI |
| apleek 60 mikrog/24 timmar + 13 mikrog/24 timmar depotplåster | FR/H/0547/001 | 31074 | BAYER OY | FI |
| EILEEN 60 mikrogrammi/13 mikrogrammi/24 tunnis transdermaalne plaaster | FR/H/0547/001 | 839514 | BAYER PHARMA AG | EE |
| apleek 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch | FR/H/0547/001/DC | PL 04854/0145 | GEDEON RICHTER PLC | UK |
| Apleek | FR/H/0547/001/DC | 51611 | BAYER AB | DK |
| apleek 60 microgram/24 uur + 13 microgram/24 uur pleister voor transdermaal gebruik | FR/H/0547/001 | RVG 112679 | BAYER BV | NL |
| apleek 60 mÍkrógrömm/24 klst. + 13 mÍkrógrömm /24 klst. forðaplástur | FR/H/0547/001/DC | IS/1/14/023/01 | BAYER AB | IS |
| Eileen 60 mikrogramų/ 13 mikrogramų/ 24 val. transderminis pleistras | FR/H/0547/001/DC | LT/1/14/3535/001 | BAYER PHARMA AG | LT |
| apleek 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch | FR/H/0547/001/DC | PA1410/69/1 | BAYER LTD | IE |
| Eileen 60 mikrogramų/ 13 mikrogramų/ 24 val. transderminis pleistras | FR/H/0547/001/DC | LT/1/14/3535/002 | BAYER PHARMA AG | LT |

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| Eileen 60 mikrogramų/ 13 mikrogramų/ 24 val. transderminis pleistras | FR/H/0547/001/DC | LT/1/14/3535/003 | BAYER PHARMA AG | LT |
| apleek 60 Mikrogramm/24 Stunden + 13 Mikrogramm/24 Stunden Transdermales Pflaster | FR/H/0547/001/DC | 1-35535 | BAYER AUSTRIA GMBH | AT |
| Eileen 60 mikrogrami/13 mikrogrami/24 stundās transdermāls plāksteris | FR/H/0547/001 | 14-0115 | Gedeon Richter Plc. | LV |
| apleek 60 mikrogramov/24 hodín + 13 mikrogramov/24 hodín transdermálna náplast' | FR/H/0547/001 | 17/0143/14-S | BAYER SPOL SRO | SK |
| apleek® 60 Mikrogramm/24 Stunden + 13 Mikrogramm/24 Stunden transdermales Pflaster | FR/H/0547/001/DC | 88394.00.00 | JENAPHARM GMBH & CO KG | DE |
| apleek 0,06 mg/0,013 mg cada 24 horas parche transdémico | FR/H/0547/001 | 79.138 | BAYER HISPANIA SL | ES |
| аплийк 60 микрограма/24 часа + 13 микрограма/24 часа трансдермален пластир | FR/H/0547/001 | 20140147 | BAYER PHARMA AG | BG |
| apleek 60 micrograme/24 ore + 13 micrograme/24 ore plature transdermic | FR/H/0547/001/DC | 6542/2014/01-02-03 | BAYER PHARMA AG | RO |
| apleek 60 microgramms/24 hours + 13 microgramms/24 hours transdermal patch | FR/H/0547/001/DC | 5363-I-640/14 | BAYER D.O.O | SI |

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| apleek 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch | FR/H/0547/001 | MA513/04901 | BAYER PLC | MT |
| apleek 60 μικρογραμμάρια/24 ώρες + 13 μικρογραμμάρια/24 ώρες διαδερμικό έμπλαστρο | FR/H/0547/001 | 22062 | BAYER HELLAS SA | CY |
| apleek 60 microgrammes/24 heures + 13 microgrammes/24 heures, dispositif transdermique | FR/H/0547/001/DC | 34009 278 845 2 8 | BAYER HEALTHCARE | FR |
| Lisvy 60 mikrogramů/24 hodin + 13 mikrogramů/24 hodin transdermální náplast | FR/H/0547/001/DC | 17/129/14-C | Gedeon Richter Plc | CZ |
| apleek 60 μικρογραμμάρια/24 ώρες + 13 μικρογραμμάρια/24 ώρες διαδερμικό έμπλαστρο | FR/H/0547/001/DC | 73711/2-9-2014 | BAYER HELLAS SA | GR |
| apleek 60 microgrammes/24 heures + 13 microgrammes/24 heures, dispositif transdermique | FR/H/0547/001/DC | 34009 278 846 9 6 | BAYER HEALTHCARE | FR |
| apleek 60 microgrammes/24 heures + 13 microgrammes/24 heures, dispositif transdermique | FR/H/0547/001/DC | 34009 586 743 6 5 | BAYER HEALTHCARE | FR |
| apleek 60 Mikrogramm/24 Stunden + 13 Mikrogramm/24 transdermales Pflaster | FR/H/0547/001 | 2014060099 | BAYER SA NV | LU |
| apleek 60 microgrammes/24 heures + 13 microgrammes/24 heures dispositif transdermique | FR/H/0547/001 | 2014060099 | BAYER SA NV | LU |

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| apleek 60 mikrogramm/24 óra és 13 mikrogramm/24 óra transzdermális tapasz | FR/H/0547/001/DC | OGYI-T-22643/01 | BAYER PHARMA AG | HU |
| apleek 60 mikrogramm/24 óra és 13 mikrogramm/24 óra transzdermális tapasz | FR/H/0547/001/DC | OGYI-T-22643/03 | BAYER PHARMA AG | HU |
| apleek 60 mikrogramm/24 óra és 13 mikrogramm/24 óra transzdermális tapasz | FR/H/0547/001/DC | OGYI-T-22643/02 | BAYER PHARMA AG | HU |
| apleek 60 mikrogramów/24 godziny + 13 mikrogramów/24 godziny system transdermalny plaster | FR/H/0547/001/DC | 22229 | BAYER PHARMA AG | PL |
| Apleek 60 microgramas/24 horas + 13 microgramas/24 horas adesivo transdérmico | FR/H/0547/001/DC | 5635446 | BERLEX ESPECIALIDADES FARMACEUTICAS LDA | PT |
| Apleek 60 microgramas/24 horas + 13 microgramas/24 horas adesivo transdérmico | FR/H/0547/001/DC | 5638440 | BERLEX ESPECIALIDADES FARMACEUTICAS LDA | PT |
| Apleek 60 microgramas/24 horas + 13 microgramas/24 horas adesivo transdérmico | FR/H/0547/001/DC | 5635453 | BERLEX ESPECIALIDADES FARMACEUTICAS LDA | PT |
| Enciela 60 microgrammi/24 ore + 13 microgrammi/24 ore cerotto transdermico | FR/H/0547/001/DC | 042423018 | BAYER SPA | IT |
| Enciela 60 microgrammi/24 ore + 13 microgrammi/24 ore cerotto transdermico | FR/H/0547/001/DC | 042423032 | BAYER SPA | IT |

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| Enciela 60 microgrammi/24 ore + 13 microgrammi/24 ore cerotto transdermico | FR/H/0547/001/DC | 042423020 | BAYER SPA | IT |
| Apleek | FR/H/0547/001/DC | BE452302 | BAYER SA NV | BE |