



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2016
EMA/499815/2016
Procedure Management and Business Support

Marketing authorisations which are recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established as adopted by the CHMP on 21 July 2016

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1443



| Member State EU/EEA | Marketing Authorisation Holder | Applicant | Invented name | Active Substance | Strength | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|--------------------|---|----------------------|----------------|---------------------|-------------------------|
| Austria | | Lupin (Europe) Ltd | Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Austria | | Lupin (Europe) Ltd | Abacavir/Lamivudin Sandoz 600 mg/300 mg - Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Belgium | | Lupin (Europe) Ltd | Abacavir/Lamivudin Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Belgium | | Mylan bvba | Abacavir/Lamivudin Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Bulgaria | Sandoz d.d. | | Abacavir/Lamivudin Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Croatia | | Lupin (Europe) Ltd | Abacavir/Lamivudin Sandoz 600 mg/300 mg filmom obložene tablete | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Cyprus | | Lupin (Europe) Ltd | Abacavir/Lamivudine Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Denmark | | Lupin (Europe) Ltd | Abacavir/Lamivudine Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Denmark | | Mylan AB | Abacavir /Lamivudine Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Estonia | | Lupin (Europe) Ltd | ABACAVIR/LAMIVUDINE SANDOZ | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Finland | | Lupin (Europe) Ltd | Abacavir/Lamivudine Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Finland | | Mylan AB | Abacavir/Lamivudine Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |

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| France | | Venipharm | BAMIVENI | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| France | | Venipharm | BAMIVUDINE | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| France | | Venipharm | VIRAMUDINE | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Germany | | Lupin (Europe) Ltd | Abacavir/Lamivudin 600 mg / 300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Germany | | Lupin (Europe) Ltd | Abacavir/Lamivudine Hormosan 600 mg/300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Germany | | Lupin (Europe) Ltd | Abacavir/Lamivudin HEXAL 600 mg/300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Germany | | Lupin (Europe) Ltd | Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Germany | | Lupin (Europe) Ltd | Abacavir/Lamivudin Klinge 600 mg/300 mg Filmtabletten | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Ireland | | Generics (UK) Limited | Abacavir / Lamivudine | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Ireland | | Lupin (Europe) Ltd | Abacavir/Lamivudine Rowex | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Italy | | Lupin (Europe) Ltd | ABACAVIR E LAMIVUDINA LUPIN | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |

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| Italy | | Lupin (Europe) Ltd | ABACAVIR E LAMIVUDINA SANDOZ | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Italy | | Lupin (Europe) Ltd | ABACAVIR E LAMIVUDINA MYLAN | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Italy | | Lupin (Europe) Ltd | ABACAVIR E LAMIVUDINA ARISTO | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Lithuania | | Lupin (Europe) Ltd | Abacavir/Lamivudine Sandoz 600mg/300 mg plėvele dengtos tabletės | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Norway | | Mylan AB | Abacavir/Lamivudin Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Poland | | Lupin (Europe) Ltd | Abacavir+Lamivudine Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Poland | | Lupin (Europe) Ltd | Abacavir + Lamivudine Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Portugal | | Lupin (Europe) Ltd | Abacavir + Lamivudina Lupin | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Portugal | | Lupin (Europe) Ltd | Abacavir + Lamivudina Sandoz | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Portugal | | Mylan, Lda. | Abacavir + Lamivudina Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Romania | | Lupin (Europe) Ltd | Abacavir/lamivudină Sandoz 600 mg/300 mg, film-coated tablets | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |

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| Slovenia | | Lupin (Europe) Ltd | Abacavir/lamivudin Sandoz 600 mg/300 mg filmsko obložene tablete | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Spain | | Lupin (Europe) Ltd | Abacavir/Lamivudina Amneal 600 mg/300 mg comprimidos recubiertos con película EFG | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Spain | | Lupin (Europe) Ltd | Abacavir/Lamivudina Aristo 600 mg/300 mg comprimidos recubiertos con película EFG | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Spain | | Sandoz B.V. | Abacavir/Lamivudina Sandoz 600 mg/300 mg comprimidos recubiertos con película EFG | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Spain | Mylan Pharmaceuticals, S.L. | | Abacavir/Lamivudina Mylan 600 mg/300 mg comprimidos recubiertos con película EFG | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| Sweden | | Lupin (Europe) Ltd | Abacavir/Lamivudine Sandoz | abacavir/lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |

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| Sweden | | Mylan AB | Abacavir /Lamivudine Mylan | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| The Netherlands | | Lupin (Europe) Ltd | Abacavir/Lamivudine Aristo | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| The Netherlands | | Lupin (Europe) Ltd | Abacavir/Lamivudine Lupin | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| The Netherlands | | Lupin (Europe) Ltd | Abacavir/Lamivudine Lupin | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| United Kingdom | | Aristo Pharma GmbH | Abacavir/lamivudine 600mg/300mg film coated tablets | abacavir/ lamivudine | 600 mg/ 300 mg | Tablet | Oral use |
| United Kingdom | | Lupin (Europe) Ltd | Abacavir/lamivudine 600mg/300mg film coated tablets | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| United Kingdom | | Lupin (Europe) Ltd | Abacavir/lamivudine 600mg/300mg film coated tablets | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |
| United Kingdom | | Generics (UK) Limited | Abacavir/lamivudine 600mg/300mg film coated tablets | abacavir/ lamivudine | 600 mg/ 300 mg | Film-coated tablet | Oral use |