

Bioequivalence Requirements for Generic Products Containing Scheduled Poison in Dosage Forms of Effervescent, Dispersible, Orodispersible, Sublingual, Lozenges, Buccal and Chewable Tablets/ Capsules

The Drug Control Authority (DCA) in their 284th meeting, has decided to enforce the bioequivalence (BE) requirements on generic products containing scheduled poison in dosage forms of effervescent, dispersible, orodispersible, sublingual, buccal and chewable tablets/ capsules effective from 1st January 2018 for all new product application/submission. This requirement is also applicable for registered products with renewal due date from 1st January 2019 onwards.

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|---|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| 1 | ACYCLOVIR 800MG | ZOVIRAX TABLET 800MG (DISPERSIBLE) MAL19950570ARZ | GLAXO WELLCOME S.A., SPAIN |
| | ACYCLOVIR 400MG | ZOVIRAX DISPERSIBLE TABLETS 400MG MAL19962830A | THE WELLCOME FOUNDATION LTD, UNITED KINGDOM |
| | ACYCLOVIR 200MG | ZOVIRAX DISPERSIBLE TABLET 200MG MAL19962829ARZ | GLAXO WELLCOME S.A., SPAIN |
| 2 | ARIPIPIRAZOLE | ARISA 10MG ORODISPERSIBLE TABLET MAL23056005AZ | PHARMATHEN INTERNATIONAL S.A. (GREECE) |
| | | ARISA 15MG ORODISPERSIBLE TABLET MAL23056006AZ | PHARMATHEN INTERNATIONAL S.A. (GREECE) |
| 3 | ASENAPINE MALEATE (EQ 5MG BASE) | SAPHRIS SUBLINGUAL TABLET 5MG MAL20112129ACRZ | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |
| | ASENAPINE MALEATE (EQ 10MG BASE) | SAPHRIS SUBLINGUAL TABLET 10MG MAL20112130ACRZ | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|---|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| 4 | BILASTINE 10MG | BILAXTEN 10MG ORODISPERSIBLE TABLETS MAL21046009AZ | A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY |
| 5 | BUPRENORPHINE HYDROCHLORIDE (EQ 0.2MG BASE) | TEMGESIC SUBLINGUAL TABLET 0.2MG MAL19860975AZ | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) | SUBUTEX SUBLINGUAL TABLET 8MG MAL20013547A | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) | SUBUTEX SUBLINGUAL TABLET 2MG MAL20013546A | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 0.4MG BASE) | SUBUTEX SUBLINGUAL TABLET 0.4MG MAL20013545A | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM |
| 6 | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE) | SUBOXONE 8 MG SUBLINGUAL TABLETS MAL20061582ACRZ | RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE) | SUBOXONE 2MG SUBLINGUAL TABLETS MAL20061581ACRZ | RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE) | SUBOXONE SUBLINGUAL FILM 8MG/2MG MAL13075058ACZ | MONOSOL RX, UNITED STATES |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|--|---|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE) | SUBOXONE SUBLINGUAL FILM 2MG/0.5MG MAL13075057ACZ | MONOSOL RX, UNITED STATES |
| 7 | BUPROPION HYDROCHLORIDE 150MG | WELLBUTRIN SR TABLETS MAL20081803ARZ | GLAXOSMITHKLINE LLC, UNITED STATES |
| 8 | DEFERASIROX 125MG | EXJADE 125MG DISPERSIBLE TABLETS MAL20061603ARZ | NOVARTIS PHARMA STEIN AG, SWITZERLAND |
| | DEFERASIROX 250MG | EXJADE 250MG DISPERSIBLE TABLETS MAL20061604A | NOVARTIS PHARMA STEIN AG SWITZERLAND |
| | DEFERASIROX 500MG | EXJADE 500MG DISPERSIBLE TABLETS MAL20061605ARZ | NOVARTIS PHARMA STEIN AG, SWITZERLAND |
| | | Exjade Dispersible Tablets manufactured by Novartis Pharma Stein AG, Switzerland can be obtained from United Arab Emirates, Bahrain, Brazil, Canada, Switzerland, Chile, China, Ecuador, Indonesia, Jordan, Kuwait, Kazakhstan, Morocco, Macedonia, New Zealand, Oman, Panama, Philippines, Palestine, Paraguay, Qatar, Serbia, Thailand, Turkey, Taiwan, Ukraine, United States and South Africa. <i>(Source of information: Novartis Corporation (Malaysia) Sdn Bhd, 2022)</i> | |
| 9 | DESLORATADINE 2.5MG | AJALORIN 2.5MG ORODISPERSIBLE TABLET MAL19016047ACZ | GENEPHARM S.A., GREECE |
| | DESLORATADINE 5MG | AJALORIN 2.5MG ORODISPERSIBLE TABLET MAL19016044ACZ | GENEPHARM S.A., GREECE |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|---|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| 10 | DONEPEZIL HYDROCHLORIDE 10MG | ARICEPT EVESS ORODISPERSIBLE TABLET 10MG MAL09042405ACRZ | BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN |
| | DONEPEZIL HYDROCHLORIDE 5MG | ARICEPT EVESS ORODISPERSIBLE TABLET 5MG MAL09042397ACRZ | BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN |
| 11 | ERDOSTEINE 300MG | ERDOMED® 300MG DISPERSIBLE TABLETS MAL20076015ARZMA | EDMOND PHARMA S.R.L, ITALY |
| 12 | ESCITALOPRAM OXALATE (EQ 20MG BASE) | AJALOPRAM 20 MG ORODISPERSIBLE TABLET MAL18086103ACZ | GENEPHARM S.A., GREECE |
| | ESCITALOPRAM OXALATE (EQ 15MG BASE) | AJALOPRAM 15MG ORODISPERSIBLE TABLET MAL18086104ACZ | GENEPHARM S.A., GREECE |
| | ESCITALOPRAM OXALATE (EQ 10MG BASE) | AJALOPRAM 10MG ORODISPERSIBLE TABLET MAL18086106ACZ | GENEPHARM S.A., GREECE |
| | ESCITALOPRAM OXALATE (EQ 5MG BASE) | AJALOPRAM 5MG ORODISPERSIBLE TABLET MAL18086105ACZ | GENEPHARM S.A., GREECE |
| 13 | FENTANYL CITRATE (EQ 400MCG BASE) | ABSTRAL 400 MICROGRAM SUBLINGUAL TABLETS MAL17085057ACZ | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM |
| | FENTANYL CITRATE (EQ 200MCG BASE) | ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS MAL17085056ACZ | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|---|---|---|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | | ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS MAL14025004ACZ | RECIPHARM STOCKHOLM AB, SWEDEN |
| | | ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS MAL17085055ACZ | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM |
| | | ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS MAL14025003ACZ | RECIPHARM STOCKHOLM AB, SWEDEN |
| 14 | FLURBIPROFEN 8.75MG | STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE MAL13045049AZ | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM |
| | | STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE MAL18016023ASZ | RECKITT BENCKISER HEALTHCARE MANUFACTURING (THAILAND) LIMITED |
| 15 | GIMERACIL 7.28MG, OTERACIL POTASSIUM 24.5MG AND TEGAFUR 25MG | TS-ONE OD TABLET 25 MAL19071005ARZ | TAIHO PHARMACEUTICAL CO.,LTD, JAPAN |
| | GIMERACIL 5.8MG, OTERACIL POTASSIUM 19.6MG AND TEGAFUR 20MG | TS-ONE OD TABLET 20 MAL19071004ARZ | TAIHO PHARMACEUTICAL CO.,LTD, JAPAN |
| 16 | GLYCERYL TRINITRATE 0.5MG | GTN ACTAVIS TABLET 500 MCG MAL19871706ACZ | ACCORD-UK LTD, UNITED KINGDOM ACTAVIS UK LIMITED, UNITED KINGDOM |
| 17 | LAMOTRIGINE 50MG | LAMICTAL DISPERSIBLE TABLET 50MG MAL19930433ACRZ | DELPHARM POZNAN SPOLKA AKCYJNA(POLAND) |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|--|---|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | LAMOTRIGINE 25MG | LAMICTAL DISPERSIBLE TABLET 25MG MAL19970262ACRZ | GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND DELPHARM POZNAN SPOLKA AKCYJNA(POLAND) |
| | LAMOTRIGINE 5MG | LAMICTAL DISPERSIBLE TABLET 5MG MAL19970261ACRZ | GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND DELPHARM POZNAN SPOLKA AKCYJNA(POLAND) |
| | LAMOTRIGINE 2MG | LAMICTAL CHEWABLE DISPERSABLE 2MG TABLETS MAL20061515ARZ | GLAXO WELLCOME INC, UNITED STATES DELPHARM POZNAN SPOLKA AKCYJNA(POLAND) |
| 18 | LANSOPRAZOLE 15MG | PREVACID FDT 15 MG TABLET MAL08042459ARZ | KOKANDO CO. LTD (JAPAN) |
| | LANSOPRAZOLE 30MG | PREVACID FDT 30MG TABLET MAL08042460ARZ | KOKANDO CO. LTD (JAPAN) |
| 19 | LORATADINE 10MG | CLARITYNE RAPID TABLET 10MG MAL20014313ACZ | SCHERER DDS LTD, UNITED KINGDOM |
| | | As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2019" – 19 November 2019, Clarityne Rapid Tablet and Claritin Reditabs manufactured by Catalent U.K. Swindon Zydus Limited, United Kingdom is allowed to be used as a comparator. | |
| 20 | MIRTAZAPINE 45MG | REMERON SOLTAB 45MG MAL05023179ACR | CIMA LABS INC , UNITED STATES |

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|--|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | MIRTAZAPINE 30MG | REMERON SOLTAB 30MG MAL14015019ACRZ | ANESTA LLC, UNITED STATES CEPHALON, INC (UNITED STATES) |
| | MIRTAZAPINE 15MG | REMERON SOLTAB 15MG MAL14015018ACRZ | ANESTA LLC, UNITED STATES CEPHALON, INC (UNITED STATES) |
| 21 | MONTELUKAST SODIUM (EQ 5MG BASE) | SINGULAIR CHEWABLE TABLET 5MG MAL19990956ARZ | MERCK SHARP & DOHME LTD, UNITED KINGDOM |
| 22 | MONTELUKAST SODIUM (EQ 4MG BASE) | SINGULAIR 4MG CHEWABLE TABLET MAL20020121ARZ | MERCK SHARP & DOHME LTD, UNITED KINGDOM |
| 23 | NICOTINE 4MG | NICOTINELL FRUIT 4MG, CHEWING-GUM MAL06011709ACRZ | FERTIN PHARMA A/S , DENMARK |
| | | This product can be obtained from Denmark, Iceland, Israel, New Zealand, Switzerland and United Kingdom. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i> | |
| | NICOTINE 2MG | NICOTINELL FRUIT 2MG, CHEWING-GUM MAL06011708ACRZ | FERTIN PHARMA A/S, DENMARK |
| | | This product can be obtained from Austria, Belgium, Denmark, Finland, France, Iceland, Ireland, Israel, Republic of Korea, Luxembourg, Netherland, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i> | |
| | NICOTINE 4MG | NICOTINELL MINT 4MG, CHEWING-GUM MAL06011711ACRZ | FERTIN PHARMA A/S, DENMARK |
| | | This product can be obtained from Denmark, Finland, Iceland, Israel, New Zealand, Norway, Sweden and United Kingdom. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i> | |

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|-----|---|--|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | NICOTINE 2MG | NICOTINELL MINT 2MG, CHEWING-GUM MAL06011710ACRZ | FERTIN PHARMA A/S , DENMARK |
| | | This product can be obtained from Denmark, Finland, Hong Kong, Iceland, Israel, Japan, Republic of Korea, New Zealand, Norway, Sweden, Thailand & United Kingdom. <i>Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i> | |
| | NICOTINE RESINATE (EQ 4MG BASE) | NICORETTE ICY MINT 4 MG GUM MAL15045059ARZ | MCNEIL AB, SWEDEN |
| | NICOTINE RESINATE (EQ 2MG BASE) | NICORETTE ICY MINT 2 MG GUM MAL15045076ARZ | MCNEIL AB, SWEDEN |
| | NICOTINE POLACRILEX (EQ 4MG BASE) | NIQUITIN 4MG LOZENGES MAL06100577ARZ | GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES |
| | NICOTINE POLACRILEX (EQ 2MG BASE) | NIQUITIN 2MG LOZENGES MAL06100578ARZ | GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES |
| | NICOTINE POLACRILEX (EQ 4MG BASE) | NIQUITIN 4MG MINT LOZENGES MAL09051546AZ | GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES |
| | NICOTINE POLACRILEX (EQ 2MG BASE) | NIQUITIN 2MG MINT LOZENGES MAL09051545AZ | GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES |
| | NICOTINE BITARTRATE DIHYDRATE (EQ 1MG BASE) | NICOTINELL MINT 1MG LOZENGE MAL06011707ACRZ | SANICO N.V., BELGIUM |
| | NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE) | SKIIP NICOTINE MIN _v I LOZENGE 2MG (CHERRY FLAVOUR) MAL25026002AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|--|--|---|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 2MG (CINNAMON FLAVOUR) MAL25026003AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |
| | NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 2MG (MINT FLAVOUR) MAL25026001AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |
| | NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG (CHERRY FLAVOUR) MAL25026005AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |
| | NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG (CINNAMON FLAVOUR) MAL25026006AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |
| | NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG (CINNAMON FLAVOUR) MAL25026004AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA |
| 24 | OLANZAPINE 10MG | ZYPREXA ZYDIS 10MG ORODISPERSIBLE TABLET MAL04125491ACRZ | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |
| | OLANZAPINE 5MG | ZYPREXA ZYDIS 5MG ORODISPERSIBLE TABLET MAL04125490ACRZ | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |
| 25 | PERINDOPRIL ARGININE 10MG | COVERSYL OD 10MG, ORODISPERSIBLE TABLETS MAL13095087AZ | SERVIER (IRELAND) INDUSTRIES LTD, IRELAND |
| | PERINDOPRIL ARGININE 5MG | COVERSYL OD 5MG, ORODISPERSIBLE TABLETS MAL13095085AZ | SERVIER (IRELAND) INDUSTRIES LTD, IRELAND |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|---|--|--|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| | PERINDOPRIL ARGININE 2.5MG | COVERSYL OD 2.5MG, ORODISPERSIBLE TABLETS MAL13095086AZ | SERVIER (IRELAND) INDUSTRIES LTD, IRELAND |
| 26 | PIROXICAM 20MG | FELDENE DISPERSIBLE TABLET MAL19962549ACZ | FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE |
| 27 | RANITIDINE HYDROCHLORIDE (EQ 150MG BASE) | ZANTAC EFFERVESCENT TABLET 150MG MAL07011019AZ | GLAXOWELLCOME PRODUCTION , FRANCE |
| 28 | RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG | RHZ KID DT (RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS) MAL25056006ACZ | OXALIS LABS (INDIA) |
| 29 | SILDENAFIL CITRATE (EQ 100MG BASE) | AJENAFIL 100MG CHEWABLE TABLET MAL18046144AZ | GENEPHARM S.A., GREECE |
| | SILDENAFIL CITRATE (EQ 50MG BASE) | AJENAFIL 50MG CHEWABLE TABLET MAL18046145AZ | GENEPHARM S.A., GREECE |
| | SILDENAFIL CITRATE (EQ 25MG BASE) | AJENAFIL 25MG CHEWABLE TABLET MAL18046146AZ | GENEPHARM S.A., GREECE |
| 30 | SILDENAFIL CITRATE | HOVID ERECOR ORODISPERSIBLE FILMS 50MG MAL23096012ACZ | ZIM LABORATORIES LIMITED (INDIA) |
| 31 | TADALAFIL 20MG | LEBIVA ODS-20 TADALAFIL ORALLY DISINTEGRATING STRIPS 20MG MAL2309611ACZ | ZIM LABORATORIES LIMITED (INDIA) |
| 32 | TADALAFIL 5MG | CALIBERI ORODISPERSIBLE FILM 5MG MAL21036001AZ | CTCBIO INC, SOUTH KOREA |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS | |
|-----|---|--|---------------------------------|
| | | PRODUCT NAME AND MAL NO. | MANUFACTURER |
| 33 | TADALAFIL 10MG | HOVID ERETAF ORODISPERSIBLE FILMS 10MG | ZIM LABORATORIES LIMITED, INDIA |
| 34 | TADALAFIL 20MG | HOVID ERETAF ORODISPERSIBLE FILMS 20MG | ZIM LABORATORIES LIMITED, INDIA |
| 35 | VERDANAFIL HYDROCHLORIDE (EQ 10MG BASE) | LEVITRA 10 MG ORODISPERSIBLE TABLETS MAL12035080ARZ | BAYER AG (LEVERKUSEN), GERMANY |

Note:

This list is non-exhaustive and will be updated from time to time. For further clarification, kindly email to be_sug@npra.gov.my

Updated on 20/04/2026