

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
1.	ALENDRONATE SODIUM (EQ 70MG BASE) AND CHOLECALCIFEROL 5600 IU	FOSAMAX PLUS 70MG/5600I.U. COMBINATION TABLET MAL08031392ACRZ	FROSST IBERICA, S.A., SPAIN
2.	ALISKIREN HEMIFUMARATE AND HYDROCHLOROTHIA ZIDE	RASILEZ HCT 300/25MG FILM-COATED TABLET MAL20091954AR	NOVARTIS PHARMA S.P.A, ITALY
		RASILEZ HCT 300/12.5MG FILM-COATED TABLET MAL20091953AR	NOVARTIS PHARMA S.P.A, ITALY
		RASILEZ HCT 150/25MG FILM-COATED TABLET MAL20091952AR	NOVARTIS PHARMA S.P.A, ITALY
		RASILEZ HCT 150/12.5MG FILM-COATED TABLET MAL20091951AR	NOVARTIS PHARMA S.P.A, ITALY
3.	ALVERINE CITRATE 60MG AND SIMETHICONE 300MG	METEOSPASMYL CAPSULE MAL19990251ACZ	LABORATOIRES GALENIQUES VERNIN, FRANCE
4.	AMILORIDE HYDROCHLORIDE 5MG AND HYDROCHLOROTHIA ZIDE 50MG	MODURETIC 50/5 TABLET MAL19920200AR	FROSST IBERICA S.A, SPAIN
		Product can be obtained in the following countries:- <ol style="list-style-type: none"> i. Asia Pacific region: Australia, French Polynesia, Hong Kong, New Caledonia, Taiwan ii. US region: United States iii. Europe region: France, Ireland, Italy, Martinique, Spain, UK, Belgium, Cyprus, Czech Republic, Greece, Luxembourg, Portugal, Slovak Republic, Austria, Estonia, Finland, Norway, Switzerland iv. Latin America region: Argentina, Brazil, Brazil Supera, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Falkland Islands, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Peru, Uruguay, Venezuela v. Others: Angola, Ivory Coast, Kenya, Libya, Mali, Morocco, Nigeria, South Africa, Turkey, Ukraine (Source of information: Merck Sharp & Dohme (M) Sdn Bhd, 2014)	

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		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016 – 16 Jun 2016, Moduretic Tablet from Aspen Port Elizabeth Pty Ltd, South Africa is allowed to be used as comparator.	
5.	AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM	CADUET FILM-COATED TABLET 10MG/80MG MAL20061549ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 10MG/40MG MAL20061548ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 10MG/20MG MAL20061547ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 10MG/10MG MAL20061546ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 5MG/80MG MAL20061545AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 5MG/40MG MAL20061544ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 5MG/20MG MAL20061543ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		CADUET FILM-COATED TABLET 5MG/10MG MAL20061542ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
6.	AMLODIPINE BESYLATE, ATORVASTATIN CALCIUM TRIHYDRATE AND PERINDOPRIL ARGININE	TRIVERAM 40MG/10MG/10MG (ATORVASTATIN/PERINDOPRIL ARGININE/AMLODIPINE) FILM-COATED TABLETS MAL21056008AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
		TRIVERAM 20MG/10MG/10MG (ATORVASTATIN/PERINDOPRIL ARGININE/AMLODIPINE) FILM-COATED TABLETS MAL21056007AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
		TRIVERAM 20MG/10MG/5MG (ATORVASTATIN/PERINDOPRIL ARGININE/AMLODIPINE) FILM- COATED TABLETS MAL21056006AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
		TRIVERAM 20MG/5MG/5MG (ATORVASTATIN/PERINDOPRIL ARGININE/AMLODIPINE) FILM- COATED TABLETS MAL21056005AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
7.	AMLODIPINE BESYLATE, HYDROCHLOROTHIA ZIDE AND VALSARTAN	EXFORGE HCT 10/320/25 MG FILM- COATED TABLET MAL15015054ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE HCT 10/320/25MG FILM- COATED TABLET MAL20102039ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		EXFORGE HCT 10/160/25 MG FILM- COATED TABLET MAL15015058ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE HCT 10/160/25MG FILM- COATED TABLET MAL20102038ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		EXFORGE HCT 10/160/12.5MG FILM-COATED TABLET MAL15015057ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE HCT 10/160/12.5MG FILM-COATED TABLET MAL20102037ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		EXFORGE HCT 5/160/25 MG FILM- COATED TABLET MAL15015061ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE HCT 5/160/25MG FILM- COATED TABLET MAL20102036ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND

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		EXFORGE HCT 5/160/12.5MG FILM-COATED TABLET MAL15015052ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE HCT 5/160/12.5MG FILM-COATED TABLET MAL20102035ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
8.	AMLODIPINE BESYLATE AND OLMESARTAN MEDOXOMIL	AZOREN 40 MG/10 MG FILM-COATED TABLETS MAL12055005ARZ	DAIICHI SANKYO EUROPE GMBH, GERMANY
		AZOREN 40 MG/5 MG FILM-COATED TABLETS MAL12055004ARZ	DAIICHI SANKYO EUROPE GMBH, GERMANY
		AZOREN 20 MG/5 MG FILM-COATED TABLETS MAL12055003ARZ	DAIICHI SANKYO EUROPE GMBH, GERMANY
9.	AMLODIPINE BESYLATE AND PERINDOPRIL ARGININE	COVERAM 10MG/10MG TABLET MAL20091913AZ	SERVIER (IRELAND) INDUSTRIES LTD., IRELAND
		COVERAM 10MG/5MG TABLET MAL20091912AZ	SERVIER (IRELAND) INDUSTRIES LTD., IRELAND
		COVERAM 5MG/10MG TABLET MAL20091911AZ	SERVIER (IRELAND) INDUSTRIES LTD., IRELAND
		COVERAM 5MG/5MG TABLET MAL20091910AZ	SERVIER (IRELAND) INDUSTRIES LTD., IRELAND
10.	AMLODIPINE BESYLATE AND PERINDOPRIL TERT-BUTYLAMINE	AMOPRIL 5MG/4MG TABLET MAL 22036006AZ	ADAMED PHARMA S.A. (POLAND)
		AMOPRIL 5MG/8MG TABLET MAL 22036005AZ	ADAMED PHARMA S.A. (POLAND)
		AMOPRIL 10MG/4MG TABLET MAL 22036004AZ	ADAMED PHARMA S.A. (POLAND)
		AMOPRIL 10MG/8MG TABLET MAL 22036003AZ	ADAMED PHARMA S.A. (POLAND)
11.	AMLODIPINE BESYLATE AND TELMISARTAN	TWYNSTA TABLET 80/10MG MAL20112138ACZ	CIPLA LIMITED, INDIA
		TWYNSTA TABLET 80/5MG	CIPLA LIMITED, INDIA

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
		MAL20112137ACZ	
		TWYNSTA TABLET 40/10MG MAL20112136ACZ	CIPLA LIMITED, INDIA
		TWYNSTA TABLET 40/5MG MAL20112135ACZ	CIPLA LIMITED, INDIA
12.	AMLODIPINE BESYLATE AND VALSARTAN	EXFORGE 10MG/320MG FILM-COATED TABLET MAL11040003ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		EXFORGE 10MG/160MG FILM-COATED TABLET MAL20081729ARZ	NOVARTIS FARMA S.P.A., ITALY NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE 5MG/320MG FILM-COATED TABLET MAL11040002ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		EXFORGE 5MG/160MG FILM-COATED TABLET MAL20081728ARZ	NOVARTIS FARMA S.P.A., ITALY NOVARTIS FARMACEUTICA S.A., SPAIN
		EXFORGE 5MG/80MG FILM-COATED TABLET MAL20081727ARZ	NOVARTIS FARMA S.P.A., ITALY NOVARTIS PHARMA STEIN AG, SPAIN
13.	AMLODIPINE CAMSYLATE AND LOSARTAN POTASSIUM	COZAAR XQ 5/100MG TABLET MAL12025078ACRZ	HANMI PHARM. CO., LTD. (PALTAN SITE), SOUTH KOREA
		COZAAR XQ 5/50 MG TABLET MAL12025077ACRZ	HANMI PHARM. CO., LTD. (PALTAN SITE), SOUTH KOREA
14.	AMOXYCILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE	AUGMENTIN TABLET 1G MAL19972945ARZ	SMITHKLINE BEECHAM PHARMACEUTICALS, UNITED KINGDOM
		AUGMENTIN TABLET 625MG MAL19986474ARZ	SMITHKLINE BEECHAM PHARMACEUTICALS, UNITED KINGDOM

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
		AUGMENTIN TABLET 375MG MAL19871292AZ	SMITHKLINE BEECHAM PHARMACEUTICALS, UNITED KINGDOM
15.	ARTESUNATE AND MEFLOQUINE HYDROCHLORIDE	ARTESUNATE AND MEFLOQUINE HYDROCHLORIDE TABLETS 100/220MG MAL12035082AZ	CIPLA LTD, INDIA
		ARTESUNATE AND MEFLOQUINE HYDROCHLORIDE TABLETS 25/55 MG MAL12035081AZ	CIPLA LTD, INDIA
16.	ARTHEMETHER 20MG AND LUMEFANTRINE 120MG	RIAMET TABLET MAL20032242ARZ	NOVARTIS SAGLIK, TURKEY BEIJING NOVARTIS PHARMA LTD, CHINA
17.	ATENOLOL AND CHLORTHALIDONE	TENORETIC TABLET MAL19871032AZ	ASTRAZENECA UK LTD, UNITED KINGDOM
		TENORET 50 TABLET MAL19871033AZ	ASTRAZENECA UK LTD, UNITED KINGDOM
18.	BENSERAZIDE HYDROCHLORIDE AND LEVODOPA	MADOPAR ROCHE TABLET 250MG MAL19871099ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY F. HOFFMANN-LA ROCHE LTD SWITZERLAND
		MADOPAR ROCHE 125 CAPSULE MAL19871097ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY F. HOFFMANN-LA ROCHE LTD SWITZERLAND
19.	BISOPROLOL HEMIFUMARATE AND HYDROCHLOROTHIA ZIDE	LODOZ 10MG TABLET MAL05051114A	MERCK KGAA, GERMANY
		LODOZ 5MG TABLET MAL05051113AZ	MERCK HEALTHCARE KGAA, GERMANY

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		LODOZ 2.5MG TABLET MAL05051115ASZ	MERCK HEALTHCARE KGAA, GERMANY
		LODOZ MAL20040552A	PT MERCK INDONESIA, INDONESIA
20.	CAFFEINE 100MG AND ERGOTAMINE TARTRATE 1MG	CAFERGOT TABLET MAL13035053ACZ	CENEXI SAS, FRANCE
		CAFERGOT TABLET MAL19871105AC	NOVARTIS PHARM UK LTD, UNITED KINGDOM
21.	CANDESARTAN CILEXETIL AND HYDROCHLOROTHIA ZIDE	ATACAND PLUS TABLET 32/12.5MG MAL10043677A	ASTRA ZENECA AB, SWEDEN
		ATACAND PLUS TABLETS 16/12.5MG MAL20021128ARZ	ASTRA ZENECA AB, SWEDEN
		BLOPRESS PLUS TABLET 16/12.5MG MAL08021476ACRZ	DELPHARM NOVARA S.R.L (ITALY)
22.	CARBIDOPA AND LEVODOPA	SINEMET TABLET CR 50/200 CONTROLLED-RELEASE TABLET MAL12125048ACRZ	MYLAN PHARMACEUTICALS INC., UNITED STATES
		SINEMET TABLET 25/250 MG MAL12085069ACRZ	MYLAN PHARMACEUTICALS INC., UNITED STATES
		SINEMET 25/250 TABLET MAL19913442A	MERCK SHARP & DOHME (AUSTRALIA) PTY. LTD., AUSTRALIA
		SINEMET TABLET 25/250MG MAL19871095AR	MERCK SHARP & DOHME INT, UNITED STATES
		SINEMET TABLET 25/100 MG MAL12085068ACRZ	MYLAN PHARMACEUTICALS INC., UNITED STATES
		SINEMET 25/100 TABLET MAL19913441A	MERCK SHARP & DOHME (AUSTRALIA) PTY. LTD., AUSTRALIA
		SINEMET 25/100 TABLET MAL19871096AR	MERCK SHARP & DOHME INT, UNITED STATES

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		<p>This product is available in Argentina, Australia, Austria, Bulgaria, Ecuador, Egypt, Estonia, France, Germany, Ireland, Italy, Jamaica, Japan, Lithuania, Netherlands, New Zealand, Northern Ireland, Portugal, South Africa, Spain, Switzerland, Taiwan, Trinidad & Tobago, United Kingdom, United States.</p> <p><i>(Source of information: Organon (M) Sdn Bhd, 2023)</i></p>	
23.	CARBIDOPA MONOHYDRATE, LEVODOPA AND ENTACAPONE	STALEVO 200/50/200MG FILM-COATED TABLET MAL09102942ACRZ	ORION CORP, FINLAND
		STALEVO 150/37.5/200MG FILM-COATED TABLETS MAL20051355ACRZ	ORION CORP, FINLAND
		STALEVO 125/31.25/200MG FILM-COATED TABLET MAL11030094ACRZ	ORION CORP, FINLAND
		STALEVO 100/25/200MG FILM-COATED TABLETS MAL20051339ACRZ	ORION CORP, FINLAND
		STALEVO 75/18.75/200MG FILM-COATED TABLET MAL11030095ACRZ	ORION CORP, FINLAND
		STALEVO 50/12.5/200MG FILM-COATED TABLETS MAL20051345ACRZ	ORION CORP, FINLAND
24.	CLOPIDOGREL HYDROGEN SULPHATE (EQ 75MG BASE) AND ACETYLSALICYLIC ACID 100MG	COPLAVIX 75/100MG FILM-COATED TABLET MAL12115075AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
25.	CODEINE PHOSPHATE AND PARACETAMOL	PANADEINE FORTE TABLET MAL19871079A	WINTHROP LABS, AUSTRALIA
		<p>This product is available in Australia, United Kingdom, Finland, Sweden, Ireland & Malta.</p> <p><i>(Source of information: Sanofi Aventis (Malaysia) Sdn Bhd, 2017)</i></p>	
		<p>As agreed upon "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2017" – 27 September 2017, Panadeine Forte Tablet manufactured by Sanofi India Limited, India is allowed to be used as comparator.</p>	

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
		PANADEINE TABLET MAL19950068AZ	SANOFI INDIA LIMITED, INDIA AVENTIS PHARMA LIMITED, INDIA
26.	COBICISTAT 150MG, ELVITEGRAVIR 150MG, EMTRICITABINE 200MG AND TENOFOVIR ALAFENAMIDE FUMARATE (EQ 10MG BASE)	GENVOYA (ELVITEGRAVIR 150MG/ COBICISTAT 150MG/ EMTRICITABINE 200MG/ TENOFOVIR ALAFENAMIDE 10MG) FILM-COATED TABLETS MAL17025022ACZ	PATHEON INC, CANADA
27.	CYPROTERONE ACETATE 1MG AND ESTRADIOL VALERATE 2MG	CLIMEN 28 SUGAR COATED TABLET MAL20040218AZ	DELPHARM LILLE SAS, FRANCE
28.	CYPROTERONE ACETATE 2MG AND ETHINYLESTRADIOL 0.035MG	DIANE 35 TABLET MAL19900568AZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY SCHERING GHBH & CO PRODUCTIONS KG, GERMANY
		DIANE-35 TABLET MAL20001806ASC	PT SCHERING INDONESIA, INDONESIA
29.	DESOGESTREL 0.15MG AND ETHINYLESTRADIOL 0.02MG	MERCILON TABLETS MAL19900640AZ	N.V. ORGANON, NETHERLANDS
		MERCILON TABLET MAL19962539AZ	ORGANON (IRELAND) LTD., IRELAND
30.	DESOGESTREL 0.15MG AND ETHINYLESTRADIOL 0.03MG	MARVELON TABLET MAL19872093AZ	N.V. ORGANON, NETHERLANDS
31.	DROSPERINONE 3MG AND ETHINYLESTRADIOL 0.02MG	YAZ TABLETS MAL20091884ACRZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY SCHERING GMBH & CO. GERMANY

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32.	DROSPIRENONE 3MG AND ETHINYLESTRADIOL 30MCG	YASMIN TABLET MAL20040023ARZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY SCHERING GMBH, GERMANY
33.	DROSPIRENONE 2MG AND ESTRADIOL HEMIHYDRATE 1MG	ANGELIQ TABLET MAL20061594ARZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY
34.	DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE	DUODART 0.5MG/0.4MG MAL 20112150ACRZ	CATALENT GERMANY SCHORNDORF GMBH (GERMANY)
35.	DYDROGESTERONE AND ESTRADIOL	FEMOSTON CONTI 1/5MG FILM- COATED TABLET MAL20040952AZ	ABBOTT BIOLOGICAL B. V, NETHERLANDS
		FEMOSTON CONTI 0.5MG/2.5MG FILM COATED TABLET MAL16075032AZ	ABBOTT BIOLOGICAL B. V, NETHERLANDS
		FEMOSTON 2/20 TABLET MAL19991348A	SOLVAY PHARMACEUTICALS B.V, NETHERLANDS
		FEMOSTON 2/10 TABLET MAL06021201AZ	ABBOTT BIOLOGICAL B. V, NETHERLANDS
		FEMOSTON 1/10 TABLET MAL20040819AZ	ABBOTT BIOLOGICAL B. V, NETHERLANDS
36.	EFAVIRENZ 600MG, EMTRICITABINE 200MG AND TENOFIVIR DISOPROXIL FUMARATE 300MG	VIRADAY TABLETS (TENOFIVIR DISOPROXIL FUMARATE 300MG + EMTRICITABINE 200MG + EFAVIRENZ 600 MG) MAL13065053AZ	CIPLA LTD, INDIA
37.	EMPAGLIFLOZIN AND LINAGLIPTIN	GLYXAMBI 25MG/ 5MG FILM COATED TABLET MAL18016005AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY
		GLYXAMBI 10MG/ 5MG FILM COATED TABLET MAL18016004AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY

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38.	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE	JARDIANCE DUO 12.5MG/ 1000MG FILM-COATED TABLETS MAL18016148AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
		JARDIANCE DUO 12.5MG/ 850MG FILM-COATED TABLETS MAL18016146AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
		JARDIANCE DUO 12.5MG/ 500MG FILM-COATED TABLETS MAL18016056AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
		JARDIANCE DUO 5MG/ 500MG FILM-COATED TABLETS MAL18016142AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
39.	EMTRICITABINE 200MG, RILPIVIRINE HYDROCHLORIDE (EQ 25MG BASE) AND TENOFOVIR ALAFENAMIDE FUMARATE (EQ 25MG BASE)	ODEFSEY (200MG EMTRICITABINE/ 25MG RILPIVIRINE/ 25MG TENOFOVIR ALAFENAMIDE) FILM COATED TABLETS MAL18116091ACZ	PATHEON INC, CANADA
40.	EMTRICITABINE 200MG AND TENOFOVIR DISOPROXIL FUMARATE 300MG	TENVIR EM TABLETS MAL20091962AZ	CIPLA LTD, INDIA
41.	EMTRICITABINE 200MG AND TENOFOVIR ALAFENAMIDE FUMARATE (EQ 25MG BASE)	DESCOVY® (EMTRICITABINE 200MG/ TENOFOVIR ALAFENAMIDE 25MG) FILM COATED TABLETS MAL18116088ACZ	PATHEON INC, CANADA
		DESCOVY® (EMTRICITABINE 200MG/ TENOFOVIR ALAFENAMIDE 10MG) FILM COATED TABLETS MAL18116089ACZ	PATHEON INC, CANADA

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42.	ESTRADIOL HEMIHYDRATE (EQ 1MG BASE) AND NORETHISTERONE ACETATE 0.5MG	ACTIVELLE TABLET MAL20001814AZ	NOVO NORDISK A/S, DENMARK
43.	ESTRADIOL VALERATE 2MG AND NORGESTREL 0.5MG	PROGYLUTON TABLETS MAL20021014AZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY
44.	ETHAMBUTOL HYDROCHLORIDE 275MG, ISONIAZIDE 75MG, RIFAMPICIN 150MG AND PYRAZINAMIDE 400MG	AKURIT-4 TABLET MAL20051429AZ	LUPIN LIMITED, INDIA
45.	ETHINYLESTRADIOL 0.03MG AND GESTODENE 0.075MG	GYNERA TABLET MAL09122026ACZ	SCHERING DO BRASIL QUIMICA E FARMACEUTICA LTDA., BRAZIL
46.	ETHINYLESTRADIOL 0.02MG AND GESTODENE 0.075MG	MELIANE SUGAR COATED TABLETS MAL20001807AZ	DELPHARM LILLE S.A.S., FRANCE
47.	ETHINYLESTRADIOL 0.02MG AND LEVONORGESTREL 0.1MG	LOETTE 21 TABLET MAL19992694AZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
48.	ETHINYLESTRADIOL 0.03MG AND LEVONORGESTREL 0.15MG	MICROGYNON 30 TABLET MAL19900570AZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY
		NORDETTE 21 TABLET MAL20013009AZ	SCHERING AG BERLIN, GERMANY PFIZER IRELAND PHARMACEUTICALS, IRELAND
49.	ETHINYLESTRADIOL (0.03MG; 0.04MG; 0.03MG) AND LEVONORGESTREL (0.05MG; 0.075MG; 0.125MG)	TRINORDIOL 21 TABLET MAL20000740A	PFIZER IRELAND PHARMACEUTICALS, IRELAND

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50.	ETHINYL ESTRADIOL 0.03MG, LEVONORGESTREL 0.15MG AND FERROUS FUMARATE 75MG	MICROGYNON 30 ED FE TABLET MAL19900571AZ	SCHERING AG BERLIN, GERMANY
51.	EZETIMIBE AND ATORVASTATIN CALCIUM	ATOZET 10MG/10MG FILM-COATED TABLETS MAL17035025ACRZ	MSD INTERNATIONAL GMBH, PUERTO RICO
		ATOZET 10MG/20MG FILM-COATED TABLETS MAL17035022ACRZ	MSD INTERNATIONAL GMBH, PUERTO RICO
		ATOZET 10MG/40MG FILM-COATED TABLETS MAL17035021ACRZ	MSD INTERNATIONAL GMBH, PUERTO RICO
		ATOZET 10MG/80MG FILM-COATED TABLETS MAL17035026ACRZ	MSD INTERNATIONAL GMBH, PUERTO RICO
52.	EZETIMIBE AND SIMVASTATIN	VYTORIN 10/80MG TABLET MAL20041215ARZ	MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE
		VYTORIN 10/40MG TABLET, MAL20041214ARZ	MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE
		VYTORIN 10/20MG TABLET, MAL20041213ARZ	MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE
		VYTORIN 10/10MG TABLET MAL20041212ARZ	MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE
		<i>This product can be obtained from Australia. (Source of information: Merck Sharp & Dohme (Malaysia) Sdn Bhd, 2016)</i>	
53.	GIMERACIL, OTERACIL	TS-ONE CAPSULE 20 MAL12075066ARZ	TAIHO PHARMACEUTICAL CO. LTD., JAPAN

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	POTASSIUM AND TEGAFUR	TS-ONE CAPSULE 25 MAL12075067ARZ	TAIHO PHARMACEUTICAL CO. LTD., JAPAN
54.	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE	GLUCOVANCE 500/5MG MAL20051297AZ	MERCK SANTE S.A.S., FRANCE
		GLUCOVANCE 500MG/2.5MG MAL20051296AZ	MERCK SANTE S.A.S., FRANCE
		GLUCOVANCE 250MG/1.25MG MAL20051295A	MERCK SANTE S.A.S., FRANCE
55.	GLIMEPIRIDE AND METFORMIN HYDROCHLORIDE	AMARYL M 2/500MG TABLET MAL20091867AZ	HANDOK PHARMACEUTICALS CO. LTD., KOREA
		AMARYL M 1/250MG TABLET MAL20091866AZ	HANDOK PHARMACEUTICALS CO. LTD., KOREA
56.	HYDROCHLOROTHIAZIDE AND IRBESARTAN	COAPROVEL 300/25MG TABLET MAL08091408AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		COAPROVEL 300MG/12.5MG TABLET MAL20014478AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		COAPROVEL 150MG/12.5MG TABLET MAL20014479AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
57.	HYDROCHLOROTHIAZIDE AND LOSARTAN	FORTZAAR TABLET MAL20013017ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		HYZAAR TABLET 100/12.5MG MAL06081219ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		HYZAAR TABLET 50 / 12.5 MG MAL19990960ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
58.	HYDROCHLOROTHIAZIDE AND OLMESARTAN MEDOXOMIL	OLMETEC PLUS 40/25MG FILM-COATED TABLET MAL20071702ARZ	DAIICHI SANKYO EUROPE GMBH, GERMANY
		OLMETEC PLUS 40/12.5MG FILM-COATED TABLET MAL20071701ARZ	DAIICHI SANKYO EUROPE GMBH, GERMANY
		OLMETEC PLUS 20/12.5MG FILM-COATED TABLET	DAIICHI SANKYO EUROPE GMBH, GERMANY

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		MAL20071700ARZ	
59.	HYDROCHLOROTHIAZIDE DAN TELMISARTAN	MICARDIS PLUS 80/25MG TABLET, MAL09032035A	BOEHRINGER INGELHEIM, WEST GERMANY
		This product can be obtained from Philippines, Korea, Hong Kong, Germany, Switzerland, Poland, Netherlands, Belgium, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, Norway, Portugal, Cyprus, Slovakia, Slovenia, Austria, Sweden, Bulgaria, Canada, and United States. <i>(Source of information: Boehringer Ingelheim (M) Sdn Bhd, 2018).</i>	
		MICARDIS PLUS 40/12.5MG TABLET MAL20034439AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE BOEHRINGER INGELHEIM, WEST GERMANY
		MICARDIS PLUS 80/12.5MG TABLET MAL20034440AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE BOEHRINGER INGELHEIM, WEST GERMANY
60.	HYDROCHLOROTHIAZIDE AND TRIAMTERENE	DYAZIDE TABLET MAL19950581A	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
		DYAZIDE TABLET MAL19871039A	SMITHKLINE & FRENCH (AUST), AUSTRALIA
61.	HYDROCHLOROTHIAZIDE AND VALSARTAN	CO-DIOVAN 320/25MG FILM-COATED TABLET MAL09051534ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CO-DIOVAN 320/12.5MG FILM-COATED TABLET MAL09051533ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CO-DIOVAN 160/25MG FILM COATED TABLET MAL09062166ARSZ	NOVARTIS PHARMA S.P.A, ITALY
		CO-DIOVAN 160/12.5MG FILM-COATED TABLET MAL09062165ARSZ	NOVARTIS PHARMA S.P.A, ITALY

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		CO-DIOVAN 80/12.5MG FILM-COATED TABLET MAL09062164ARSZ	NOVARTIS FARMA S.P.A, ITALY
		CO-DIOVAN TABLETS MAL20000246A	NOVARTIS PHARMA AG, SWITZERLAND
62.	INDAPAMIDE AND PERINDOPRIL ARGININE	COVERSYL PLUS 10MG/2.5MG FILM-COATED TABLET MAL20091950AZ	SERVIER (IRELAND) INDUSTRIE LTD, IRELAND
		COVERSYL PLUS 5MG/1.25MG FILM-COATED TABLET MAL20081839AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
63.	INDAPAMIDE AND PERINDOPRIL TERT-BUTYLAMINE	COVERSYL PLUS 4MG/1.25MG TABLET MAL20013354AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		COVERSYL PLUS 4MG/1.25MG TABLET MAL09011458ACSZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
		PRETERAX TABLET MAL20020003AZ	LES LABS SERVIER INDUSTRIE, FRANCE
64.	ISONIAZID 150MG AND RIFAMPICIN 300MG	RIMACTAZID 300MG SUGAR COATED TABLET MAL19871621A	NOVARTIS SOUTH AFRICA (PTY) LTD, SOUTH AFRICA
		This product can be obtained from Egypt, Saudi Arabia and Spain . (Source of information: Novartis Corporation (M) Sdn. Bhd, 2016)	
65.	LAMIVUDINE 150MG AND ZIDOVUDINE 300MG	COMBIVIR TABLET MAL19991350ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
66.	LAMIVUDINE 300MG AND TENOFOVIR DISOPROXIL FUMARATE 300MG	LAMIHOPE-T (LAMIVUDINE 300MG AND TENOFOVIR DISOPROXIL FUMARATE 300MG FILM-COATED TABLETS) MAL20026052AZ	MACLEODS PHARMACEUTICALS LTD, INDIA
67.	LEDIPASVIR 90MG AND SOFOSBUVIR 400MG	HARVONI® (LEDIPASVIR 90MG/SOFOSBUVIR 400MG) FILM-COATED TABLETS MAL16035013AZ	GILEAD SCIENCES IRELAND UC, IRELAND
68.	LINAGLIPTIN AND METFORMIN HYDROCHLORIDE	TRAJENTA DUO 2.5MG / 1000MG FILM-COATED TABLETS MAL13025058AZ	BOEHRINGER INGELHEIM PROMECO S.A. DE C.V., MEXICO
		TRAJENTA DUO 2.5MG / 850MG FILM-COATED TABLETS MAL13025057AZ	BOEHRINGER INGELHEIM PROMECO S.A. DE C.V., MEXICO
		TRAJENTA DUO 2.5MG / 500MG FILM-COATED TABLETS MAL13025056AZ	BOEHRINGER INGELHEIM PROMECO S.A. DE C.V., MEXICO
69.	LOPINAVIR AND RITONAVIR	KALETRA FILM-COATED TABLET MAL08031363ARZ	ABBVIE DEUTSCHLAND GMBH & CO. KG, GERMANY
		KALETRA 100MG/25MG FILM-COATED TABLET MAL10063000AZ	ABBVIE DEUTSCHLAND GMBH & CO. KG, GERMANY
		KALETRA CAPSULES MAL20020995ACZ	CARDINAL HEALTH 409 INC, UNITED STATES
70.	METFORMIN HYDROCHLORIDE AND SITAGLIPTIN PHOSPHATE	JANUMET 50/1000MG MAL20081791ACRZ	PATHEON PUERTO RICO, INC, UNITED STATES MSD INTERNATIONAL GMBH, SINGAPORE
		JANUMET 50/850MG MAL20081790ACRZ	PATHEON PUERTO RICO, INC, UNITED STATES MSD INTERNATIONAL GMBH, SINGAPORE

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		JANUMET 50/500MG MAL20081789ACRZ	PATHEON PUERTO RICO, INC, UNITED STATES MSD INTERNATIONAL GMBH, SINGAPORE
71.	METFORMIN HYDROCHLORIDE AND VILDAGLIPTIN	GALVUS MET 50/1000MG FILM-COATED TABLET MAL20091865ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTD. LTD., SINGAPORE NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GALVUS MET 50/1000MG FILM-COATED TABLET MAL14125130ARSZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY
		GALVUS MET 50/850MG FILM-COATED TABLET MAL20091864ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTD. LTD., SINGAPORE NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GALVUS MET 50/850MG FILM-COATED TABLET MAL14125129ARSZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY
		GALVUS MET 50/500MG FILM-COATED TABLET MAL12035005ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTD. LTD., SINGAPORE NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GALVUS MET 50/500MG FILM-COATED TABLET MAL14125131ARSZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY
72.	MONTELUKAST 10MG AND	GLENCET M FILM COATED TABLET MAL23046005AZ	GLENMARK PHARMACEUTICALS LIMITED (INDIA)

**LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE
(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	LEVOCETIRIZINE DIHYDROCHLORIDE 5MG		
73.	ORPHENADRINE CITRATE 35MG AND PARACETAMOL 450MG	NORGESIC TABLET MAL13115130ACZ	ADCOCK INGRAM LIMITED - A MEDREICH GROUP COMPANY, INDIA
		NORGESIC TABLET MAL19871086A	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
74.	PARACETAMOL 500MG AND IBUPROFEN 150MG	MAXIGESIC 500MG/150MG FILM COATED TABLET MAL15125050ACZ	SIGMA LABORATORIES PVT. LTD, INDIA
75.	PARACETAMOL 500MG AND PHENYLEPHRINE HYDROCHLORIDE 5MG	PANADOL COLD+FLU-ND CAPLET MAL09062126ACRZ	ASPEN PHARMA PTY LTD, AUSTRALIA
		PANADOL SINUS RELIEF PE CAPLET MAL09062126AZ	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
76.	PARACETAMOL 500MG AND PSEUDOEPHEDRINE HYDROCHLORIDE 30MG	PANADOL C TABLET MAL19950231AZ	STERLING DRUG (MALAYA) SDN BHD, MALAYSIA
77.	PARACETAMOL 325MG AND TRAMADOL HYDROCHLORIDE 37.5MG	ULTRACET TABLET MAL20051462AZ	JANSSEN CILAG SPA, ITALY
			JANSSEN KOREA LTD, KOREA
78.	PHENYLEPHRINE HYDROCHLORIDE 10MG + TRIPROLIDINE HYDROCHLORIDE 2.5MG	ACTIDIL TABLET 2.5MG MAL19890070A	THE WELLCOME FOUNDATION LTD, LONDON, UNITED KINGDOM
		+ CODRAL RELIEF DECONGESTANT	JOHNSON & JOHNSON AUSTRALIA
79.	PSEUDOEPHEDRINE HYDROCHLORIDE 60MG AND	ACTIFED TABLET MAL19860267A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM

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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	TRIPROLIDINE HYDROCHLORIDE 2.5MG		WELLCOME LTD, AUSTRALIA
		ACTIFED TABLET MAL19989031AC	PARKE DAVIS PTY LTD, AUSTRALIA
		Products can be obtained from Korea, Singapore, Vietnam, Cambodia, Indonesia, Sri Lanka, India and Thailand. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2012)</i>	
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014" – 18 August 2014, Actifed Tablet from Aspen bad Oldesloe, Germany, GSK Pulogadung, Indonesia and Samil Pharm, Republic of Korea are allowed to be used as comparator.	
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015, 7 September 2015, the following product is being added as additional comparator in Malaysia.	
		FEDAC TABLET MAL19900594AZ	PT ACTAVIS, INDONESIA DRUG HOUSES OF AUSTRALIA PTE LTD, SINGAPORE
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016' – 13 January 2017, Actifed Tablet from Glaxo Wellcome GmbH & Co., Bad Oldesloe, Germany is allowed to be used as a comparator.	
80.	PYRIMETHAMINE 25MG AND SULFADOXINE 500MG	FANSIDAR ROCHE TABLET MAL19871340ARZ	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
81.	SACUBITRIL AND VALSARTAN	ENTRESTO 200MG FILM-COATED TABLETS MAL15125063ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTE. LTD., SINGAPORE NOVARTIS FARMA S.P.A, ITALY
		ENTRESTO 100MG FILM-COATED TABLETS MAL15125062ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTE. LTD., SINGAPORE

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(FIXED DOSE COMBINATION)**

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
			NOVARTIS FARMA S.P.A, ITALY
		ENTRESTO 50MG FILM-COATED TABLETS MAL15125061ARZ	NOVARTIS SINGAPORE PHARMACEUTICAL MANUFACTURING PTE. LTD., SINGAPORE NOVARTIS FARMA S.P.A, ITALY
82.	SULPHADIAZINE 410MG AND TRIMETHOPRIM 90MG	TRIGLOBE TABLET 500MG MAL19870919AR	ASTRAZENECA SWEDEN, SWEDEN
83.	SULPHAMETHOXAZOLE 400MG AND TRIMETHOPRIM 80MG.	BACTRIM ROCHE TABLET MAL19870887A	F. HOFFMAN LA ROCHE LTD, SWITZERLAND
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013 – 13 March 2013, Bactrim Tablet from Roche Toluca, Mexico and Roche (Phillipine) Inc, Filipina are allowed to be used as a comparator.	
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014" – 18th August 2014, the following product is being added as additional comparator in Malaysia.	
		PHARMANIAGA CO-TRIMOXAZOLE TABLET MAL19871882AZ	PHARMANIAGA MANUFACTURING BERHAD

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 29/4/2024