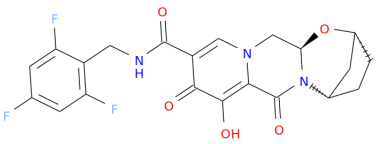
LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

Supported by



Bictegravir (BIC)

Developer(s)

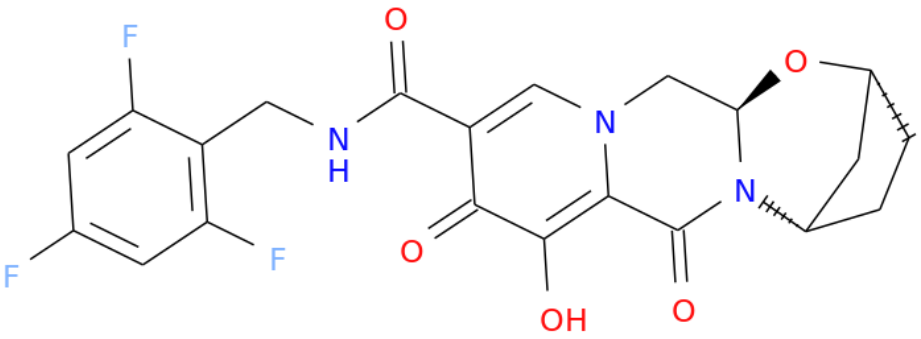
Gilead Sciences, Inc.

Originator

https://www.gilead.com/

United States

Drug structure



Bictegravir chemical structure

MedChemExpress

Drug information

Associated long-acting platforms

Oral solid form

Administration route

Oral

Therapeutic area(s)

HIV

Use case(s)

Treatment

Use of drug

Ease of administration

Self-administered

Frequency of administration

Other/Variable/Unknown : once daily within regimen

User acceptance

Not provided

Dosage

Available dose and strength

various fixed dose combinations

Maximum dose

Not provided

Recommended dosing regimen

Not provided

Additional comments

Not provided

Dosage link(s)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210251s000lbl.pdf
https://www.ema.europa.eu/en/documents/product-information/biktarvy-epar-product-information_en.pdf

Drug information

Drug's link(s)

Not provided

Generic name

https://go.drugbank.com/drugs/DB11799

Brand name

One of the three compounds of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

Compound type

Small molecule

Drug class/category

Integrase strand transfer inhibitor (INSTI)

Summary

Bictegravir is an integrase inhibitor used to treat HIV infections. Alternative names are GS-9883 and GS-9883-01. Bictegravir is used in combination with tenofovir alafenamide and emtricitabine to treat human immunodeficiency virus-1 (HIV-1) infection.

Approval status

In the US, it may be used in treatment-naive patients weighing at least 14 kg. Alternatively, it may be used to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir. In Europe, it is approved for use in patients 2

years of age and older with evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.

Regulatory authorities

Approved in many HICs and LMICs

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

Not provided

Tentative equipment list for manufacturing

Not provided

Manufacturing

Not provided

Specific analytical instrument required for characterization of formulation

Not provided

Clinical trials

Not provided

Excipients

Proprietary excipients used

No proprietary excipient used

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Patent info

Compound patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Bictegravir sodium Expiry date: 2035-06-19 The present Invention relates to sodium (2R,5S,13aR)-7,9-dioxo-10 -((2,4,6-trifluorobenzyl)carbamoyl)-2,3,4,5,7,9,13,13a-octahydro-2,5-methanopyrido[1',2':4,5] pyrazino[2,1-b][1,3]oxazepin-8-olate Form I.	WO2015196116	Compound	Gilead Sciences Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Argentina, China, Cuba, Dominican Republic, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Bosnia and Herzegovina, Montenegro, Moldova, Republic of, Mexico, Peru, Philippines, El Salvador, Benin, Cameroon, Burkina Faso, Chad, Guinea-Bissau, Comoros, Mali, Senegal, Congo, Guinea, Gabon, Niger, Equatorial Guinea, Mauritania, Togo, Côte d'Ivoire, Central African Republic, Bolivia (Plurinational State of), Brazil, Colombia, Malaysia, Nigeria, Pakistan, South Africa, Ukraine	Canada, Australia, Israel, Japan, Korea, Republic of, Singapore, Taiwan, Province of China, United States of America, Chile, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Malta, Norway, Romania, Latvia, Lithuania, Slovenia, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates, Panama, Trinidad and Tobago, New Zealand, Bahamas, Hong Kong, Macao
Filed	Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia	Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia, Hong Kong

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), China, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Morocco, Moldova, Republic of, India, Botswana, Gambia (the), Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Sao Tome and Principe, Sudan, Eswatini, Tanzania, United Republic of, Zambia, Zimbabwe, Ecuador, Egypt, Guatemala, Indonesia, Paraguay, South Africa, Venezuela (Bolivarian Republic of), Viet Nam, Thailand	Japan, United States of America, World Intellectual Property Organization (WIPO), Costa Rica, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia, Uruguay, New Zealand, Hong Kong

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Bictegravir synthesis Expiry date: 2035-06-16 Methods of making compounds of Formula (I) are disclosed.	WO2015195656	Process	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Argentina, China, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, Montenegro, Mexico, Brazil, India	Canada, Australia, Israel, Japan, Korea, Republic of, Singapore, Taiwan, Province of China, United States of America, Russian Federation, Belgium, Germany, France, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Portugal, Ireland, Czechia, Slovakia, Hungary, Poland, Norway, Slovenia, New Zealand, Hong Kong, Macao
Filed	Argentina	Singapore, United States of America, Bahamas, Hong Kong
Not in force	World Intellectual Property Organization (WIPO), China, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Morocco, Mexico	Australia, Israel, United States of America, World Intellectual Property Organization (WIPO), Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Bictegravir compounds Expiry date: 2033-12-19 Compounds for use in the treatment of human immunodeficiency virus (HIV) infection are disclosed. The compounds have the following Formula (I): including stereoisomers and pharmaceutically acceptable salts thereof, wherein R1, X, W, Y1, Y2, &Zgr;1 and Z4 are as defined herein. Methods associated with preparation and use of such compounds, as well as pharmaceutical compositions comprising such compounds, are also disclosed.	WO2014100323	Compound	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income

Granted	Argentina, Brazil, China, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Moldova, Republic of, Mexico, Peru, Philippines, Botswana, Gambia (the), Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Sudan, Eswatini, Tanzania, United Republic of, Uganda, Zambia, Zimbabwe, El Salvador, Ethiopia, Fiji, India, Benin, Cameroon, Burkina Faso, Chad, Guinea-Bissau, Comoros, Mali, Senegal, Congo, Guinea, Gabon, Niger, Equatorial Guinea, Mauritania, Togo, Côte d'Ivoire, Central African Republic, Colombia, Grenada, Indonesia, Kiribati, Pakistan, Paraguay, Solomon Islands, South Africa, Tuvalu, Ukraine, Viet Nam, Malaysia, Saint Lucia	Canada, Australia, Hong Kong, Israel, Japan, Korea, Republic of, New Zealand, Singapore, United States of America, Chile, Costa Rica, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, Croatia, Romania, Latvia, Lithuania, Slovenia, Anguilla, Bermuda, Falkland Islands (Malvinas), Montserrat, Panama, Seychelles, Turks and Caicos Islands, Bahamas, Guyana, Gibraltar, Jersey, Macao, Guernsey
Filed	Brazil, China, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Bolivia (Plurinational State of), Ecuador, El Salvador, Congo, democratic Republic of the, Indonesia, Jamaica, Nepal, Thailand, Venezuela (Bolivarian Republic of)	Canada, Australia, Israel, Japan, Taiwan, Province of China, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates
Not in force	World Intellectual Property Organization (WIPO), Argentina, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, North Macedonia, Albania, Bosnia and Herzegovina, Serbia, Moldova, Republic of, Mexico, Philippines, Uganda, Egypt	Israel, Japan, Korea, Republic of, United States of America, World Intellectual Property Organization (WIPO), Costa Rica, Russian Federation, Spain, Monaco, Malta, San Marino, Uruguay

Supporting material

Publications

There are no publication

Additional documents

No documents were uploaded

Useful links

There are no additional links

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Not provided