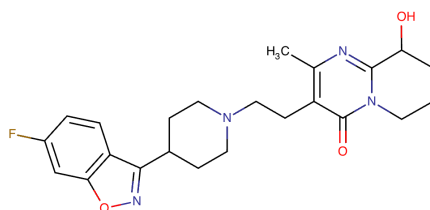


Developed by



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## Paliperidone

## Developer(s)

Janssen/Johnson & Johnson

Originator

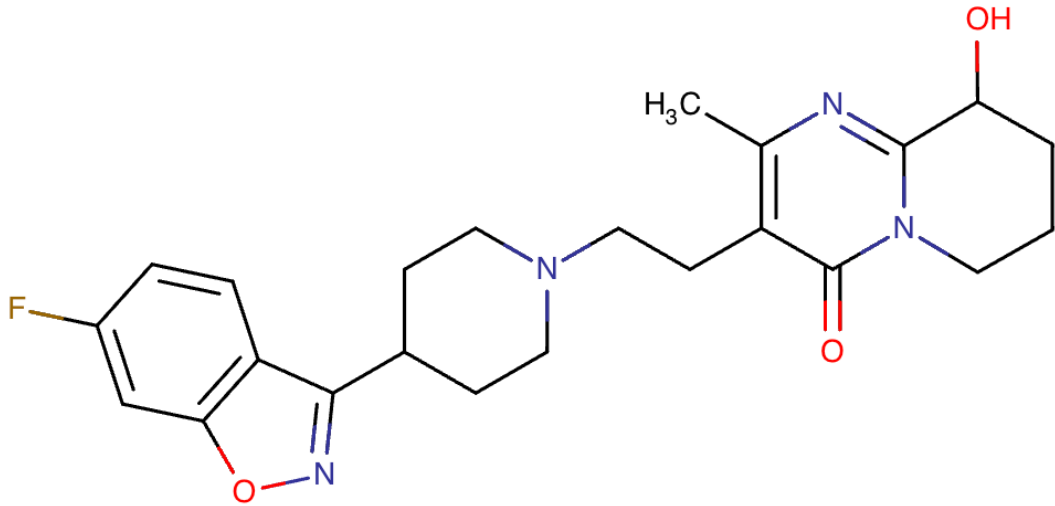
<https://www.janssen.com/>

Belgium



Janssen Pharmaceuticals is a subsidiary company of Johnson & Johnson headquartered in Beerse, Belgium. They focus on manufacturing and developing pharmaceutical products for use in areas such as, Immunology, Infectious Diseases & Vaccines, Pulmonary Hypertension, Cardiovascular & Metabolism, Oncology, and Neuroscience.

## Drug structure



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Paliperidone Chemical Structure

Sourced From DrugBank

# Drug information

## Associated long-acting platforms

Not provided

## Administration route

Oral, Intramuscular

## Therapeutic area(s)

Mental health

## Use case(s)

Treatment

## Use of drug

### Ease of administration

Administered by a nurse

Administered by a specialty health worker

Self-administered

### Frequency of administration

Not provided

### User acceptance

Not provided

## Dosage

### Available dose and strength

Not provided

### Maximum dose

Not provided

### Recommended dosing regimen

Not provided

### Additional comments

Not provided

### Dosage link(s)

Not provided

## Drug information

### Drug's link(s)

Not provided

### Generic name

Paliperidone Palmitate

### Brand name

Not provided

### Compound type

Small molecule

### Drug class/category

Not provided

### Summary

Paliperidone is an atypical antipsychotic drug indicated for the treatment of both schizophrenia & schizoaffective disorder. Paliperidone is the primary active metabolite of risperidone and functions by strongly binding to dopaminergic D2- and serotonergic 5-HT<sub>2</sub>-receptors and selectively blocking monoamine effects. Although paliperidone is a potent D<sub>2</sub>-antagonist, it has less of impact on motor function and catalepsy than traditional neuroleptics. Paliperidone palmitate is the palmitate ester prodrug of paliperidone and displays modest solubility in polar solvents. Several long-acting injectable aqueous nanocrystal formulations of paliperidone palmitate are available as once-monthly (PP1M), three-monthly (PP3M) and six-monthly (PP6M) extended-release suspensions for intramuscular injection.

### Approval status

Unknown

## **Regulatory authorities**

Unknown

## **Delivery device(s)**

Not provided

# **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**

Not provided

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

Not provided

## **Residual solvents used**

Not provided

## Patent info

# Compound patent families

## Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Paliperidone dosing regimen Expiry date: 2028-12-17 The present invention provides a method of treating patients in need of treatment with long acting injectable paliperidone palmitate formulations.	WO2009080651	Dose/Regimen	Janssen Pharmaceutica Nv	No	

## Patent status

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

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Granted	Belarus, Azerbaijan, Moldova, Republic of, Armenia, Kazakhstan, Albania, Serbia, Bosnia and Herzegovina, Türkiye, North Macedonia, Ukraine, Malaysia, Philippines, Mexico, Sri Lanka, South Africa	Australia, Canada, Russian Federation, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Hong Kong, Japan, Korea, Republic of, New Zealand, United States of America, Singapore
Filed	Ecuador, Guatemala, Nicaragua, Indonesia	Finland, Hong Kong, Israel, Korea, Republic of
Not in force	World Intellectual Property Organization (WIPO), Brazil, China, Colombia, Tajikistan, Turkmenistan, Kyrgyzstan, Albania, Serbia, Bosnia and Herzegovina, Türkiye, North Macedonia, India	World Intellectual Property Organization (WIPO), Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Israel, United States of America

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## Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
<p>Paliperidone depot formulation for injection</p> <p>Expiry date: 2018-11-10</p> <p>The present invention is concerned with a pharmaceutical composition suitable as a depot formulation for administration via intramuscular or subcutaneous injection, comprising:</p> <p>(1) as an active ingredient a therapeutically effective amount of a 9-hydroxy-risperidone fatty acid ester or a salt, or a stereoisomer or a stereoisomeric mixture thereof in submicron form and (2) a pharmaceutically acceptable carrier; wherein the pharmaceutically acceptable carrier is water and the active ingredient is suspended therein: and with a process of preparing such a composition. The invention further concerns such a pharmaceutical composition for use as a medicament in the treatment of psychosis, schizophrenia, schizoaffective disorders, non-schizophrenic psychoses, behavioural disturbances associated with neurodegenerative disorders, e.g. in dementia, behavioural disturbances in mental retardation and autism, Tourette's syndrome, bipolar mania, depression, anxiety.</p>	WO9925354	Composition	Janssen Pharmaceutica N.V	No	

## Patent status

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

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

Filed

Not in force

World Intellectual Property Organization (WIPO), Eswatini, Uganda, Zambia, Zimbabwe, Malawi, Ghana, Sudan, Botswana, Lesotho, Kenya, Gambia (the), Argentina, Brazil, China, Tajikistan, Belarus, Azerbaijan, Moldova, Republic of, Turkmenistan, Armenia, Kyrgyzstan, Kazakhstan, Albania, North Macedonia, Indonesia, Malaysia, Congo, Mauritania, Guinea-Bissau, Niger, Senegal, Cameroon, Mali, Togo, Burkina Faso, Benin, Côte d'Ivoire, Central African Republic, Guinea, Gabon, Chad, Türkiye, Ukraine, South Africa, Viet Nam, Mexico

World Intellectual Property Organization (WIPO), Australia, Bulgaria, Canada, Czechia, Russian Federation, Estonia, Liechtenstein, Italy, Denmark, Belgium, United Kingdom, Greece, Netherlands, Switzerland, Spain, Slovenia, Austria, Romania, Cyprus, Finland, France, Latvia, Ireland, Germany, Luxembourg, Portugal, Lithuania, Monaco, Sweden, Hong Kong, Croatia, Hungary, Israel, Japan, Korea, Republic of, Norway, New Zealand, Poland, Slovakia, United States of America, Singapore, Brunei Darussalam

## Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
<p>Paliperidone aqueous suspensions</p> <p>Expiry date: 2017-05-12</p> <p>The present invention is concerned with a pharmaceutical composition suitable as a depot formulation for administration via intramuscular or subcutaneous injection, comprising:</p> <p>(1) as an active ingredient a therapeutically effective amount of a 9-hydroxyrisperidone fatty acid ester or a salt, or a stereoisomer or a stereoisomeric mixture thereof and (2) a pharmaceutically acceptable carrier; wherein the pharmaceutically acceptable carrier is water and the active ingredient is suspended therein; and with a process of preparing such a composition. The invention further concerns such a pharmaceutical composition for use as a medicament in the treatment of schizophrenia, non-schizophrenic psychoses, behavioural disturbances associated with neurodegenerative disorders, e.g. in dementia, behavioural disturbances in mental retardation and autism, bipolar mania, depression, anxiety.</p>	WO9744039	Composition	JANSSEN PHARMACEUTICA NV [BE]	No	

## Patent status

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

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

Not in force

World Intellectual Property Organization (WIPO), Argentina, Brazil, China, Tajikistan, Belarus, Azerbaijan, Moldova, Republic of, Turkmenistan, Armenia, Kyrgyzstan, Kazakhstan, Albania, Indonesia, Mexico, Malaysia, Türkiye, Ukraine, South Africa

World Intellectual Property Organization (WIPO), Australia, Bulgaria, Canada, Cyprus, Czechia, Germany, Russian Federation, Estonia, Liechtenstein, Italy, Denmark, Belgium, United Kingdom, Greece, Netherlands, Switzerland, Spain, Slovenia, Austria, Romania, Finland, France, Latvia, Ireland, Luxembourg, Portugal, Lithuania, Monaco, Sweden, Hong Kong, Croatia, Hungary, Israel, Japan, Korea, Republic of, Norway, New Zealand, Poland, Slovakia, Taiwan, Province of China, United States of America

## Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
<p>Paliperidone compound and analogues and their use as antipsychotics</p> <p>Expiry date: 2009-10-16</p> <p>There is disclosed a process for preparing an enantiomeric form of the compound having the formula:or a pharmaceutically acceptable acid addition salt thereof,wherein said process comprises the steps of:(a) reacting a racemic mixture of said compound with a chiral acid or acid chloride selected from the group consisting of tartaric acid, malic acid, mandelic acid, camphor sulfonic acid, 4,5-dihydro-1H-2-benzopyran-2-carboxylic acid, and the acid chlorides thereof, to form a mixture of diastereomeric salts or esters;(b) physically separating said mixture of diastereomeric salts or esters by selective crystallization or chromatography; and(c) converting said separated diastereomeric salts or esters into the corresponding enantiomeric forms of said compound by hydrolysis in an acidic or basic aqueous medium.</p>	CA2000786	Compound	Janssen Pharmaceutica, N. V	No	

## Patent status

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

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

Not in force

South Africa

Canada, Australia, Chile, Cyprus, Germany, Denmark, Liechtenstein, Italy, Belgium, United Kingdom, Greece, Netherlands, Switzerland, Spain, Austria, France, Luxembourg, Sweden, Finland, Hong Kong, Ireland, Israel, Japan, Korea, Republic of, Norway, New Zealand, Portugal, United States of America



# 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