

**PALIPERIDONE PALMITATE- paliperidone palmitate**  
**TOLMAR Inc.**

**Paliperidone Palmitate Extended-Release Injectable Suspension**

**PRINCIPAL DISPLAY PANEL**

**FOR EXPORT ONLY**

NDC 63646-711-39

**Paliperidone Palmitate Extended-Release  
Injectable Suspension**


**39 mg**

**R<sub>x</sub> only**

Each 0.25 mL prefilled plastic syringe contains: 39 mg paliperidone palmitate, polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide and water for injection.

Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.

Manufactured by:  
Tolmar, Inc.  
Fort Collins, CO 80526



**FOR EXPORT ONLY**

NDC 63646-712-78

**Paliperidone Palmitate Extended-Release  
Injectable Suspension**


**78 mg**

**R<sub>x</sub> only**

Each 0.5 mL prefilled plastic syringe contains: 78 mg paliperidone palmitate, polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide and water for injection.

Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.

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Tolmar, Inc.  
Fort Collins, CO 80526



**FOR EXPORT ONLY**

NDC 63646-713-17

**Paliperidone Palmitate Extended-Release  
Injectable Suspension**

**117 mg**

**R<sub>x</sub> only**

Each 0.75 mL prefilled plastic syringe contains: 117 mg paliperidone palmitate, polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide and water for injection.

Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.



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**FOR EXPORT ONLY**

NDC 63646-710-56

**Paliperidone Palmitate Extended-Release  
Injectable Suspension**

**156 mg**

**R<sub>x</sub> only**

Each 1 mL prefilled plastic syringe contains: 156 mg paliperidone palmitate, polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide, and water for injection.

Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.



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**FOR EXPORT ONLY**

NDC 63646-714-34

**Paliperidone Palmitate Extended-Release  
Injectable Suspension**

**234 mg**

**R<sub>x</sub> only**

Each 1.5 mL prefilled plastic syringe contains: 234 mg paliperidone palmitate, polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide and water for injection.

Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.



Manufactured by:  
Tolmar, Inc.  
Fort Collins, CO 80526

# PALIPERIDONE PALMITATE

paliperidone palmitate kit

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63646-711
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-711-39	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2022	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 SYRINGE	0.25 mL

## Part 1 of 1

# PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

## Product Information

<b>Item Code (Source)</b>	NDC:63646-701
<b>Route of Administration</b>	INTRAMUSCULAR

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PALIPERIDONE PALMITATE</b> (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	39 mg in 0.25 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-701-39	0.25 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2022	

## PALIPERIDONE PALMITATE

paliperidone palmitate kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63646-712
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-712-78	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2022	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 SYRINGE	0.5 mL

## Part 1 of 1

## PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

### Product Information

<b>Item Code (Source)</b>	NDC:63646-702
<b>Route of Administration</b>	INTRAMUSCULAR

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PALIPERIDONE PALMITATE</b> (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	78 mg in 0.5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-702-78	0.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2022	

## PALIPERIDONE PALMITATE

paliperidone palmitate kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63646-713
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-713-17	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2022	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 SYRINGE	0.75 mL

## Part 1 of 1

### PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

## Product Information

Item Code (Source)	NDC:63646-703
Route of Administration	INTRAMUSCULAR

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PALIPERIDONE PALMITATE (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	117 mg in 0.75 mL

## Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-703-17	0.75 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2022	

## PALIPERIDONE PALMITATE

paliperidone palmitate kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63646-710
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-710-56	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 SYRINGE	1 mL

## Part 1 of 1

## PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

### Product Information

Item Code (Source)	NDC:63646-700
Route of Administration	INTRAMUSCULAR

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PALIPERIDONE PALMITATE (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	156 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HF16D95)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-700-56	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2022	

## PALIPERIDONE PALMITATE

paliperidone palmitate kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63646-714
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-714-34	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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<b>Part 1</b>	1 SYRINGE	1.5 mL
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## Part 1 of 1

### PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

#### Product Information

<b>Item Code (Source)</b>	NDC:63646-704
<b>Route of Administration</b>	INTRAMUSCULAR

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PALIPERIDONE PALMITATE</b> (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	234 mg in 1.5 mL

#### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63646-704-34	1.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Export only		01/01/2022	
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**Labeler - TOLMAR Inc. (791156578)**

**Establishment**

Name	Address	ID/FEI	Business Operations
TOLMAR, INC.		079112310	analysis(63646-711, 63646-701, 63646-712, 63646-702, 63646-713, 63646-703, 63646-710, 63646-700, 63646-714, 63646-704) , label(63646-711, 63646-701, 63646-712, 63646-702, 63646-713, 63646-703, 63646-710, 63646-700, 63646-714, 63646-704) , manufacture(63646-711, 63646-701, 63646-712, 63646-702, 63646-713, 63646-703, 63646-710, 63646-700, 63646-714, 63646-704) , pack(63646-711, 63646-701, 63646-712, 63646-702, 63646-713, 63646-703, 63646-710, 63646-700, 63646-714, 63646-704)

Revised: 1/2024

TOLMAR Inc.