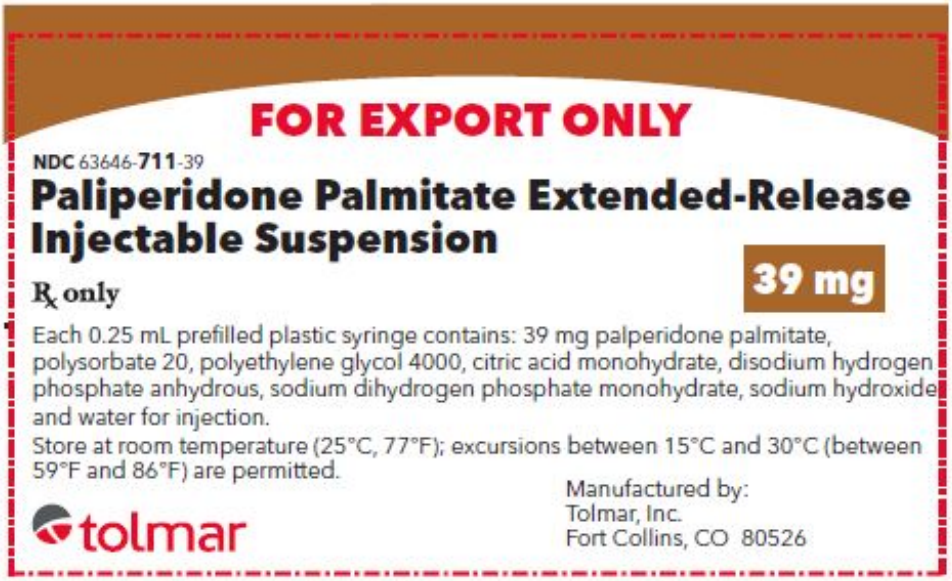
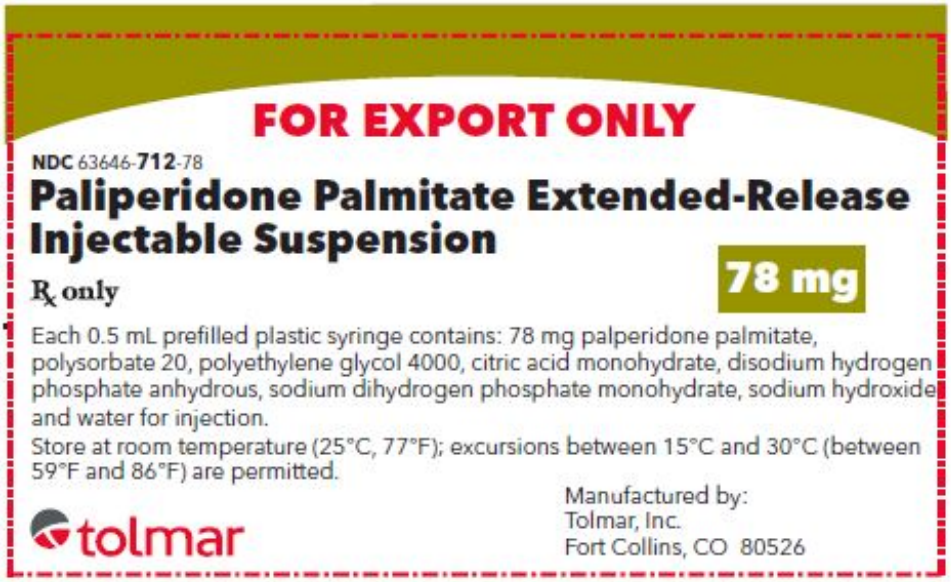
PALIPERIDONE PALMITATE- paliperidone palmitate
TOLMAR Inc.

Paliperidone Palmitate Extended-Release Injectable Suspension

PRINCIPAL DISPLAY PANEL





FOR EXPORT ONLY

NDC 63646-**713**-17

Paliperidone Palmitate Extended-Release Injectable Suspension

117 mg

℞ only

Each 0.75 mL prefilled plastic syringe contains: 117 mg palperidone 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.

tolmar

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

FOR EXPORT ONLY

NDC 63646-**710**-56

Paliperidone Palmitate Extended-Release Injectable Suspension

156 mg

℞ only

Each 1 mL prefilled plastic syringe contains: 156 mg palperidone 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.

tolmar

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

FOR EXPORT ONLY

NDC 63646-**714**-34

Paliperidone Palmitate Extended-Release Injectable Suspension

234 mg

℞ only

Each 1.5 mL prefilled plastic syringe contains: 234 mg palperidone 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.

tolmar

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

PALIPERIDONE PALMITATE

paliperidone palmitate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63646-711

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	
Item Code (Source)	NDC:63646-701
Route of Administration	INTRAMUSCULAR

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PALIPERIDONE PALMITATE (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	39 mg in 0.25 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
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:63646-701-39	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

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

Item Code (Source)	NDC:63646-702
Route of Administration	INTRAMUSCULAR

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
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:63646-702-78	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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63646-713

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: 4R4HFI6D95)	
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

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**
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
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:63646-700-56	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			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63646-714

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**

Part 1	1 SYRINGE	1.5 mL

Part 1 of 1

PALIPERIDONE PALMITATE

paliperidone palmitate injection, suspension, extended release

Product Information	
Item Code (Source)	NDC:63646-704
Route of Administration	INTRAMUSCULAR

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PALIPERIDONE PALMITATE (UNII: R8P8USM8FR) (PALIPERIDONE - UNII:838F01T721)	PALIPERIDONE PALMITATE	234 mg in 1.5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
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:63646-704-34	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	

Labeler - TOLMAR Inc. (791156578)

Establishment

Name	Address	ID/FEI	Business Operations
TOLMAR 1201 Cornerstone LLC		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: 1/2022 TOLMAR Inc.