

**ONDANSETRON- ondansetron tablet, film coated  
DIRECT RX**

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**ONDANSETRON 4mg**

**DESCRIPTION**

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**CLINICAL PHARMACOLOGY**

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**INDICATIONS AND USAGE**

1. Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy.
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
3. Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
4. Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, ondansetron tablets, USP are recommended even where the incidence of postoperative nausea and/or vomiting is low.

**CONTRAINDICATIONS**

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**WARNINGS**

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**ADVERSE REACTIONS**

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**DRUG ABUSE AND DEPENDENCE**

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**OVERDOSAGE**

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**DOSAGE AND ADMINISTRATION**

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**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL**

**D** **ONDANSETRON**  
4mg 20 Tabs

Generic For: **ZOFRAN**  
Each film-coated tablet contains: Ondansetron hydrochloride USP (dihydrate) equivalent to 4mg of ondansetron

Lot# Discard After: 04/18  
Prod# 565-20

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg For: Aurichindo Pharma USA, Inc. Dayton, NJ 08810  
NDC 65862-187-30

Mfg Lot: 3/23/2016

**AP4LLF**  
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.  
**RX ONLY-KEEP OUT OF REACH OF CHILDREN**  
Dosage: See package insert. Store between 68-77 degrees F

**M**  
NDC 61919-565-20

**May cause drowsiness or dizziness.**

ONDANSETRON 4mg  
NDC 61919-565-20 20  
Lot Exp Date 04/18  
Mfg NDC 65862-187-30

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ONDANSETRON 4mg  
NDC 61919-565-20 20  
Lot Exp Date 04/18  
Mfg NDC 65862-187-30

**D** **ONDANSETRON**  
4mg 10 Tabs

Generic For: **ZOFRAN**  
Each film-coated tablet contains: Ondansetron hydrochloride USP (dihydrate) equivalent to 4mg of ondansetron

Lot# Discard After: 01/20  
Prod# 565-10

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg For: Aurichindo Pharma USA, Inc. Dayton, NJ 08810  
NDC 65862-187-30

Mfg Lot: 8/21/2018

**AP4L7**  
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.  
**RX ONLY-KEEP OUT OF REACH OF CHILDREN**  
Dosage: See package insert. Store between 68-77 degrees F

**M**  
NDC 61919-565-10

**May cause drowsiness or dizziness.**

ONDANSETRON 4mg  
NDC 61919-565-10 10 Tabs  
Lot Exp Date 01/20  
Mfg NDC 65862-187-30

ONDANSETRON 4mg  
NDC 61919-565-10 10 Tabs  
Lot Exp Date 01/20  
Mfg NDC 65862-187-30

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ONDANSETRON 4mg  
NDC 61919-565-10 10 Tabs  
Lot Exp Date 01/20  
Mfg NDC 65862-187-30

<b>ONDANSETRON</b>			
ondansetron tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:61919-565(NDC:65862-187)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
ONDANSETRON HYDROCHLORIDE (UNII: NMH84OZK2B) (ONDANSETRON - UNII:4AF302ESOS)		ONDANSETRON	4 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
STARCH, CORN (UNII: O8232NY3SJ)			

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSE 2910 (6 MPAS)</b> (UNII: 0WZ8WG20P6)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	white (WHITE TO OFF WHITE)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	F;91
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-565-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2016	
2	NDC:61919-565-10	1 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078539	03/23/2016	

**Labeler** - DIRECT RX (079254320)

### Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-565)

Revised: 9/2018

DIRECT RX