ONDANSETRON- ondansetron tablet, film coated
DIRECT RX

ONDANSETRON 4mg

DESCRIPTION

-

CLINICAL PHARMACOLOGY

-

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

-

WARNINGS

-

ADVERSE REACTIONS

-

DRUG ABUSE AND DEPENDENCE

-

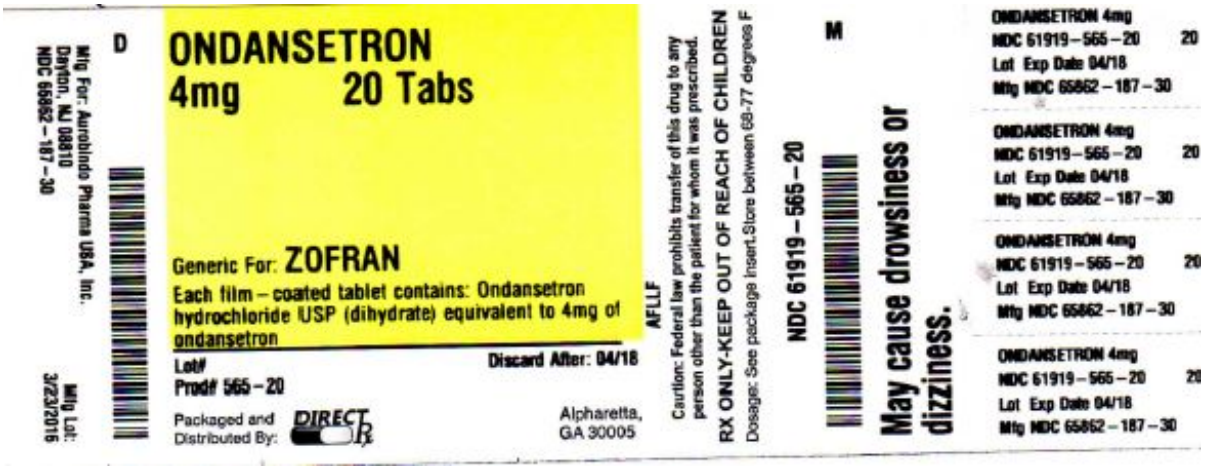
OVERDOSAGE

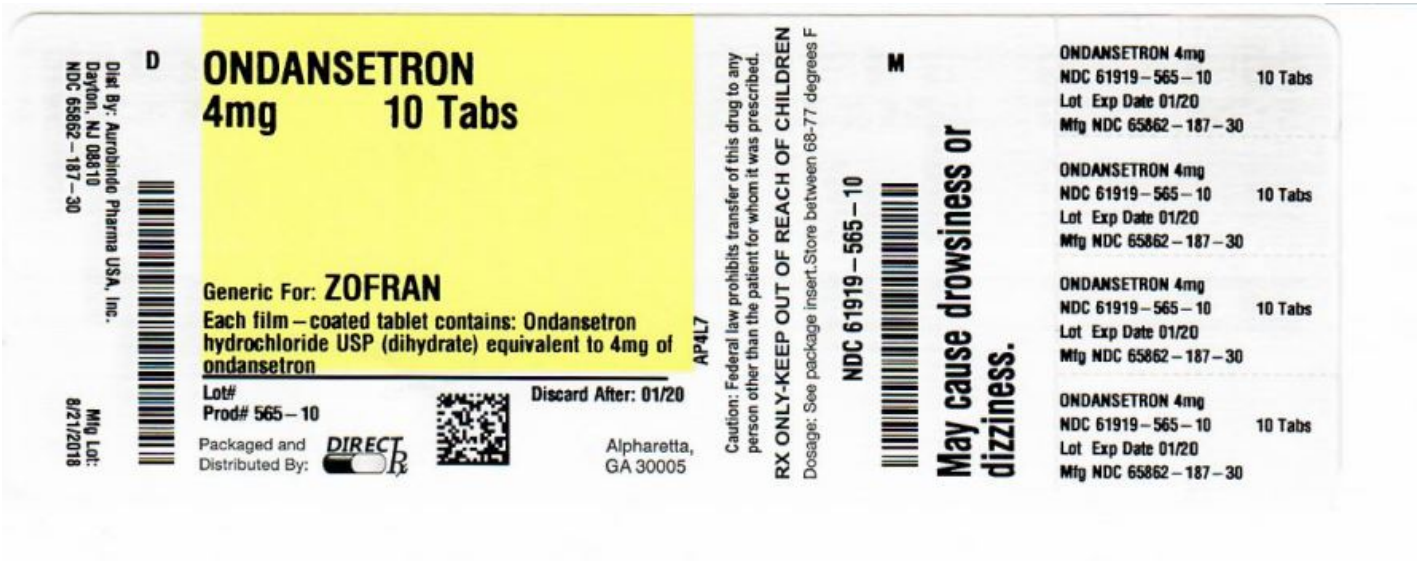
-

DOSAGE AND ADMINISTRATION

-

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL





ONDANSETRON

ondansetron tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-565(NDC:65862-187)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ONDANSETRON HYDROCHLORIDE (UNII: NMH84OZK2B) (ONDANSETRON - UNII:4AF302ESOS)	ONDANSETRON	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	white (WHITE TO OFF WHITE)	**Score**	no score
Shape	OVAL	**Size**	6mm
Flavor		**Imprint Code**	F;91
Contains			

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