ZOFRAN- ondansetron hcl 8mg tablet, film coated
Advanced Rx Pharmacy of Tennessee, LLC

Ondansetron HCl 8mg tablets #30

Dosage and Administration Section

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

The recommended dosage regimens for adult and pediatric patients are described in Table 1 and Table 2, respectively.

Corresponding doses of ondansetron tablets, ondansetron orally disintegrating tablets and ondansetron oral solution may be used interchangeably.

Table 1: Adult Recommended Dosage Regimen for Prevention of Nausea and Vomiting
Indication
Dosage Regimen
Highly Emetogenic Cancer Chemotherapy
A single 24 mg dose administered 30 minutes before the start of single-day highly emetogenic chemotherapy, including cisplatin greater than or equal to 50 mg/m2
Moderately Emetogenic Cancer Chemotherapy
8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8 mg dose 8 hours after the first dose.

Then administer 8 mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.
Radiotherapy
For total body irradiation: 8 mg administered 1 to 2 hours before each fraction of radiotherapy each day.

For single high-dose fraction radiotherapy to the abdomen: 8 mg administered 1 to 2 hours before radiotherapy, with subsequent 8 mg doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy.

For daily fractionated radiotherapy to the abdomen: 8 mg administered 1 to 2 hours before radiotherapy, with subsequent 8 mg doses every 8 hours after the first dose for each day radiotherapy is given.
Postoperative
16 mg administered 1 hour before induction of anesthesia.

Table 2: Pediatric Recommended Dosage Regimen for Prevention of Nausea and Vomiting
Indication
Dosage Regimen
Moderately Emetogenic Cancer Chemotherapy
12 to 17 years of age: 8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8 mg dose 8 hours after the first dose.

Then administer 8 mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

4 to 11 years of age: 4 mg administered 30 minutes before the start of chemotherapy, with a subsequent 4 mg dose 4 and 8 hours after the first dose.

Then administer 4 mg three times a day for 1 to 2 days after completion of chemotherapy.

2.2 Dosage in Hepatic Impairment

In patients with severe hepatic impairment (Child-Pugh score of 10 or greater), do not exceed a total daily dose of 8 mg [see USE IN SPECIFIC POPULATIONS (8.6), CLINICAL PHARMACOLOGY (12.3)].

Indications and Usage Section

1 INDICATIONS AND USAGE

Ondansetron tablets are indicated for the prevention of nausea and vomiting associated with:

highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m2
initial and repeat courses of moderately emetogenic cancer chemotherapy
radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

Ondansetron tablets are also indicated for the prevention of postoperative nausea and/or vomiting.

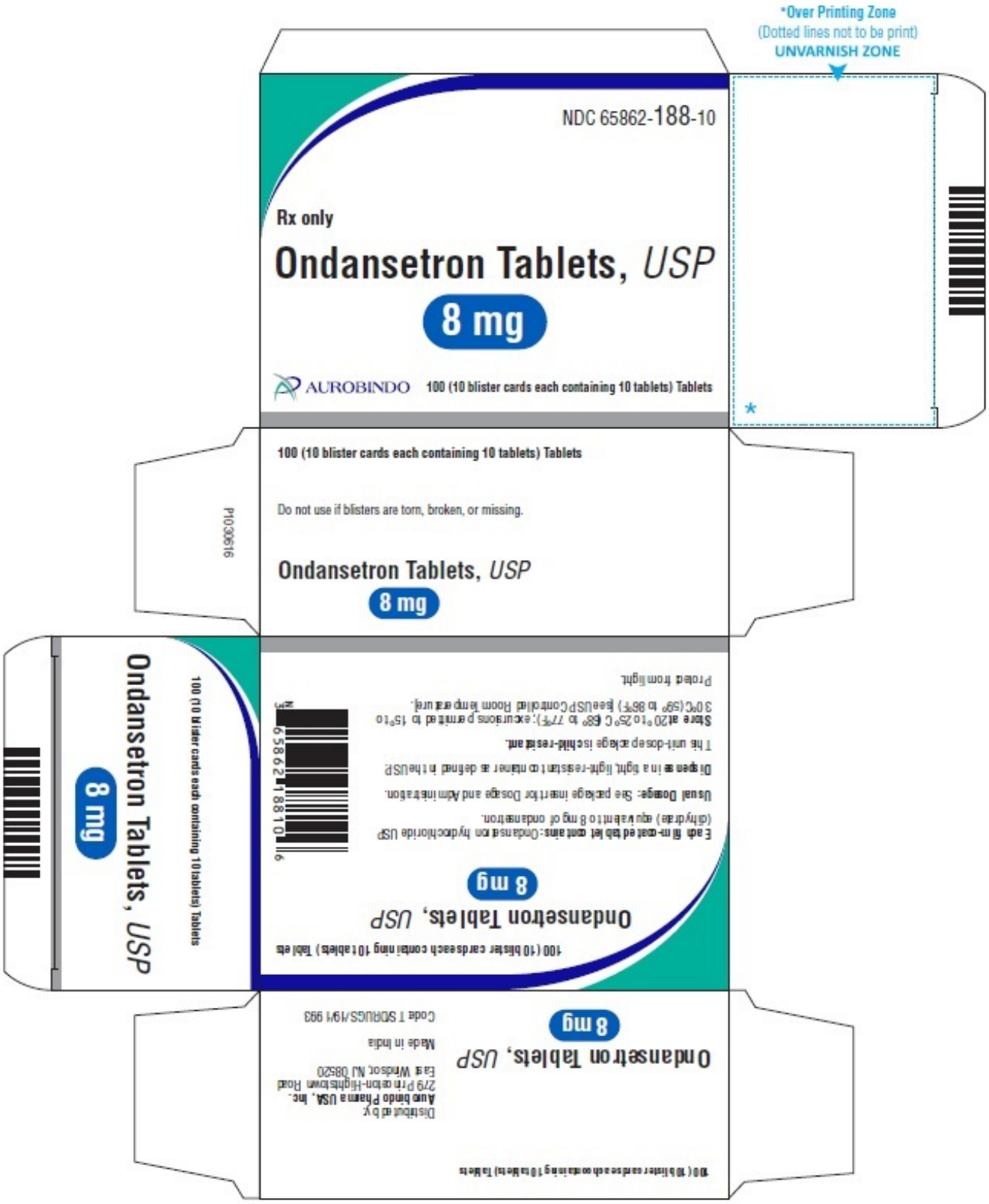
Contraindications Section

4 CONTRAINDICATIONS

Ondansetron tablets are contraindicated in patients:

known to have hypersensitivity (e.g., anaphylaxis) to ondansetron or any of the components of the formulation [see ADVERSE REACTIONS (6.2)]
receiving concomitant apomorphine due to the risk of profound hypotension and loss of consciousness

Principal Display Panel



ZOFRAN

ondansetron hcl 8mg tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0075(NDC:65862-188)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ONDANSETRON HYDROCHLORIDE (UNII: NMH84OZK2B) (ONDANSETRON - UNII:4AF302ESOS)	ONDANSETRON	8 mg

Product Characteristics

Color	yellow	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	F;92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0075-4	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078539	07/31/2007	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0075)

Revised: 10/2020 Advanced Rx Pharmacy of Tennessee, LLC