

**ONDANSETRON- ondansetron tablet, film coated**  
**HF Acquisition Co LLC, DBA HealthFirst**

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**ONDANSETRON TABLETS USP 4mg\***

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use ONDANSETRON TABLETS safely and effectively. See full prescribing information for ONDANSETRON TABLETS.

ONDANSETRON tablets, for oral use

Initial U.S. Approval: 1991

**INDICATIONS AND USAGE**

Ondansetron tablets are 5-HT<sub>3</sub> receptor antagonist indicated for the prevention of:

nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m<sup>2</sup> ( 1 )

nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy ( 1 )

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 ( 1 )

postoperative nausea and/or vomiting (1)

**DOSAGE AND ADMINISTRATION**

See full prescribing information for the recommended dosage in adults and pediatrics (2)

Patients with severe hepatic impairment: do not exceed a total daily dose of 8 mg ( 2.2, 8.6)

**DOSAGE FORMS AND STRENGTHS**

Tablets: 4 mg, 8 mg, 16 mg and 24 mg ( 3 )

**CONTRAINDICATIONS**

3.  
Patients known to have hypersensitivity (e.g., anaphylaxis) to ondansetron or any components of the formulation. ( 4 )

4.

Concomitant use of apomorphine ( 4)

## WARNINGS AND PRECAUTIONS

5.

Hypersensitivity reactions including anaphylaxis and bronchospasm: Discontinue ondansetron if suspected. Monitor and treat promptly per standard of care until signs and symptoms resolve ( 5.1)

6.

QT interval prolongation and Torsade de Pointes: Avoid in patients with congenital long QT syndrome; monitor with electrocardiograms (ECGs) if concomitant electrolyte abnormalities, cardiac failure or arrhythmias, or use of other QT prolonging drugs. ( 5.2)

7.

Serotonin syndrome: Reported with 5-HT<sub>3</sub> receptor antagonists alone but particularly with concomitant use of serotonergic drugs. If such symptoms occur, discontinue ondansetron and initiate supportive treatment. If concomitant use of ondansetron with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome. ( 5.3)

8.

Masking of progressive ileus and/or gastric distention following abdominal surgery or chemotherapy-induced nausea and vomiting: Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction. ( 5.4)

## ADVERSE REACTIONS

The most common adverse reactions in adults for the:

4.

prevention of chemotherapy-induced (greater than or equal to 5%) are: headache, malaise/fatigue, constipation, diarrhea ( 6.1)

5.

prevention of radiation-induced nausea and vomiting (greater than or equal to 2%) are: headache, constipation, and diarrhea ( 6.1)

6.

prevention of postoperative nausea and vomiting (greater than or equal to 9%) are: headache and hypoxia (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Dr. Reddy's Laboratories Inc., at 1-888-375-3784 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 4/2021

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## **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/m<sup>2</sup> .

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.

## **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 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/m <sup>2</sup>
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) 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)].

## 3 DOSAGE FORMS AND STRENGTHS

Ondansetron tablets USP, 4 mg (ondansetron hydrochloride USP, equivalent to 4 mg of

ondansetron) are white, round, biconvex, film coated tablets debossed “R” on one side and “153” on other side.

Ondansetron tablets USP, 8 mg (ondansetron hydrochloride USP, equivalent to 8 mg of ondansetron) are yellow, round, biconvex, film coated tablets debossed “R” on one side and “154” on other side.

Ondansetron tablets USP, 16 mg (ondansetron hydrochloride USP, equivalent to 16 mg of ondansetron) are white, round, biconvex, film coated tablets debossed “R” on one side and “155” on other side.

Ondansetron tablets USP, 24 mg (ondansetron hydrochloride USP, equivalent to 24 mg of ondansetron) are pink, round, biconvex, film coated tablets debossed “R” on one side and “156” on other side.

## **4 CONTRAINDICATIONS**

Ondansetron is contraindicated in patients:

1.  
known to have hypersensitivity (e.g., anaphylaxis) to ondansetron or any of the components of the formulation [see Adverse Reactions ( 6.2)]
2.  
receiving concomitant apomorphine due to the risk of profound hypotension and loss of consciousness

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Hypersensitivity Reactions**

Hypersensitivity reactions, including anaphylaxis and bronchospasm, have been reported in patients who have exhibited hypersensitivity to other selective 5-HT<sub>3</sub> receptor antagonists. If hypersensitivity reactions occur, discontinue use of ondansetron; treat promptly per standard of care and monitor until signs and symptoms resolve [see Contraindications ( 4)].

### **5.2 QT Prolongation**

Electrocardiogram (ECG) changes including QT interval prolongation have been seen in patients receiving ondansetron. In addition, postmarketing cases of Torsade de Pointes have been reported in patients using ondansetron. Avoid ondansetron in patients with congenital long QT syndrome. ECG monitoring is recommended in patients with electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmias, or patients taking other medicinal products that lead to QT prolongation [see Clinical Pharmacology ( 12.2)].

### **5.3 Serotonin Syndrome**

The development of serotonin syndrome has been reported with 5-HT<sub>3</sub> receptor antagonists alone. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors, mirtazapine, fentanyl, lithium, tramadol, and intravenous methylene blue). Some of the reported

cases were fatal. Serotonin syndrome occurring with overdose of ondansetron alone has also been reported. The majority of reports of serotonin syndrome related to 5-HT<sub>3</sub> receptor antagonist use occurred in a post-anesthesia care unit or an infusion center.

Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, with or without gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of ondansetron and other serotonergic drugs. If symptoms of serotonin syndrome occur, discontinue ondansetron and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if ondansetron is used concomitantly with other serotonergic drugs [see Drug Interactions ( 7.1), Overdosage ( 10)].

#### 5.4 Masking of Progressive Ileus and Gastric Distension

The use of ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting may mask a progressive ileus and/or gastric distension. Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction.

Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction.

## 6 ADVERSE REACTIONS

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following adverse reactions have been reported in clinical trials of patients treated with ondansetron, the active ingredient of ondansetron. A causal relationship to therapy with ondansetron was unclear in many cases.

#### Prevention of Chemotherapy-Induced Nausea and Vomiting

The most common adverse reactions reported in greater than or equal to 4% of 300 adults receiving a single 24 mg dose of ondansetron orally in 2 trials for the prevention of nausea and vomiting associated with highly emetogenic chemotherapy (cisplatin greater than or equal to 50 mg/m<sup>2</sup>) were: headache (11%) and diarrhea (4%).

The most common adverse reactions reported in 4 trials in adults for the prevention of nausea and vomiting associated with moderately emetogenic chemotherapy (primarily cyclophosphamide-based regimens) are shown in Table 3.

Table 3: Most Common Adverse Reactions in Adults for the Prevention of Nausea and Vomiting Associated with Moderately Emetogenic Chemotherapy [Primarily Cyclophosphamide-based Regimens]

Adverse Reaction	Ondansetron 8 mg Twice Daily (n = 242)	Placebo (n = 262)
Headache	58 (24%)	34 (13%)
Malaise/fatigue	32 (13%)	6 (2%)
Constipation	22 (9%)	1 (<1%)
Diarrhea	15 (6%)	10 (4%)

a Reported in greater than or equal to 5% of patients treated with ondansetron and at a rate that exceeded placebo.

#### Less Common Adverse Reactions

Central Nervous System: Extrapyramidal reactions (less than 1% of patients).

Hepatic: Aspartate transaminase (AST) and/or alanine transaminase (ALT) values exceeded twice the upper limit of normal in approximately 1% to 2% of 723 patients receiving ondansetron and cyclophosphamide-based chemotherapy in US clinical trials. The increases were transient and did not appear to be related to dose or duration of therapy. On repeat exposure, similar transient elevations in transaminase values occurred in some courses, but symptomatic hepatic disease did not occur. The role of cancer chemotherapy in these biochemical changes is unclear.

Liver failure and death has been reported in cancer patients receiving concurrent medications, including potentially hepatotoxic cytotoxic chemotherapy and antibiotics. The etiology of the liver failure is unclear.

Integumentary: Rash (approximately 1% of patients). Other (less than 2%): Anaphylaxis, bronchospasm, tachycardia, angina, hypokalemia, electrocardiographic alterations, vascular occlusive events, and grand mal seizures. Except for bronchospasm and anaphylaxis, the relationship to ondansetron is unclear.

#### Prevention of Radiation-Induced Nausea and Vomiting

The most common adverse reactions (greater than or equal to 2%) reported in patients receiving ondansetron and concurrent radiotherapy were similar to those reported in patients receiving ondansetron and concurrent chemotherapy and were headache, constipation, and diarrhea.

Prevention of Postoperative Nausea and Vomiting The most common adverse reactions reported in adults in trial(s), of prevention of postoperative nausea and vomiting are shown in Table 4. In these trial(s) patients were receiving multiple concomitant perioperative and postoperative medications in both treatment groups.

Table 4: Most Common Adverse Reactions in Adults<sup>a</sup> for the Prevention of Postoperative Nausea and Vomiting



Adverse Reaction	Ondansetron 16 mg as a Single Dose (n = 550)	Placebo (n = 531)
Headache	49 (9%)	27 (5%)
Hypoxia	49 (9%)	35 (7%)
Pyrexia	45 (8%)	34 (6%)
Dizziness	36 (7%)	34 (6%)
Gynecological disorder	36 (7%)	33 (6%)
Anxiety/agitation	33 (6%)	29 (5%)
Urinary retention	28 (5%)	18 (3%)
Pruritus	27 (5%)	20 (4%)

a Reported in greater than or equal to 5% of patients treated with ondansetron and at a rate that exceeded placebo.

## 6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of ondansetron. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

### Cardiovascular

Arrhythmias (including ventricular and supraventricular tachycardia, premature ventricular contractions, and atrial fibrillation), bradycardia, electrocardiographic alterations (including second-degree heart block, QT/QTc interval prolongation, and ST segment depression), palpitations, and syncope. Rarely and predominantly with intravenous ondansetron, transient ECG changes including QT interval prolongation have been reported.

### General

General Flushing. Rare cases of hypersensitivity reactions, sometimes severe (e.g., anaphylactic reactions, angioedema, bronchospasm, shortness of breath, hypotension, laryngeal edema, stridor) have also been reported.

Laryngospasm, shock, and cardiopulmonary arrest have occurred during allergic reactions in patients receiving injectable ondansetron.

### Hepatobiliary

Liver enzyme abnormalities.

Lower Respiratory

Hiccups.

Neurology Oculogyric crisis, appearing alone, as well as with other dystonic reactions.

Skin Urticaria, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Eye Disorders Cases of transient blindness, predominantly during intravenous administration, have been reported. These cases of transient blindness were reported to resolve within a few minutes up to 48 hours.

## **7 DRUG INTERACTIONS**

### **7.1 Serotonergic Drugs**

Serotonin syndrome (including altered mental status, autonomic instability, and neuromuscular symptoms) has been described following the concomitant use of 5-HT<sub>3</sub> receptor antagonists and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). Monitor for the emergence of serotonin syndrome. If symptoms occur, discontinue ondansetron and initiate supportive treatment [see Warnings and Precautions ( 5.3)].

### **7.2 Drugs Affecting Cytochrome P-450 Enzymes**

Ondansetron does not itself appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liver [see Clinical Pharmacology (12.3)]. Because ondansetron is metabolized by hepatic cytochrome P-450 drug-metabolizing enzymes (CYP3A4, CYP2D6, CYP1A2), inducers or inhibitors of these enzymes may change the clearance and, hence, the half-life of ondansetron. In patients treated with potent inducers of CYP3A4 (i.e., phenytoin, carbamazepine, and rifampin), the clearance of ondansetron was significantly increased and ondansetron blood concentrations were decreased. However, on the basis of available data, no dosage adjustment for ondansetron is recommended for patients on these drugs [see Clinical Pharmacology ( 12.3)].

### **7.3 Tramadol**

Although no pharmacokinetic drug interaction between ondansetron and tramadol has been observed, data from 2 small trials indicate that when used together, ondansetron may increase patient-controlled administration of tramadol. Monitor patients to ensure adequate pain control when ondansetron is administered with tramadol.

### **7.4 Chemotherapy**

Carmustine, etoposide, and cisplatin do not affect the pharmacokinetics of ondansetron.

In a crossover trial in 76 pediatric patients, intravenous ondansetron did not increase systemic concentrations of high-dose methotrexate.

### **7.5 Alfentanil and Atracurium**

Ondansetron does not alter the respiratory depressant effects produced by alfentanil or the degree of neuromuscular blockade produced by atracurium. Interactions with general or local anesthetics have not been studied.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

Available data do not reliably inform the association of ondansetron and adverse fetal outcomes. Published epidemiological studies on the association between ondansetron and fetal outcomes have reported inconsistent findings and have important methodological limitations hindering interpretation (see Data). Reproductive studies in rats and rabbits did not show evidence of harm to the fetus when ondansetron was administered during organogenesis at approximately 6 and 24 times the maximum recommended human oral dose of 24 mg/day, based on body surface area, respectively [see Data].

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

#### Data

##### Human Data

Methodological limitations of the epidemiology studies preclude a reliable evaluation of the potential risk of adverse fetal outcomes with the use of ondansetron in pregnancy.

Two large retrospective cohort studies of ondansetron use in pregnancy have been published. In one study with 1,349 infants born to women who reported the use of ondansetron or received an ondansetron prescription in the first trimester, no increased risk for major congenital malformations was seen in aggregate analysis. In this same study, however, a sub-analysis for specific malformations reported an association between ondansetron exposure and cardiovascular defect (odds ratio (OR) 1.62 [95% CI (1.04, 2.14)]) and cardiac septal defect (OR 2.05 [95% CI (1.19, 3.28)]). The second study examined 1970 women who received ondansetron prescription during pregnancy and reported no association between ondansetron exposure and major congenital malformations, miscarriage or stillbirth, and infants of low-birth weight or small for gestational age. Important methodological limitations with these studies include the uncertainty of whether women who filled a prescription actually took the medication, the concomitant use of other medications or treatments, and other unadjusted confounders that may account for the study findings.

A case-control study evaluating associations between several common non-cardiac malformations and multiple antiemetic drugs reported an association between maternal use of ondansetron and isolated cleft palate (reported adjusted OR = 2.37 [95% CI (1.18, 4.76)]). However, this association could be a chance finding, given the large number of drugs-birth defect comparisons in this study. It is unknown whether ondansetron exposure in utero in the cases of cleft palate occurred during the time of palate formation (the palate is formed between the 6th and 9th weeks of pregnancy) or whether mothers of infants with cleft palate used other medications or had other risk factors for cleft palate in the offspring. In addition, no cases of isolated cleft palate were identified in the aforementioned 2 large retrospective cohort studies. At this time, there is no clear evidence that ondansetron exposure in early pregnancy can cause cleft palate.

## Animal Data

In embryo-fetal development studies in rats and rabbits, pregnant animals received oral doses of ondansetron up to 15 mg/kg/day and 30 mg/kg/day, respectively, during the period of organogenesis. With the exception of a slight decrease in maternal body weight gain in the rabbits, there were no significant effects of ondansetron on the maternal animals or the development of the offspring. At doses of 15 mg/kg/day in rats and 30 mg/kg/day in rabbits, the maternal exposure margin was approximately 6 and 24 times the maximum recommended human oral dose of 24 mg/day, respectively, based on body surface area.

In a pre-and postnatal developmental toxicity study, pregnant rats received oral doses of ondansetron up to 15 mg/kg/day from Day 17 of pregnancy to litter Day 21. With the exception of a slight reduction in maternal body weight gain, there were no effects upon the pregnant rats and the pre-and postnatal development of their offspring, including reproductive performance of the mated F1 generation. At a dose of 15 mg/kg/day in rats, the maternal exposure margin was approximately 6 times the maximum recommended human oral dose of 24 mg/day, based on body surface area.

## 8.2 Lactation

### Risk Summary

It is not known whether ondansetron is present in human milk. There are no data on the effects of ondansetron on the breastfed infant or the effects on milk production. However, it has been demonstrated that ondansetron is present in the milk of rats.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ondansetron and any potential adverse effects on the breast fed infant from ondansetron or from the underlying maternal condition.

## 8.4 Pediatric Use

The safety and effectiveness of orally administered ondansetron have been established in pediatric patients 4 years and older for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. Use of ondansetron in these age-groups is supported by evidence from adequate and well-controlled studies of ondansetron in adults with additional data from 3 open-label, uncontrolled, non-US trials in 182 pediatric patients aged 4 to 18 years with cancer who were given a variety of cisplatin or noncisplatin regimens [see Dosage and Administration ( 2.2), Clinical Studies ( 14.1)].

Additional information on the use of ondansetron in pediatric patients may be found in ondansetron Injection prescribing information.

The safety and effectiveness of orally administered ondansetron have not been established in pediatric patients for:

- prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy
- prevention of nausea and vomiting associated with radiotherapy
- prevention of postoperative nausea and/or vomiting

## 8.5 Geriatric Use

Of the total number of subjects enrolled in cancer chemotherapy-induced and postoperative nausea and vomiting in US-and foreign-controlled clinical trials, for which there were subgroup analyses, 938 (19%) were aged 65 years and older.

No overall differences in safety or effectiveness were observed between subjects 65 years of age and older and younger subjects. A reduction in clearance and increase in elimination half-life were seen in patients older than 75 years compared with younger subjects [see Clinical Pharmacology ( 12.3)]. There were an insufficient number of patients older than 75 years of age and older in the clinical trials to permit safety or efficacy conclusions in this age-group. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dosage adjustment is needed in elderly patients.

### 8.6 Hepatic Impairment

No dosage adjustment is needed in patients with mild or moderate hepatic impairment.

In patients with severe hepatic impairment, clearance is reduced and the apparent volume of distribution is increased, resulting in a significant increase in the half-life of ondansetron. Therefore, do not exceed a total daily dose of 8 mg in patients with severe hepatic impairment (Child-Pugh score of 10 or greater) [see Dosage and Administration ( 2.2), Clinical Pharmacology ( 12.3)].

### 8.7 Renal Impairment

No dosage adjustment is recommended for patients with any degree of renal impairment (mild, moderate, or severe). There is no experience beyond first-day administration of ondansetron [see Clinical Pharmacology ( 12.3)].

## 9 DRUG ABUSE AND DEPENDENCE

Animal studies have shown that ondansetron is not discriminated as a benzodiazepine nor does it substitute for benzodiazepines in direct addiction studies.

## 10 OVERDOSAGE

There is no specific antidote for ondansetron overdose. Patients should be managed with appropriate supportive therapy.

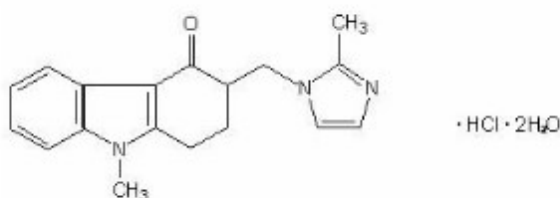
In addition to the adverse reactions listed above, the following adverse reactions have been described in the setting of ondansetron overdose: "Sudden blindness" (amaurosis) of 2 to 3 minutes' duration plus severe constipation occurred in one patient that was administered 72 mg of ondansetron intravenously as a single dose. Hypotension (and faintness) occurred in a patient that took 48 mg of ondansetron tablets. Following infusion of 32 mg over only a 4-minute period, a vasovagal episode with transient second-degree heart block was observed. In all instances, the adverse reactions resolved completely.

Pediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeding estimated ingestion of 5 mg per kg) in young children. Reported symptoms included somnolence, agitation, tachycardia, tachypnea, hypertension, flushing, mydriasis, diaphoresis, myoclonic movements,

horizontal nystagmus, hyperreflexia, and seizure. Patients required supportive care, including intubation in some cases, with complete recovery without sequelae within 1 to 2 days.

## 11 DESCRIPTION

The active ingredient in ondansetron tablets is ondansetron hydrochloride as the dihydrate, the racemic form of ondansetron and a selective blocking agent of the serotonin 5-HT<sub>3</sub> receptor type. Chemically it is ( $\pm$ ) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate. It has the following structural formula:



The molecular formula is  $\text{C}_{18}\text{H}_{19}\text{N}_3\text{O} \cdot \text{HCl} \cdot 2\text{H}_2\text{O}$ , representing a molecular weight of 365.86.

Ondansetron HCl dihydrate USP is a white to off-white powder that is soluble in methanol, sparingly soluble in purified water and in alcohol, and slightly soluble in isopropyl alcohol, in dichloromethane, very slightly soluble in acetone, in chloroform and in ethyl acetate.

Each 4 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 4 mg of ondansetron.

Each 8 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 8 mg of ondansetron.

Each 16 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 16 mg of ondansetron.

Each 24 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 24 mg of ondansetron.

Each tablet also contains the inactive ingredients colloidal silicon dioxide, hypromellose 2910(5cP) (for the 4 mg and 16 mg tablets only) and hypromellose 2910 (6cP) (for the 8 mg and 24 mg tablets only), iron oxide red and iron oxide black (for the 24 mg tablet only), iron oxide yellow (for the 8 mg and 24 mg tablets only), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sodium starch glycolate, and titanium dioxide.

## **12 CLINICAL PHARMACOLOGY**

The molecular formula is  $C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$ , representing a molecular weight of 365.86.

Ondansetron HCl dihydrate USP is a white to off-white powder that is soluble in methanol, sparingly soluble in purified water and in alcohol, and slightly soluble in isopropyl alcohol, in dichloromethane, very slightly soluble in acetone, in chloroform and in ethyl acetate.

Each 4 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 4 mg of ondansetron.

Each 8 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 8 mg of ondansetron.

Each 16 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 16 mg of ondansetron.

Each 24 mg ondansetron tablets USP for oral administration contains ondansetron HCl dihydrate USP equivalent to 24 mg of ondansetron.

Each tablet also contains the inactive ingredients colloidal silicon dioxide, hypromellose 2910(5cP) (for the 4 mg and 16 mg tablets only) and hypromellose 2910 (6cP) (for the 8 mg and 24 mg tablets only), iron oxide red and iron oxide black (for the 24 mg tablet only), iron oxide yellow (for the 8 mg and 24 mg tablets only), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sodium starch glycolate, and titanium dioxide.

Table 5: Pharmacokinetics in Male and Female Healthy Subjects after a Single Dose of a Ondansetron 8 mg Tablet

Age-group(years)Sex (M/F)	MeanWeight(kg)	N	Peak PlasmaConcentration(ng/mL)	Tine ofPeak Plasma Concentration(h)	Mean Elimination Half-life(h)	Systemic Plasma Clearance L/h/kg	AbsoluteBioavailability
18 to 40 M	69	6	26.2	2	3.1	0.403	0.483
F	62.7	5	42.7	1.7	3.5	0.354	0.663
61 to 74 M	77.5	6	24.1	2.1	4.1	0.384	0.585
F	60.2	6	52.4	1.9	4.9	0.255	0.643
≥75 M	78	5	37	2.2	4.5	0.277	0.619
F	67.6	6	46.1	2.1	6.2	0.249	0.747

Table 6: Pharmacokinetics in Male and Female Healthy Subjects after a Single Dose of a Ondansetron 24 mg Tablet

Age-group (years) Sex (M/F)	Mean Weight (kg)	N	Peak Plasma Concentration (ng/mL)	Time of Peak Plasma Concentration (h)	Mean Elimination Half-life (h)
18 to 43 M F	84.1 71.8	8 8	125.8 194.4	1.9 1.6	4.7 5.8

Renal Impairment: Renal impairment is not expected to significantly influence the total clearance of ondansetron as renal clearance represents only 5% of the overall clearance. However, the mean plasma clearance of ondansetron was reduced by about 50% in patients with severe renal impairment (creatinine clearance less than 30 mL/min). The reduction in clearance was variable and not consistent with an increase in half-life [see Use in Specific Populations ( 8.7)].

Hepatic Impairment: In patients with mild-to-moderate hepatic impairment, clearance is reduced 2-fold and mean half-life is increased to 11.6 hours compared with 5.7 hours in healthy subjects. In patients with severe hepatic impairment (Child-Pugh score of 10 or greater), clearance is reduced 2-fold to 3-fold and apparent volume of distribution is



increased with a resultant increase in half-life to 20 hours [see Dosage and Administration ( 2.2), Use in Specific Populations ( 8.6)].

### Drug Interaction Studies

**CYP 3A4 Inducers:** Ondansetron elimination may be affected by cytochrome P-450 inducers. In a pharmacokinetic trial of 16 epileptic patients maintained chronically on CYP3A4 inducers, carbamazepine, or phenytoin, a reduction in AUC, C<sub>max</sub>, and t<sub>1/2</sub> of ondansetron was observed. This resulted in a significant increase in the clearance of ondansetron. However, this increase is not thought to be clinically relevant [see Drug Interactions ( 7.2)].

**Chemotherapeutic Agents:** Carmustine, etoposide, and cisplatin do not affect the pharmacokinetics of ondansetron [see Drug Interactions (7.4)].

**Antacids:** Concomitant administration of antacids does not alter the absorption of ondansetron.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment Of Fertility

Carcinogenic effects were not seen in 2 year studies in rats and mice with oral ondansetron doses up to 10 mg/kg per day and 30 mg/kg per day, respectively (approximately 4 and 6 times the maximum recommended human oral dose of 24 mg per day, based on body surface area).

Ondansetron was not mutagenic in standard tests for mutagenicity.

Oral administration of ondansetron up to 15 mg/kg per day (approximately 6 times the maximum recommended human oral dose of 24 mg per day, based on body surface area) did not affect fertility or general reproductive performance of male and female rats.

## 14 CLINICAL STUDIES

### 14.1 Prevention of Chemotherapy-Induced Nausea and Vomiting

#### Highly Emetogenic Chemotherapy

In 2 randomized, double-blind, monotherapy trials, a single 24 mg oral dose of ondansetron was superior to a relevant historical placebo control in the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m<sup>2</sup>. Steroid administration was excluded from these clinical trials. More than 90% of patients receiving a cisplatin dose greater than or equal to 50 mg/m<sup>2</sup> in the historical placebo comparator, experienced vomiting in the absence of antiemetic therapy.

The first trial compared oral doses of ondansetron 24 mg as a single dose, 8 mg every 8 hours for 2 doses, and 32 mg as a single dose in 357 adult cancer patients receiving chemotherapy regimens containing cisplatin greater than or equal to 50 mg/m<sup>2</sup>. The first or single dose was administered 30 minutes prior to chemotherapy. A total of 66% of patients in the ondansetron 24 mg once-a-day group, 55% in the ondansetron 8 mg twice-a-day group, and 55% in the ondansetron 32 mg once-a-day group, completed

the 24 hour trial period with 0 emetic episodes and no rescue antiemetic medications, the primary endpoint of efficacy. Each of the 3 treatment groups was shown to be statistically significantly superior to a historical placebo control.

In the same trial, 56% of patients receiving a single 24 mg oral dose of ondansetron experienced no nausea during the 24 hour trial period, compared with 36% of patients in the oral ondansetron 8 mg twice-a-day group ( $P = 0.001$ ) and 50% in the oral ondansetron 32 mg once-a-day group. Dosage regimens of ondansetron 8 mg twice daily and 32 mg once daily are not recommended for the prevention of nausea and vomiting associated with highly emetogenic chemotherapy [see Dosage and Administration (2.1)].

In a second trial, efficacy of a single 24 mg oral dose of ondansetron for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m<sup>2</sup>, was confirmed.

### Moderately Emetogenic Chemotherapy

A randomized, placebo-controlled, double-blind trial was conducted in the US in 67 patients receiving a cyclophosphamide-based chemotherapy regimen containing doxorubicin. The first 8 mg dose of ondansetron was administered 30 minutes before the start of chemotherapy, with a subsequent dose 8 hours after the first dose, followed by 8 mg of ondansetron twice a day for 2 days after the completion of chemotherapy.

Ondansetron was significantly more effective than placebo in preventing vomiting. Treatment response was based on the total number of emetic episodes over the 3 day trial period. The results of this trial are summarized in Table 7:

Table 7: Emetic Episodes-Treatment Response in Patients Receiving Moderately Emetogenic Chemotherapy (Cyclophosphamide-based Regimen Containing Doxorubicin)

	Ondansetron(n = 33)	Placebo (n = 34)	P Value
Treatment response	20 (61%)	2 (6%)	<0.001
0 Emetic episodes	6 (18%)	8 (24%)	<0.001
1 to 2 Emetic episodes	7 (21%)	24 (71%)	
More than 2 emetic episodes/withdrawn			
Median number of emetic episodes	0	Undefined <sup>a</sup>	
Median time to first emetic episode (hours)	Undefined <sup>b</sup>	6.5	

a Median undefined since at least 50% of the patients were withdrawn or had more than 2 emetic episodes.

b Median undefined since at least 50% of patients did not have any emetic episodes.

In a double-blind, US trial in 336 patients receiving a cyclophosphamide-based chemotherapy regimen containing either methotrexate or doxorubicin, ondansetron 8 mg administered twice a day, was as effective as ondansetron 8 mg administered 3

times a day in preventing nausea and vomiting. ondansetron 8 mg three times daily is not a recommended regimen for the treatment of moderately emetogenic chemotherapy [see Dosage and Administration (2.1)].

Treatment response was based on the total number of emetic episodes over the 3 day trial period. See Table 8 for the details of the dosage regimens studied and results of this trial.

Table 8: Emetic Episodes-Treatment Response after Ondansetron Tablets Administered Twice a Day and Three Times a Day

	Ondansetron Tablets	
	8 mg Twice Daily <sup>a</sup> (n = 165)	8 mg Three Times a Day <sup>b</sup> (n = 171)
Treatment response 0 Emetic episodes 1-2 Emetic episodes More than 2 emetic episodes/withdrawn	101 (61%) 16 (10%) 48 (29%)	99 (58%) 17 (10%) 55 (32%)
Median number of emetic episodes	0	0
Median time to first emetic episode (h)	Undefined <sup>c</sup>	Undefined <sup>c</sup>
Median nausea scores (0-100) <sup>d</sup>	6	6

a The first 8 mg dose was administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent 8 mg dose 8 hours after the first dose, followed by 8 mg administered twice a day for 2 days after the completion of chemotherapy.

b The first 8 mg dose was administered 30 minutes before the start of emetogenic chemotherapy, with subsequent 8 mg doses at 4 hours and 8 hours after the first dose, followed by 8 mg administered 3 times a day for 2 days after the completion of chemotherapy.

c Median undefined since at least 50% of patients did not have any emetic episodes.

d Visual analog scale assessment: 0 = no nausea, 100 = nausea as bad as it can be.

## Re-treatment

In single-arm trials, 148 patients receiving cyclophosphamide-based chemotherapy were re-treated with ondansetron 8 mg three times daily during subsequent chemotherapy for a total of 396 re-treatment courses. No emetic episodes occurred in 314 (79%) of the re-treatment courses, and only 1 to 2 emetic episodes occurred in 43 (11%) of the re-treatment courses.

## Pediatric Trials

Three open-label, single-arm, non-US trials have been performed with 182 pediatric patients aged 4 to 18 years with cancer who were given a variety of cisplatin or noncisplatin regimens. The initial dose of ondansetron injection ranged from 0.04 to 0.87 mg per kg (total dose of 2.16 mg to 12 mg) followed by the administration of oral doses of ondansetron ranging from 4 to 24 mg daily for 3 days. In these trials, 58% of the 170 evaluable patients had a complete response (no emetic episodes) on Day 1. In 2 trials,

the response rates to ondansetron 4 mg three times a day in patients younger than 12 years was similar to ondansetron 8 mg three times daily in patients 12 to 18 years. Prevention of emesis in these pediatric patients was essentially the same as for adults.

## 14.2 Radiation-Induced Nausea and Vomiting

### Total Body Irradiation

In a randomized, placebo-controlled, double-blind trial in 20 patients, 8 mg of ondansetron administered 1.5 hours before each fraction of radiotherapy for 4 days was significantly more effective than placebo in preventing vomiting induced by total body irradiation. Total body irradiation consisted of 11 fractions (120 cGy per fraction) over 4 days for a total of 1,320 cGy. Patients received 3 fractions for 3 days, then 2 fractions on Day 4.

### Single High-Dose Fraction Radiotherapy

In an active-controlled, double-blind trial in 105 patients receiving single high-dose radiotherapy (800 to 1,000 cGy) over an anterior or posterior field size of greater than or equal to 80 cm<sup>2</sup> to the abdomen, ondansetron was significantly more effective than metoclopramide with respect to complete control of emesis (0 emetic episodes). Patients received the first dose of ondansetron (8 mg) or metoclopramide (10 mg) 1 to 2 hours before radiotherapy. If radiotherapy was given in the morning, 8 mg of ondansetron or 10 mg of metoclopramide was administered in the late afternoon and repeated again before bedtime. If radiotherapy was given in the afternoon, patients took 8 mg of ondansetron or 10 mg of metoclopramide only once before bedtime. Patients continued the doses of oral medication three times daily for 3 days.

### Daily Fractionated Radiotherapy

In an active-controlled, double-blind trial in 135 patients receiving a 1-to 4-week course of fractionated radiotherapy (180 cGy doses) over a field size of greater than or equal to 100 cm<sup>2</sup> to the abdomen, ondansetron was significantly more effective than prochlorperazine with respect to complete control of emesis (0 emetic episodes). Patients received the first dose of ondansetron (8 mg) or prochlorperazine (10 mg) 1 to 2 hours before the first daily radiotherapy fraction, with subsequent 8 mg doses approximately every 8 hours on each day of radiotherapy.

## 14.3 Postoperative Nausea and Vomiting

In 2 placebo-controlled, double-blind trials (one conducted in the US and the other outside the US) in 865 females undergoing inpatient surgical procedures, ondansetron 16 mg as a single dose or placebo was administered one hour before the induction of general balanced anesthesia (barbiturate, opioid, nitrous oxide, neuromuscular blockade, and supplemental isoflurane or enflurane), ondansetron tablets was significantly more effective than placebo in preventing postoperative nausea and vomiting.

No trials have been performed in males.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

Ondansetron Tablets Ondansetron tablets USP, 4 mg (ondansetron hydrochloride USP, equivalent to 4 mg of ondansetron) are white, round, biconvex, film coated tablets debossed "R" on one side and "153" on other side and are supplied in the following

dosage forms.

NDC 51662-1539-1

ONDANSETRON TABLETS USP 4mg\* (4 PACK)

HF Acquisition Co LLC, DBA HealthFirst

Mukilteo, WA 98275

Also supplied in the following manufacture supplied dosage forms

Ondansetron Tablets Ondansetron tablets USP, 4 mg (ondansetron hydrochloride USP, equivalent to 4 mg of ondansetron) are white, round, biconvex, film coated tablets debossed "R" on one side and "153" on other side and are supplied in bottles of 30, 100, 500, unit-dose packages of 100 (10 x 10) and unit-dose packages of 3 (1 x 3).

Cartons of 100 tablets (10 tablets each blister pack x 10), NDC 0904-6551-61

Ondansetron tablets USP, 8 mg (ondansetron hydrochloride USP, equivalent to 8 mg of ondansetron) are yellow, round, biconvex, film coated tablets debossed "R" on one side and "154" on other side and are supplied in bottles of 30, 100, 500, unit-dose packages of 100 (10 x 10) and unit-dose packages of 3 (1 x 3).

Cartons of 100 tablets (10 tablets each blister pack x 10), NDC 0904-6552-61

Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature). Dispense in tight container as defined in the USP. Store blisters in cartons.

## **17 PATIENT COUNSELING INFORMATION**

### **QT Prolongation**

Inform patients that ondansetron may cause serious cardiac arrhythmias such as QT prolongation. Instruct patients to tell their healthcare provider right away if they perceive a change in their heart rate, if they feel lightheaded, or if they have a syncopal episode.

### **Hypersensitivity Reactions**

Inform patients that ondansetron may cause hypersensitivity reactions, some as severe as anaphylaxis and bronchospasm. Instruct patients to immediately report any signs and symptoms of hypersensitivity reactions, including fever, chills, rash, or breathing problems to their healthcare provider.

### **Masking of Progressive Ileus and Gastric Distension**

Inform patients following abdominal surgery or those with chemotherapy-induced nausea and vomiting that ondansetron may mask signs and symptoms of bowel obstruction. Instruct patients to immediately report any signs or symptoms consistent with a potential bowel obstruction to their healthcare provider.

### **Drug Interactions**

- Instruct the patient to report the use of all medications, especially apomorphine, to their healthcare provider. Concomitant use of apomorphine and ondansetron may cause a significant drop in blood pressure and loss of consciousness.
- Advise patients of the possibility of serotonin syndrome with concomitant use of ondansetron and another serotonergic agent such as medications to treat depression and migraines. Advise patients to seek immediate medical attention if the following

symptoms occur: changes in mental status, autonomic instability, neuromuscular symptoms with or without gastrointestinal symptoms.

Rx Only

Manufactured by:

Dr. Reddy's Laboratories Limited

Bachupally - 500 090 INDIA

Distributed By:

MAJOR® PHARMACEUTICALS

Livonia, MI 48152

Refer to package label for Distributor's NDC Number

Revised: 1117

**PRINCIPAL DISPLAY PANEL - 51662-1539-1 ONDANSETRON TABLETS USP  
4mg\* (4 PACK)**

51662-1539-1

Ondansetron Tablets USP

4 mg\* (4 PACK)



NDC 0904-6551-61

Unit Dose

**ONDANSETRON  
TABLETS USP**

**4 mg\***

**Rx only**

100 TABLETS



NDC 0904-6551-61

Unit Dose

**ONDANSETRON  
TABLETS USP**

**4 mg\***

\*Each film-coated tablet contains:  
Ondansetron hydrochloride USP equivalent to  
ondansetron 4 mg.

Usual Dosage: See product insert for dosage,  
administration, prescribing information,  
precautions and warnings.

SEE INSERT FOUND AT  
[WWW.MAJORPHARMACEUTICALS.COM](http://WWW.MAJORPHARMACEUTICALS.COM)

Store at 20°-25°C (68°-77°F) (See USP Controlled  
Room Temperature).

Dispense in a tight, light-resistant container.

Keep this and all medication out of the reach  
of children. This Unit Dose package is not child  
resistant and is Intended for Institutional Use Only.

PN: 11121

Rev. 03/18

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Bachupally - 500 090 INDIA

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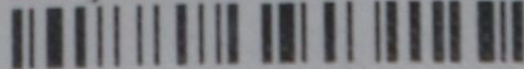
LOT #: M03200D

NDC 0904-6551-61

**ONDANSETRON**

4 mg\* USP, One Tablet

Major Pharm./Livonia, MI 48152



EXP. 09/2022

LOT #: M03200D

NDC 0904-6551-61

**ONDANSETRON**

4 mg\* USP, One Tablet

Major Pharm./Livonia, MI 48152



EXP. 09/2022

**ONDANSETRON**

ondansetron tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:51662-1539(NDC:0904-6551)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ONDANSETRON HYDROCHLORIDE</b> (UNII: NMH84OZK2B) (ONDANSETRON - UNII:4AF302ESOS)	ONDANSETRON	4 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	R;153
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1539-1	4 in 1 BAG	10/06/2021	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076183	10/06/2021	

**Labeler** - HF Acquisition Co LLC, DBA HealthFirst (045657305)

**Registrant** - HF Acquisition Co LLC, DBA HealthFirst (045657305)

**Establishment**

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1539)

Revised: 1/2024

HF Acquisition Co LLC, DBA HealthFirst