

# Prenavo

8mg  
Tablets

پرپی نیوو ۸ ملی گرام گولیاں  
اونڈینسٹرون

**Prenavo (Ondansetron)** is a medication used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, or surgery. It is also effective for treating gastroenteritis. The molecular weight of Ondansetron is 293.4 g/mol. The molecular formula is  $C_{15}H_{19}N_3O$

#### COMPOSITION:

Prenavo 8mg Tablet

Each film coated tablet contains: Ondansetron(as hydrochloride dihydrate) .....8mg (USP Specification)

#### CLINICAL PHARMACOLOGY:

##### Pharmacokinetics

##### Absorption

Ondansetron is absorbed from the gastrointestinal tract and undergoes some first-pass metabolism. Mean bioavailability in healthy subjects, following administration of a single 8-mg tablet, is approximately 56%.

##### Distribution

Plasma protein binding of Ondansetron as measured in vitro was 70% to 76% over the concentration range of 10 to 500 ng/mL. Circulating drug also distributes into erythrocytes.

##### Metabolism and Excretion

Ondansetron is extensively metabolized in humans, with approximately 5% of a radio labeled dose recovered as the parent compound from the urine. The metabolites are observed in the urine

##### Mechanism of Action

Ondansetron is a carbazole derivative with antiemetic activity. As a selective serotonin receptor antagonist, Ondansetron competitively blocks the action of serotonin at 5HT<sub>3</sub> receptors, resulting in suppression of chemotherapy- and radiotherapy-induced nausea and vomiting.

#### INDICATIONS AND USAGE:

Prenavo is 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 total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

#### CONTRAINDICATIONS:

Prenavo tablets must not be used in patients hypersensitive to Prenavo or any other component of product.

#### WARNINGS AND PRECAUTIONS FOR USE:

##### 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 Prenavo

**QT Prolongation:** Electrocardiogram (ECG) changes including QT interval prolongation have been seen in patients receiving Ondansetron. Avoid Prenavo in patients with congenital long QT syndrome

**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)).

**Phenylketonuria:** Phenylketonuric patients should be informed that Prenavo ODT orally disintegrating tablets contain phenylalanine (a component of aspartame). Each 8-mg orally disintegrating tablet contains less than 0.03 mg phenylalanine.

#### SIDE EFFECTS:

Headache is the most common adverse effect. Constipation, diarrhea, and dizziness is other commonly reported side effects.

##### QT prolongation

Use of Ondansetron has been associated with prolongation of the QT interval, which can lead to a potentially fatal heart rhythm known as torsades de pointes

## DRUG INTERACTIONS:

### 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)

### Drugs Affecting Cytochrome P-450 Enzymes:

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

**Tramadol:** Praveno may increase patient-controlled administration of Tramadol.

## DOUSAGE:

### 1. Adult Recommended Dosage Regimen for Prevention of Nausea and Vomiting.

#### Highly Emetogenic Cancer Chemotherapy

A single 24mg dose administered 30 minutes before the start of single-day highly emetogenic chemotherapy, including cisplatin greater than or equal to 50 mg/m

#### Moderately Emetogenic Cancer Chemotherapy

8mg 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 8mg 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 8mg doses every 8 hours after the first dose for each day radiotherapy is given

**Postoperative** 16mg administered 1 hour before induction of anesthesia

### 2. Pediatric Recommended Dosage Regimen for Prevention of Nausea and Vomiting

#### 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 4 and 8 hours after the first dose. Then administer 8 mg three times a day for 1 to 2 days after completion of chemotherapy.

**4 to 11 years of age:** 4mg administered 30 minutes before the start of chemotherapy, with a subsequent 4mg 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.

## STORAGE & INSTRUCTIONS:

Keep out of the reach of children & Store below 30° C.

Protect from sunlight & moisture

Improper storage may deteriorate the medicine

Do not use this medicine after the expiry date which is stated on the blister.

## STABILITY:

See expiry on pack.

## PRESENTATION:

Praveno 8mg Tablet in pack of 10's

Manufactured by :

  
PHARMA LORD  
PHARMA LORD | 12km, Lahore  
(PVT.) LIMITED | Road, Layyah.  
Pakistan  
www.pharma-lord.com

پرپی نیوو ۸ ملی گرام گولیاں  
اؤنڈینسٹرون

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایت: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ۳۰ ڈگری سینٹی گریڈ

درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی۔