

1.6.3 PATIENT INFORMATION LEAFLET (PIL)

OFLOX-OZ (Ofloxacin & Ornidazole Tablets)

Brand Names: OFLOX-OZ

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **OFLOX-OZ Tablets** is and what they are used for
2. Before you take **OFLOX-OZ Tablets**.
3. How to take **OFLOX-OZ Tablets**.
4. Possible side effects
5. How to store **OFLOX-OZ Tablets**.
6. Further information

1. What OFLOX-OZ Tablets is and what they are used for

OFLOX-OZ Tablet is a medicine that is used for the treatment of Bacterial infections, Urinary tract infections, Respiratory infections, Skin infections, Soft tissue infections, Sexually transmitted infections and other conditions.

OFLOX-OZ Tablet contains Ofloxacin, and Ornidazole as active ingredients.

OFLOX-OZ Tablet works by killing the infection causing bacteria; inhibiting the growth of microorganism;

2. Before you take OFLOX-OZ Tablets

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid consuming milk and dairy products
- Consult the doctor in case of pregnancy or breastfeeding
- Consult your doctor before taking this medicine if having epilepsy and multiple sclerosis
- Do not consume if you have any disease condition like epilepsy or kidney problems

OFLOX-OZ
(Ofloxacin & Ornidazole Tablets)
Module 1



- Do not consume Ofloxacin if allergic to it
- Do not drive a vehicle or operate heavy machinery after consuming the medicine

3. How to take OFLOX-OZ Tablets?

Adults: The combination tablets of Ofloxacin and Ornidazole come in a single dose tablet containing 200mg of Ofloxacin and 500mg Ornidazole.

The usual adult dosage is: One tablet taken twice daily for 5 to 10 days depending on the severity of the infection.

Children (under 8 years old): The combination comes in a suspension for children under 8 years old. This contains 50mg Ofloxacin and 125mg Ornidazole per 5 ml of suspension. The usual dosage for children under 8 years old is 2.5 ml to 5 ml two times a day. Your doctor will determine the proper dose based on your child's weight.

4. Possible side effects

The following is a list of possible side effects that may occur from all constituting ingredients of OFLOX-OZ Tablet. This is not a comprehensive list. These side effects are possible, but do not always occur. Some of the side effects may be rare but serious. Consult your doctor if you observe any of the following side effects, especially if they do not go away.

- Headache
- Diarrhea
- Photosensitivity
- Nausea
- Hallucination
- Sinus tachycardia

5. How to store OFLOX-OZ Tablets

- Keep out of the reach and sight of children.
- Store below 30⁰ C & Protect from light & moisture
- Do not use the medicine after the expiry date, which is stated on the carton after (EXP). The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What OFLOX-OZ Tablet contain

Each film coated tablet contains active ingredients Ofloxacin BP & Ornidazole. The inactive ingredients in the tablets are Microcrystalline cellulose BP, Purified Water BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Maize Starch BP, Purified Talc BP,

OFLOX-OZ
(Ofloxacin & Ornidazole Tablets)
Module 1



Colloidal Anhydrous Silica BP, Sodium Starch Glycolate (Type A) BP Magnesium Stearate BP, Hypromellose BP, Povidone K-30 BP, Titanium Dioxide (Colour Code Index: 77891) BP, Dichloromethane BP, Isopropyl Alcohol BP, Macrogol 4000 BP

7. What OFLOX-OZ Tablets look like and contents of the pack

OFLOX-OZ (Ofloxacin and Ornidazole Tablets) are a white, caplet shaped, biconvex, film coated tablets, having plain on both sides.

10 Tablets in Alu/ Alu Blister & 3 such Blister in a carton = 3 x 10's = 30 Tablets

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ochoa Laboratories

430, Mzz. F, Gundecha Indl. Complex

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Manufacturer

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Palghar – 401 404,

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8 Date of Revision of PIL