1.6 Product Information

1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

(SPC, CONTAINER LABELING & PATIENT INFORMATION LEAFLET, MOCK-UPS AND SPECIMENS)

SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

OFLOX-OZ (Ofloxacin & Ornidazole Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Ofloxacin BP	200 mg
Ornidazole	500 mg
Excipients	q.s

Colour: Titanium Dioxide
For full list of Excipients refer 6.1.

3. PHARMACEUTICAL FORM
Film-coated Tablets.
A white, caplet shaped, biconvex, film coated tablets, having plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
OFLOX-OZ 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.

4.2 Posology and method of administration
Adults: The combination tablets of Ofloxacin and Ornidazole come in a single dose tablet containing 200 mg 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.

4.3 Contraindications

Ofloxacin + Ornidazole and Pregnancy

USFDA pregnancy category C. May be or may not be harmful to an unborn baby. Consult your doctor if you are in gestation or plan to have a baby during Ofloxacin + Ornidazole treatment.

Ofloxacin + Ornidazole and Lactation

It is not known whether Ofloxacin + Ornidazole can pass through the breast milk or not. Nursing mothers should avoid breastfeeding while taking Ofloxacin + Ornidazole.

Ofloxacin + Ornidazole and Children

The dosage and duration should be as prescribed by a physician

4.4 Special warnings and precautions for use

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
- Do not consume ofloxacin if allergic to it
- Do not drive a vehicle or operate heavy machinery after consuming the medicine
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4.5 Interaction with other medicinal products and other forms of interaction

Ofloxacin + Ornidazole may interact with acenocoumarol, anisindione, calcium salts including calcium acetate, NSAIDs, antacids, hematinics and muscle relaxants such as vecuronium bromide.

Other Interactions

Do not consume alcohol while taking Ofloxacin + Ornidazole

4.6 Pregnancy and lactation

Ofloxacin + Ornidazole and Pregnancy

USFDA pregnancy category C. May be or may not be harmful to an unborn baby. Consult your doctor if you are in gestation or plan to have a baby during Ofloxacin + Ornidazole treatment.

Ofloxacin + Ornidazole and Lactation

It is not known whether Ofloxacin + Ornidazole can pass through the breast milk or not. Nursing mothers should avoid breastfeeding while taking Ofloxacin + Ornidazole.

4.7 Effects on ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when eating OFLOX-OZ Tablet medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if eating the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively. Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects. Please check for these effects on your body when using OFLOX-OZ Tablet. Always consult with your doctor for recommendations specific to your body and health conditions.

4.8 Adverse effect

The following is a list of possible side-effects that may occur from all constituting ingredients of Ofloxacin Ornidazole 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.

- Abnormal Taste
- Headache
- Diarrhea
- Photosensitivity
- Nausea
- Hallucination

4.9 Overdose

Do not take more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side effects. If you suspect that you or anyone else who may have overdosed of OFLOX-OZ Tablet, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ofloxacin: J01MA01
A synthetic fluoroquinolone (fluoroquinolones) antibacterial agent that inhibits the supercoiling activity of bacterial DNA gyrase, halting DNA replication.
Ofloxacin inhibits the formation of bacterial DNA gyrase. Ofloxacin is effective against Mycobacterium species including M. leprae, M. tuberculosis and Chlamydia trachomatis.

Ornidazole: J01XD03
Antiprotozoal
Imidazole derivative
Ornidazole reduce the nitro group to more reactive amine groups that interrupt with the formation of microbial DNA. The action of Ornidazole results in loss of helical structure and DNA breakdown.

5.2 Pharmacokinetic properties

Ofloxacin:
Absorption: Bioavailability of ofloxacin in the tablet formulation is approximately 98%
Protein binding: 32%
Metabolism: Hepatic
Route of elimination Elimination: is mainly by renal excretion. Between 65% and 80% of an administered oral dose of ofloxacin is excreted unchanged via the kidneys within 48 hours of dosing. Four to eight percent of an ofloxacin dose is excreted in the feces. This indicates a small degree of biliary excretion of ofloxacin.
Half-life:9 hours

Ornidazole
Absorption
Following oral administration ornidazole is rapidly absorbed. Mean absorption is 90%. Peak plasma concentrations are reached within three hours.
Distribution
The mean volume of distribution after i.v. administration is 1 litre per kg. Plasma protein binding of ornidazole is about 13%. The active ingredient of OFLOX-OZ penetrates the cerebrospinal fluid, the body fluids and the tissues very effectively. Plasma concentrations are within the range considered to be optimal for the various indications (6 to 36 mg/l). After repeated administration of 500 mg or 1000 mg every twelve hours to healthy volunteers, an accumulation factor of 1.5-2.5 was calculated.
Metabolism
Ornidazole is mainly metabolised to 2-hydroxymethyl and a-hydroxymethyl metabolites in the liver. Both main metabolites are less active against Trichomonas vaginalis and
Anaerobic bacteria than the unchanged ornidazole.

Elimination

The half-life is about thirteen hours. 85% of a single dose is eliminated within the first five days, most of this being metabolised. 4% of the dose is excreted as unaltered substance in the urine.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Raw Material	Pharmacopoeia
1.	Microcrystalline cellulose	BP
2.	Purified water	BP
3.	Methyl Hydroxybenzoate	BP
4.	Propyl Hydroxybenzoate	BP
5.	Maize Starch	BP
6.	Purified Talc	BP
7.	Colloidal Anhydrous Silica	BP
8.	Sodium Starch Glycolate (Type A)	BP
9.	Magnesium Stearate	BP
10.	Hypromellose	BP
11.	Povidone K-30	BP
12.	Titanium Dioxide (Colour Code Index: 77891	BP
13.	Dichloromethane	BP
14.	Isopropyl Alcohol	BP
15.	Macrogol 4000	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30^0 C & Protect from light & moisture.

6.5 Nature and contents of container
10 Tablets in Alu/ Alu Blister & 3 such Blister in a carton = 3 x 10's = 30 Tablets.

6.6 Special precautions for disposal
No special requirements

7. MARKETING AUTHORISATION HOLDER
Ochoa Laboratories
430, Mzz. F, Gundecha Indl. Complex
Akurli Road, kandivali (E).
Mumbai – 400101. India.
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