SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product :ZOFLONID CAPSULE (Ofloxacin and Ornidazole Capsule)

2. Qualitative and quantitative composition:

Each Capsule contains:

Ofloxacin USP……..200mg

Ornidazole …….. 500 mg

Lactic Acid Bacillus 60 million spores

as enteric Coated granules

colour :Quinoline yellow

Excipients……..…q.s

Sr. No.	Raw Material	Specification	Label Claim	Mg / Tablet (mg)	Category
1	Ofloxacin	USP	200.00	200.00	API
2	Ornidazole	IH	500.00	500.00	API
3	Lactic acid bacillus enteric coated 6000 MS / gm (30 % overages)	IH	60 million spores as enteric Coated granules	13.00	API
4	Starch	BP	---	78.67	Diluent
5	Microcrystalline cellulose	BP	---	66.67	Diluent
6	Starch (for paste)	BP	---	16.66	Binder
7	Purified talc	BP	---	10.0	Lubricant
8	Magnesium stearate	BP	---	10.0	Lubricant
9	starch	BP	---	15.0	Disintegrant
10	Purified water	BP	---	q.s	Granulating vehicle
11	Cellulose acetate phthalate	BP	---	1.33	Coating polymer
12	Methylene chloride	BP	---	q.s	Solvent
13	Acetone	BP	---	q.s	Solvent
14	Hydroxypropyl Methyl cellulose	BP	---	16.67	Coating polymer
15	Polyethylene Glycol (6000)	BP	---	2.67	Plasticizer
16	Titanium Dioxide	BP	---	5.0	Opacifier
17	Isopropyl alcohol	BP	---	q.s	Solvent
18	Methylene chloride	BP	---	q.s	Solvent
19	Color Idacol Quinoline Lake	IH	---	0.34	Colourant

3. Pharmaceutical form:

Capsule

Pale brown colored Capsule.

4. Clinical particulars:

4.1 Therapeutic indications:

Diarrhoea, Dysentery and Amoebiasis

Pelvic Inflammatory Diseases

Post Surgical Care

Typhoid Fever

4.2 Posology and method of administration:

1 capsule twice daily

Route/ Way of administration: Oral.

4.3 Contraindications:

Hypersensitivity to either quinolone group or nitroimidazole group

4.4 Special warnings and precautions for use:

Clostridium difficile - associated disease:

Diarhoea, particularly if severe and/or persistent, occuring during treatment or in the initial weeks following treatment with ofloxacin or with various other antibiotics, but especially broad

spectrum antibiotics, may be sympomatic of Clostridium difficile-associated disease, the most severe form of which is pseudo-membranous colitis.

Ofloxacin may aggravate myasthenia gravis.

Ofloxacin may negativate the isolation of Mycobacterium tuberculosis, giving false negative results, in the bacteriological diagnosis of tuberculosis.

The serum concentration of ofloxacin should be monitored in patients with severe renal impairment and haemodialysis patients.

4.5 Interaction with other medicinal products and other forms of interaction:

Concomitant administration of oral anticoagulants may increase the risk of haemorrhage due to diminished hepatic metabolism. Antacids reduce the absorption of Ofloxacin. As with other nitroimidazoles, Ornidazole may invoke a disulfiram-like reaction in some patients.

4.6 Fertility, pregnancy and lactation:

Pregnancy – Should not be used in pregnancy.

Nursing Mothers – No adequate trials are available to suggest the administration of either drug duringbreast feeding.

4.7 Effects on ability to drive and use machines:

Ofloxacin: None known

Ornidazole: Dizziness, tremor, rigidity, poor coordination, seizures, vertigo or temporary loss of consciousness may occur in patients receiving ornidazole. If they occur, such effects may affect tasks requiring alertness including the patient's ability to drive and operate machinery.

4.8 Undesirable effects:

Common side effects include nausea, abdominal pain, vomiting, insomnia, dizziness, vertigo, ataxia, mental confusion and hypersensitivity reactions. Leucopenia has also been occasionally reported.

4.9 Overdose:

No data is available on overdosage toxicity. In the event of an overdosage the stomach may be emptied and symptomatic treatment should be given.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Ofloxacin

Ofloxacin has in vitro activity against a broad spectrum of Gram-positive and Gram-negative aerobic and anaerobic bacteria. Ofloxacin is often bactericidal at concentrations equal to or slightly greater than inhibitory concentrations. Ofloxacin is thought to exert a bactericidal effect on susceptible microorganisms by inhibiting DNA gyrase, an essential enzyme that is a critical catalyst in the duplication, transcription, and repair of bacterial DNA. Ofloxacin has

been shown to be active against most strains of the following microorganisms both in vitro and in specific clinical infections.

Gram-positive Aerobes: Staphylococcus aureus, Streptococcus pneumoniae, and Streptococcus pyogenes.

Gram-negative Aerobes: Citrobacter diversus, Enterobacter aerogenes, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Neisseria gonorrhoeae, Proteus mirabilis, Pseudomonas aeruginosa

Other: Chlamydia trachomatis.

Ornidazole

Ornidazole is a 5-nitroimidazole derivative with actions similar to Metronidazole and Tinidazole and is used in the treatment of susceptible Protozoal Infections and also in Anaerobic Bacterial Infections. It is effective against Protozoa including Entamoeba histolytica, Giardia lambia and Trichomonas spp and Bacteria such as Bacteroides spp., Anaerobic cocci, Fusobacterium spp., Clostridum spp., and Gardenerlla vaginalis. It acts by damage of DNA strands or inhibition of their synthesis.

5.2 Pharmacokinetic properties:

Both Ofloxacin and Ornidazole are almost completely absorbed from the small intestine when administered orally both having almost 100% bioavailability. Subsequent plasma concentrations of Ofloxacin are obtained in 1-2 hours after oral administration. Peak plasma concentrations of Ornidazole are obtained within 2 hours of administration. The plasma elimination of Ornidazole is 12 to 15 hours and less than 15% is bound to plasma proteins. It is widely distributed in body tissues and fluids. Ornidazole is metabolised in the liver and is excreted in the urine mainly as metabolites and conjugates and to a lesser extent in the faeces.

Rationality

The pharmacokinetic behaviour of the two drugs should be similar to support the use of the two agents in fixed-dose-combination.

Both the drugs in Co-trimoxazole, which is an established combination of sulphamethoxazole and trimethoprim, have their pharmacokinetic parameters like t 1/2 (about 10 hrs for both the drugs) matching with that of each other.

Similarly, the half-lives of Ofloxacin & Ornidazole fall in the same range and hence, the time course of action of the three drugs might be similar which is an important criterion for the possibility of a rational fixed-dose-combination.

Hence, it can be said that Ofloxacin & Ornidazole/Tinidazole show synergistic potential which is one of the most important factor in deciding the feasibility of a FDC

5.3 Preclinical safety data:

There are no pre-clinical data of relevance

6. Pharmaceutical particulars:

6.1 List of excipients:

Maize starch
Microcrystalline cellulose
Purified Talc
Magnesium stearate
Purified water
Cellulose acetate phthalate
Methylene chloride
Acetone
Hydroxypropyl methyl cellulose
Polyethylene Glycol (6000)
Titanium Dioxide
Isopropyl alcohol
Methylene chloride
Color Idacol Quinoline Lake

6.2 Incompatibilities:

-Not Applicable

6.3 Shelf life:

24 months

6.4 Special precautions for storage:

Store in a dry place below 30° C. Protect from Light.

6.5 Nature and contents of container:

1 × 10 tablets

Primary Container: 10 tablets packed in ALU/PVC Blister

Secondary container: Such one blister is packed in a printed outer carton along with Pack insert.

6.6 Special precautions for disposal:

-Not Applicable

7. Marketing Authorization Holder and Manufacturing site address:

Zolon Healthcare Limited

11 Edic Buiding,Town planning

way,ilupeju,Lagos.

8. Marketing authorisation number(s):

A4-8415

9. Date of first authorisation/renewal of the authorization:

24.08.1995

10. Date of revision of the text:

23.02.2025