1. Name of the medicinal Product

1.1 Name of the medicinal Product

Sparfloxacin Tablets 200 mg

1.2 Strength

Each film coated tablet contains:

Sparfloxacin…….200 mg

Excipients……Q.S.

Colour: Tartrazine Yellow

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Sparfloxacin

2.2 Quantitative declaration

Sr. No.	Ingredients	Specifications	Standard Quantity/ Tablet (mg)	Reason for Inclusion
Stage : Mixing				
01	Sparfloxacin	In-house	200.0	Antimicrobial agent
02	Starch	BP	48.00	Binder
03	Dicalcium Phosphate (Plain)	BP	21.00	Diluent
04	Microcrystalline Cellulose	BP	60.00	Diluent
Stage : Binding				
05	Starch	BP	7.000	Binder
Stage : Lubrication				
06	Sodium Starch Glycolate	BP	20.00	Disintegrant
07	Talcum	BP	2.000	Glidant
08	Magnesium Stearate	BP	7.000	Lubricant
09	Silica	BP	1.000	Glidant

Stage : Coating				
11	Tab Coat Colour Tartrazine	In-house	7.000	Colouring agent
12	Dichloromethane	BP	70.00	Solvent
13	IPA	BP	70.00	Solvent

3. Pharmaceutical Form

Solid Oral, Film Coated Tablet

Yellow coloured round shaped biconvex film coated tablet.

4. Clinical Particulars

4.1 Therapeutic Indications

Sparfloxacin is primarily indicated in conditions like acne, bacterial infections, bronchitis, burns, conjuctivitis, cystitis, dysenteries, folliculitis, impetigo, otitis media, pneumonia, prostatitis, pyelonephritis, respiratory tract infections, sinusitis, superficial infections, surgical infections, tonsillitis, urethritis.

4.2 Posology and Method of Administration

In patients with normal renal function: Two 200-mg tablets taken on the first day as a loading dose. Thereafter, one 200-mg tablet should be taken every 24 hours for a total of 10 days of therapy (11 tablets). In patients with renal impairment (creatinine clearance <50 mL/min): Two 200-mg tablets taken on the first day as a loading dose. Thereafter, one 200-mg tablet should be taken every 48 hours for a total of 9 days of therapy (6 tablets).

4.3 Contraindications

It is essential to avoid exposure to the sun, bright natural light and UV rays throughout the entire duration of treatment and for 5 days after treatment is stopped. It is contraindicated in patient with hypersensitivity to the drug, history of tendon disease with a fluoroquinolone, Glucose-6-phosphate dehydrogenase deficiency, known QT-interval prolongation (congenital or acquired). Concomitant use of antiarrhythmic agents or any other drugs which produce torsades de pointes is inadvisable.

4.4 Special Warnings and Special Precautions for Use

Sparfloxacin should be used with caution in patients with any allergy, previous drug reactions (rash) to sunlight, kidney disease, heart conditions, certain mental. conditions (psychosis), blood vessel disease {carotid arteries), brain disorders (e.g. seizures or cancer) or tendon problems. Limit alcohol, because this drug could cause drowsiness, and alcohol can intensify drowsiness. Caution should be taken while driving or performing tasks requiring mental alertness. It should be used only when clearly needed during pregnancy or lactation. It is not recommended for use in persons under 18 years old. Avoid repeated or prolonged use of this medication because prolonged or repeated use may result in a secondary infection (e.g. oral, bladder or vaginal yeast infection).

4.5 Interaction with other medicinal products and other forms of interaction

Salts, oxides and hydroxides of magnesium, aluminium, calcium, sucralfate, zinc salts reduction of the gastrointestinal absorption of sparfloxacin. Antacids and sucralfate: reduce the GI absorption of sparfloxacin. Concomitant use with NSAIDs and theophylline: It can reduce the seizure threshold. Contraindicated concomitant medications: amiodarone, sotalol and bepridil. Inadvisable concomitant medications: bretylium, disopyramide, procainamide, quinidine astemizole, erythromycin, quinine, chloroquine, halofantrine, pentamidine, probucol, terfenadine, vincamine, some tricyclic antidepressants, some neuroleptics. Concomitant medications requiring precautions for use: Iron salts (oral use), non-potassium sparing diuretics, stimulant laxatives, amphotericin B (I.V.), corticosteroids and tetracosactide, digoxin and betablockers.

4.6 Fertility, Pregnancy and Lactation

Teratogenic Effects: Pregnancy Category C: Reproduction studies performed in rats, rabbits, and monkeys at oral doses 6.2, 4.4, and 2.6 times higher than the maximum human dose, respectively, based upon mg/m2 (corresponding to plasma concentrations 4.5- and 6.5-fold higher than in humans in the monkey and rat, respectively) did not reveal any evidence of teratogenic effects. At these doses, sparfloxacin was clearly maternally toxic to the rabbit and monkey with evidence of slight maternal toxicity observed in the rat. When administered to pregnant rats at clearly maternally toxic doses (≥9.3 times the maximum human dose based upon mg/m2), sparfloxacin induced a dose-dependent increase in the incidence of fetuses with ventricular septal defects. Among the three species tested, this effect was specific to the rat. There are, however, no adequate and well-controlled studies in pregnant women. Sparfloxacin

should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Sparfloxacin is excreted in human milk. Because of the potential for serious adverse reactions in infants nursing from mothers taking sparfloxacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability To Drive and use Machines

No or negligible influence on the ability to drive and use machines.

4.8 Undesirable Effects

Less serious side effects: nausea, vomiting, diarrhoea, or constipation; headache, lightheadedness, or drowsiness; ringing in the ears; or increased sensitivity of the skin to sunlight.

Serious side effects: an allergic reaction (difficulty breathing; closing of the throat; swelling of the lips, tongue, or face; or hives); irregular heartbeats; chest pain, chest discomfort, shortness of breath, or swelling of your legs or feet; severe dizziness; seizures; confusion or hallucinations; liver damage (yellowing of the skin or eyes, nausea, abdominal pain or discomfort, unusual bleeding or bruising, severe fatigue); or muscle or joint pain.

4.9 Overdose

In case of overdose, the patient should be monitored in a suitably equipped unit and advised to avoid sun exposure for 5 days. ECG monitoring is recommended due to the possible prolongation of the QT-interval. There is no known antidote for sparfloxacin overdosage.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Sparfloxacin is a synthetic fluoroquinolone broad-spectrum antimicrobial agent. Sparfloxacin has in vitro activity against a wide range of gram-negative and gram-positive microorganisms. Sparfloxacin exerts its antibacterial activity by inhibiting DNA gyrase, a bacterial topoisomerase. DNA gyrase is an essential enzyme which controls DNA topology and assists in DNA replication, repair, deactivation, and transcription. Quinolones differ in chemical structure and mode of action from (beta)-lactam antibiotics. Quinolones may, therefore, be active against bacteria resistant to (beta)-lactam antibiotics.

5.2 Pharmacokinetic Properties

The absorption of sparfloxacin is rapid with peak serum concentrations achieved 3 to 5 hours after the first dose. After a loading dose of 400 mg, the concentrations found in the extravascular

fluid are equivalent to plasma concentrations. 10 µg/g in pulmonary parenchyma, 16.7 µg/ml in alveolar surfactant and 2 to 5 µg/g in the bronchial mucosa. It concentrates preferentially in macrophages, in which concentrations of 40 to 50 µg/g are reached. Plasma proteins binding is 45% and metabolised in the liver to an inactive glucuronide conjugate. The terminal plasma elimination half-life is approximately 20 hours. Excretion is both faecal and urinary. Biliary excretion, mainly as the glucuronide conjugate, accounts for 10 to 20 % of the administered dose.

5.3 Preclinical Safety Data

Not Known

6. Pharmaceutical Particulars

6.1 List of Excipients

Starch BP

Dicalcium Phosphate (Plain) BP

Microcrystalline Cellulose BP

Sodium Starch Glycolate BP

Talcum BP

Magnesium Stearate BP

Silica BP

Tab Coat Colour Tartrazine In-house

Dichloromethane BP

IPA BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

For 10 X 1 X 10 pack style: Yellow coloured round shaped biconvex film coated tablet. 10 tablets are packed in a blister foil in a printed baby carton. Such 10 blisters are packed in a printed mother carton with a package insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

ARHAM REMEDIES
63, Anupam Shopping Center, Nr.Vivekanand Flat,
Jodhpur Gam Road, Satellite, Ahmedabad-380 015
E.mail – arhamremedies17@gmail.com
Phone : +91-9275012851, +91-6351715625

7.2 Name and Address of manufacturing site(s)

VITAL FORMULATIONS LTD.
I/146, Phase IV, G.I.D.C. Vithal Udyognagar,
Anand-388121, Gujarat, India
Phone-02692-236316
E-mail- vitalformulationsltd@gmail.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First Registration / Renewal of The Registration

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable