MODULE -1
ADMINISTRATIVE INFORMATION FOR
UVEX 500 TABLETS

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Uvex 500 Tablet

2. QUALITATIVE QUANTITATIVE FORMULA

SR NO	DRUG NAME	SCALE mg PER TABLET	STANDARD QUANTITY PER 1000 TABLETS
A	**Granulation**		
1	Levofloxacin Use: Levofloxacin Hemihydrate	500 mg 512.45 mg	512.450 g
2	Microcrystalline Cellulose BP (PH 101)	15 mg	15.000 g
3	Lactose Monohydrate BP	30 mg	30.000 g
4	Maize Starch BP	76.3 mg	80.115 g
5	Maize Starch BP (for paste)	18 mg	18.900 g
6	Purified Water BP	q.s.	Approx. 100.000 g
B	Lubrication		
7	Sodium Starch Glycolate BP	20 mg	20.000 g
8	Colloidal Anhydrous Silica BP	3 mg	3.000 g
9	Maize Starch (Dried)	6 mg	6.000 g
10	Purified Talc BP	9.75 mg	9.750 g
11	Magnesium Stearate BP	9.5 mg	9.500 g
C	**Colour Coating**		
12	Wincoat WT-01275 Brown	23.5 mg	23.500 g
13	Isopropyl Alcohol BP	q.s.	Approx 206.000 g
14	Methylene Chloride	q.s.	Approx. 382.000 g
D.	**Printing**		

15	Printing Ink for tablets (Black)		q.s.

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3. PHARMACEUTICAL FORM
Tablet

4. CLINIUCAL PARTICULARS
4.1 Therapeutic indications
Uvex is used to treat infections due to broad-spectrum of bacteria (Gram-positive, Gram-negative bacteria and atypical respiratory pathogens) against which the medicine is active. Some infections for which the tablets can be used to treat are: pneumonia, urinary tract infections, skin and soft tissue infection and infection of the prostate

4.2 Posology and method of administration
As directed by the Physician.
Tablet for oral administration.

4.3 Contraindications
Levofloxacin is contraindicated in persons with a history of hypersensitivity to Levofloxacin, quinolone antimicrobial agents, pregnancy, lactation, children <18 years

4.4 Special warnings and precautions for use
Drug interactions do occur with aluminium and magnesium containing antacids and ferrous sulfate, as well as sucralfate, metal cations such as iron and multivitamin preparations with zinc or didanosine resulting in significantly decreased levofloxacin absorption when administered concurrently.
Levofloxacin may significantly potentiate the anticoagulation effect of warfarin. Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concomitantly with levofloxacin and an antidiabetic agent.

4.5 Fertility, pregnancy and lactation
Levofloxacin is contraindicated in pregnancy & lactation.

4.6 Effects on ability to drive and use machines
Some undesirable effects (e.g. dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

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4.7 Side Effects
Side effects that may occur are diarrhoea, vomiting, abdominal pain, nausea, dyspepsia, rash, dizziness, headache and photosensitivity.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: quinolone antibacterials, fluoroquinolones, ATC code: J01MA12

Levofloxacin is a synthetic antibacterial agent of the fluoroquinolone class and is the S (-) enantiomer of the racemic active substance ofloxacin.

Mechanism of action

As a fluoroquinolone antibacterial agent, levofloxacin acts on the DNA-DNA-gyrase complex and topoisomerase IV.

PK/PD relationship

The degree of the bactericidal activity of levofloxacin depends on the ratio of the maximum concentration in serum (C_{max}) or the area under the curve (AUC) and the minimal inhibitory concentration (MIC).

Mechanism of resistance

Resistance to levofloxacin is acquired through a stepwise process by target site mutations in both type II topoisomerases, DNA gyrase and topoisomerase IV. Other resistance mechanisms such as permeation barriers (common in *Pseudomonas aeruginosa*) and efflux mechanisms may also affect susceptibility to levofloxacin.

Cross-resistance between levofloxacin and other fluoroquinolones is observed.

Due to the mechanism of action, there is generally no cross-resistance between levofloxacin and other classes of antibacterial agents.

5.2 Pharmacokinetic properties
Absorption

Orally administered levofloxacin is rapidly and almost completely absorbed with peak plasma concentrations being obtained within 1-2 h. The absolute bioavailability is 99-100%.

Food has little effect on the absorption of levofloxacin.

Steady state conditions are reached within 48 hours following a 500 mg once or twice daily dosage regimen.

Distribution

Approximately 30-40% of levofloxacin is bound to serum protein. The mean volume of distribution of levofloxacin is approximately 100l after single and repeated 500mg doses, indicating widespread distribution into body tissues.

Penetration into tissues and body fluids:

Levofloxacin has been shown to penetrate into bronchial mucosa, epithelial lining fluid, alveolar macrophages, lung tissue, skin (blister fluid), prostatic tissue and urine. However, levofloxacin has poor penetration intro cerebro-spinal fluid.

Biotransformation

Levofloxacin is metabolised to a very small extent, the metabolites being desmethyl-levofloxacin and levofloxacin N-oxide. These metabolites account for <5% of the dose and are excreted in urine. Levofloxacin is stereochemically stable and does not undergo chiral inversion.

Elimination

Following oral and intravenous administration of levofloxacin, it is eliminated relatively slowly from the plasma (t½: 6 - 8 hours). Excretion is primarily by the renal route (>85% of the administered dose).

The mean apparent total body clearance of levofloxacin following a 500 mg single dose was 175 +/-29.2 ml/min.

There are no major differences in the pharmacokinetics of levofloxacin following intravenous and oral administration, suggesting that the oral and intravenous routes are interchangeable.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose BP (PH 101)

Lactose Monohydrate BP

Maize Starch BP

Maize Starch BP (for paste)

Purified Water BP

Sodium Starch Glycolate BP

Colloidal Anhydrous Silica BP

Purified Talc BP

Magnesium Stearate BP

Wincoat WT-01275 Brown

Isopropyl Alcohol BP

Methylene Chloride

6.2 Incompatibilities
None

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30 ^{0}C.