

MODULE -1
ADMINISTRATIVE INFORMATION FOR
UVEX 500 TABLETS

1.5.3 PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully before you starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

- 1 What is Uvex 500 and what is it used for**
- 2 What you need to know before you take Uvex 500**
- 3 How to take Uvex 500**
- 4 Possible side effects**
- 5 How to store Uvex 500**
- 6 Contents of the pack and other information**

1 WHAT IS UVEX 500 AND WHAT IS IT USED FOR

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE UVEX 500

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

Other medicines and UVEX 500

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

MODULE -1
ADMINISTRATIVE INFORMATION FOR
UVEX 500 TABLETS

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.

Pregnancy, breast-feeding and fertility

Uvex 500 is contraindicated in pregnancy & lactation.

3. HOW TO TAKE UVEX 500

Orally

Dose

As directed by the Physician.

Tablet for oral administration.

If you take more UVEX 500 than you should

It is important not to take doses. If you have taken more than you should, contact your doctor, pharmacist or nearest hospital casualty department immediately.

If you forget to take UVEX 500

If you forget to take your dose, take it as soon as you remember, unless it is nearly time for your next dose, do not take the dose you have missed. Do not take a double the dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

5. HOW TO STORE UVEX 500

Store below 30°C, at a dry place.

Protect from light.

Keep medicines out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What UVEX 500 contains

The active substance is Levofloxacin

The other ingredients are Microcrystalline Cellulose BP (PH 101), Lactose Monohydrate BP

MODULE -1
ADMINISTRATIVE INFORMATION FOR
UVEX 500 TABLETS

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, WT-01275 Brown Isopropyl Alcohol BP, Methylene Chloride.

What UVEX 500 looks like and contents of the pack

Light brown coloured, round shaped biconvex, film coated tablets with printing “L 500” on one side in black colour. Such 10 tablets (5X2) packed in a monocarton along with an insert. Such 10 monocartons packed in a secondary carton.