SUMMARY OF PARTICULAR PRODUCTS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Name: Ofloxacin Ophthalmic Solution
Form: Ophthalmic Solution
Sthrangth：8ml:24mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	Qty/Unit	Pharm. Use	Technical specification
Ofloxacin	24mg	Active	USP

3. PHARMACEUTICAL FORM

Form: Ophthalmic Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is suitable for the treatment of bacterial conjunctivitis and bacterial keratitis caused by sensitive bacteria

4.2 Posology and method of administration

Drip into the eyelids for 3-5 times a day, 1-2 drops per time, or as directed by a physician

4.3 Contraindications

It’s contraindicated in patients with allergy to ofloxacin or other quinolones, and any component of the product.

4.4 Special warnings and special precautions for use

1. This product is limited to the Ophthalmic Solution and cannot be used with subconjunctival injection and neither can directly drip into the anterior chamber of the eye.
2. Alike other anti-infective drugs, to extend the use of this product may cause excessive growth of non-infectious microorganisms, including fungi and thus should not be used for a long time.
3. Quinolones systemic medication, even though only once, may also produce allergic reaction. Some reaction are together with shock, loss of consciousness, vascular edema (including the pharynx, larynx or facial edema), airway obstruction, dyspnea, urticaria, pruritus, etc. If rash or other signs of an allergic reaction happen, the patient should immediately stop using and rather consult a doctor.
4. Please be careful to avoid contamination of container front when using it.
5. The patients with bacterial conjunctivitis, keratitis patients are not for wearing contact lenses.

4.5 Interaction with other FPPs and other forms of interaction

Study on the drug interaction has not yet been done. However, it has been shown that some quinolones systemic use can increase the blood concentration of theophylline, disturb caffeine metabolism, and increase oral anticoagulation with warfarin and its derivatives. Taking with cyclosporin, patients may have a transient elevation of serum creatinine.

4.6 Pregnancy and lactation

At present there is no enough control research among pregnant women so only when the potential benefits of drug outweigh the potential risks to the fetus, pregnant women can use this product.

Ofloxacin can excrete through human breast milk secretion, therefore lactating women should be careful to use.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Occasionally it has transient stimulus symptom but generally does not affect the drug use, manifesting as transient burning eyes, eye pain or discomfort, pharyngitis and photophobia. It rarely has allergy, eyelid edema, eye dryness and itching.

4.9 Overdose

No case of overdose has been reported

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The product inhibits DNA reproduction by inhibiting DNA gyrase. It features as strong antibacterial activity with a broad antibacterial spectrum and has antibacterial activity gram positive and negative bacteria, and is effective to staphylococcus aureus, streptococcus pyogenes, hemolytic streptococcus, pneumococcus, escherichia coli, enterococcus spp., Citrobacter, klebsiella pneumoniae, enterobacter, serratia, proteus, pseudomonas aeruginosa, flu bloodthirsty bacillus, acinetobacter, bending rod bacteria, chlamydia sensitive strain. This product has no cross drug resistance with other antibacterial drugs.

【For Children】

Efficacy and safety of this product has not yet been established for infants below 1 year old. Immature animal orally taking quinolones can have joint disease. There is no evidence that ofloxacin Ophthalmic Solution have any effect on the bearing

joint.

【For the elders】

For efficacy and safety of using this product, there is no general difference between the old people and other patients.

5.2 Pharmacokinetic properties

Literatures show the drug concentration of the sera, urine and tear of 30 healthy women was 0.4ng/ml to 1.9ng/ml after the ofloxacin Ophthalmic Solution were used for 10 days, which was 1000 times lower than that of the normal preparation. The drug concentration of tear ranged from 5.7 to 31mg/g after they last used the Ophthalmic Solution for 40 minutes. The average drug concentration of tear was 9.2mg/g, and the ofloxacin in urine was excreted as prototype.

5.3 Preclinical safety data

This product has no cross drug resistance with other antibacterial drugs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

INACTIVE INGREDIENTS	Qty/Unit	Pharm. Use
Mannitol	0.36g	Excipient
Disodium edetate	1mg	Excipient
5%BenzalkoniumBromide Solution	0.016ml	Excipient
Water for injections	q.s.to 8ml	Solvent

6.2 Incompatibilities

Study on the drug interaction has not yet been done. However, it has been shown that some quinolones systemic use can increase the blood concentration of theophylline, disturb caffeine metabolism, and increase oral anticoagulation with warfarin and its derivatives. Taking with cyclosporin, patients may have a transient elevation of serum creatinine.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a shady place and seal well

6.5 Nature and contents of container

The inner packagingmaterial of this productaremulti-doselow-density polyethylenebottlesof medicinalOphthalmic Solution. And the bottle will be packed in a cardboard box.

6.6 Instructions for use and handling <and disposal>

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Jiangsu Farever Pharmaceutical Co., Ltd.

8.NUMBER(S) IN THE NATIONAL REGISTER OF FINISHEDPHARMACEUTICAL PRODUCTS

JIA/CHI/12

9.DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/12/2019

10. DATE OF REVISION OF THE TEXT

Dec., 20 ,2020