SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Indometacin Suppositories 0.1g

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each suppository contains: Indometacin 100mg

3. PHARMACEUTICAL FORM

Suppository

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For rheumatoid arthritis, rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and acute gouty attack etc.

4.2 Posology and method of administration

Rectal administration.

Take 50 ~ 100mg, once a day. Wash hands and anus before use. Tear 1 capsule of suppository from plastic packaging. Split the front and back sheet off from the bottom. Carefully opened and seperate the two plastic films. Take one plastic finger cover, and cover it on the index finger. Take the suppository particle out and gently push it inside the anus with the index with finger cover. The end of the suppository should make the distance of about 2 cm away from the anus.

4.3 Contraindications

1.The patients who are allergic to the product or aspirin or other nonsteroidal anti-inflammatory drugs, having angioedema or bronchial spasm, should be prohibited to use.

2. The patients who are having active ulcer, ulcerative colitis or other diseases of upper digestive tract or have history of those diseases are prohibited to use.

3. The patients who have hepatic, renal insufficiency should be used with caution or not use.

4. The pregnant and lactating women are prohibited to use.

4.4 Special warnings and special precautions for use

1. The patients who have epilepsy, Parkinson's disease or mental problems can aggravate when using this product.

2. The patients who have heart failure and hypertension should use with caution.

3. The patients who have haemophilia, aplastic anemia, or neutropenia, bleeding should use the product with caution.

4. During the time of medication, the patients should regularly check blood and liver, kidney function. The long-term drug users should regularly conduct the ophthalmological examination.

5. The dose should be no more than 200 mg within.24 hours.

6. Please do not use if the drug properties change.

4.5 Interaction with other FPPs and other forms of interaction

1. This product can aggravate toxicity of kidney when combing use of paracetamol in a long term. The product can increase the incidence of gastrointestinal ulcers when combing with the other non steroidal anti-inflammatory drugs.

2. This product can increase the risks of gastrointestinal ulcers or bleeding when the patients drink alcohol or combine with the use of aspirin, salicylic acid salt, sugar cortical hormone, corticotropin, colchicine, sulfinpyrazone.

3. This product can increase the toxicity when combing the use of digitalis, nifedipine, Vera Pammy, probenecid, methotrexate, lithium salt, Zidorf.

4. This product can strengthen the anticoagulant effect when combing the use of heparin, oral anticoagulants or thrombolytic drugs.

5. This product can strengthen the hypoglycemic effect when combining the use of insulin or oral hypoglycemic drugs. So the patients must adjust hypoglycemic drug dose.

6. This product can cause renal dysfunction when combining the use of triamterene.

7 . This product can reduce the sodium excretion and antihypertensive effect when combing the use of furosemide .

4.6 Pregnancy and lactation

Pregnant and lactating women should not use the product

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

1 Gastrointestinal reaction: The product seldom has indigestion, stomach pain, stomach burning sensation, nausea, acid reflux and rarely gastric ulcer bleeding and perforation of stomach.

2. Nervous system reactions: headache, dizziness, anxiety and insomnia.

3.Hematopoietic system: aplastic anemia, white blood cell or platelet reduction.

4.Skin and allergic reaction: pruritus, erythema multiforme, bullous erythema nodosum, asthma, urticaria, angioedema and shock.

4.9 Overdose

The test has not yet been conducted and no reliable references are available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This product is non steroidal anti-inflammatory drug and can inhibit

prostaglandin synthesis. Its anti-inflammatory, analgesic and antipyretic effects may all be related to the inhibition of prostaglandin synthesis, inhibiting the formation of inflammatory tissue pain nerve impulses, inhibiting the inflammatory reaction, and inhibitting leukocyte chemotaxis and lysosomal enzyme release. This product takes effect on the hypothalamic thermoregulatory center and causes peripheral vasodilation and sweating and thus leads hypothermia.

5.2 **Pharmacokinetic properties**

This product is absorbed by rectal mucosa absorption with rapid effect. It is metabolized by the liver, and most is conjugated with glucuronic acid. Its metabolites can hydrolyze to Indometacin and re-enter into the blood. The rest are excreted in the urine. The milk can also excrete it.

5.3 Preclinical safety data

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

INACTIVE INGREDIENTS	Qty/Unit	Pharm. Use
Polysorbate 80	8mg	Surfactant
Hard fat	792mg	Vehicle

6.2 Incompatibilities

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6.3 Shelf life

2 years

6.4 Special precautions for storage

Store it in shady places with sealing not over 30°c

6.5 Nature and contents of container

PVC plastic sheets with medical polyethylene finger covers in the cardboard box.

6.6 Instructions for use and handling <and disposal>

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Jiangsu Farever Pharmaceutical Co., Ltd.

8. MARKETING AUTHORISATION NUMBER(S)

06784/08040/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24-11-2021

10. DATE OF REVISION OF THE TEXT

Dec. 20, 2022