1.3.1 Summary of Product Characteristics (SmPC)

(1) Name of the medicinal product

Diclofenac Sodium Injection 75mg/3ml

(2) Qualitative and quantitative composition

Each ampoule(3ml) contains:

Approved name	Quantity/dose	Function
Diclofenac Sodium	75mg	Active substance
Propylene glycol	0.51g	Plasticizer
Benzyl alcohol	0.12g	Disinfectant
Anhydrous sodium sulfite	3mg	Antioxidant.
Water for injection	Be added to 3ml	Solvent

(3)Pharmaceutical form

Small volume injection

(4) Clinical particulars

①Therapeutic indications

It is used for the pain caused by rheumatism, rheumatoid arthritis, adhesive spondylitis, non-inflammatory arthralgia, vertebral arthritis, non-articular rheumatism, etc.

② Posology and method of administration

For I.M.： Deep intramuscular injection. 50 mg once, 2-3 times a day.

③ Contraindications

Allergy to aspirin or other non-steroidal anti-inflammatory drugs or a history of

asthma is contraindication.

Pregnant and lactating women are not allowed to use.

(5) Special warnings and precautions for use

1.This product is not an etiological treatment, nor can it control the course of various chronic arthritis.

2.Use with caution if there is a history of peptic ulcer or bleeding ulcer.

3.Use with caution in patients with liver or kidney damage or ulceration. Especially older people. Routine follow-up examination of liver and renal function should be conducted during medication.

4.This product contains sodium, to limit sodium intake of patients should be used with caution.
5.Interference to diagnosis: this product can cause the transient elevation of serum aminotransferase, decrease of serum uric acid content, and increase of uric acid content.
6.the medication, if gastrointestinal bleeding, liver and kidney damage, visual impairment, abnormal blood pattern and allergic reaction occur, the medication should be stopped.

(6) Interaction with other medicinal products and other forms of interaction

1.Alcohol consumption or use with other NSaids increases the risk of gastrointestinal adverse events and ulcers. Long-term use with acetaminophen can increase the toxic side effects on the kidney.
2.When used with aspirin or other salicylic acid drugs, the efficacy was not enhanced, but the incidence of gastrointestinal adverse reactions and bleeding tendency was increased.
3.There is an increased risk of bleeding when used with heparin, discoumarin and other anticoagulants and platelet aggregation inhibitors.
4.When used with furosemide, the sodium excretion and antihypertensive effect of the latter were reduced.
5.When used with verapamil and niphenyl, the plasma concentration of this product increased.
6.This product can increase the blood concentration of digoxin, with attention to adjust the dosage of digoxin.
7.When used together with antihypertensive drugs, the antihypertensive effect of the latter can be affected.
8.Benzosulfonamide can reduce the excretion of the product, increase the blood concentration, and thus increase toxicity, so reduce the dose of this product when used together.
9.This product can reduce the excretion of methotrexate, increase its blood concentration, and even reach the toxic level, so this product should not be used with medium or high dose methotrexate.
10.This product can reduce the effect of insulin and other hypoglycemic drugs, make blood sugar rise.
11.When used with potassium - preserving diuretics, hyperkalemia may occur.
12.Aspirin may reduce the bioavailability of the product

(7) Pregnancy and lactation

This product can pass through the placenta. Animal tests are toxic to fetal rats but not teratogenic. Pregnant women using this product can prolong pregnancy, cause dystocia and prolongation of labor. Therefore, pregnant women and lactating women are prohibited.

(8)Child medication

It is not recommended for children under 16.

(9) Elderly medication

Use with caution in elderly patients

(10)Adverse effects

1.There are common gastrointestinal reactions, such as stomach discomfort, burning sensation, acid reflux, poor appetite, nausea, etc., stop medicine or symptomatic treatment can disappear. Long-term application may lead to gastric ulcer, gastric bleeding and gastric perforation.

2.A few appear dropsy, little urine, electrolyte disorder.

3.Occasional neurological reactions (incidence < 1%), such as headache, dizziness, drowsiness, excitement, etc.

(11)Overdose

This experiment has not been conducted and there are no reliable references

(12)Pharmacology and toxicology

Diclofenac sodium is a non-steroidal anti-inflammatory and analgesic drug derived from phenylacetic acid. Its mechanism of action is to inhibit the activity of epoxidase, thereby blocking the conversion of arachidonic acid to prostaglandin.

At the same time, it can promote the binding of arachidonic acid to triglyceride, reduce the concentration of intracellular free arachidonic acid, and indirectly inhibit the synthesis of leukotriene. Diclofenac sodium is one of the strongest non-steroidal anti-inflammatory drugs, and it has a strong inhibitory effect on prostaglandin synthesis.

(13)Pharmacokinetics

The binding rate of plasma protein is 99.5%, about 50% in liver, 40%~65% in kidney and 35% in bile and feces.

(14) Storage

Shading and airtight storage.

(15) Shelf life

36 months.