SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1-Name of the Medicinal Product ： Diclofenac Sodium Injection 75mg/3ml

1.1 Product Name: Diclofenac Sodium Injection

1.2 Strength: 75mg/3ml

1.3 Pharmaceutical Dosage Form: solution for injection

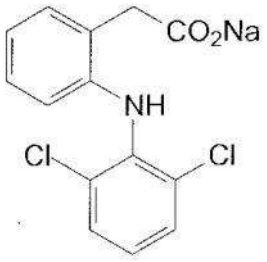
2-Quality and Quantitative Composition ：

2.1 Qualitative Declaration
The active substance of the Diclofenac Sodium Injection is Diclofenac Sodium.

Diclofenac Sodium：White or slightly yellowish, slightly hygroscopic, crystalline powder. Sparingly soluble in water, freely soluble in ethanol (96 per cent), slightly soluble in acetone, insoluble in ether.

The molecular formula of Diclofenac Sodium: $C_{14}H_{10}Cl_2NNaO_2$

The structural formula of Diclofenac Sodium :



The molecular weight of Diclofenac Sodium : 318.13

The CAS number of Diclofenac Sodium :15307-79-6

2.2 Quantitative Declaration

Diclofenac Sodium Injection 75mg/3ml

Dosage form：small volume injection

Concentration：75mg/3ml

Product description： 3ml of nearly colorless transparent liquid is filled in the glass ampoule（3ml）.

Ingredients	Quantity per ampoule （3ml）	Function of ingredients
Diclofenac Sodium	75mg	Active Ingredient
Benzyl alcohol	0.12g	Disinfectant
Anhydrous sodium sulfite	3mg	Antioxidant.
Propylene glycol	0.51g	Plasticizer
Water for injection	Be added to 3ml	Solvent

3-Pharmaceutical Form ：

Dosage form： Solution for injection
3ml of nearly colorless transparent liquid is filled in the glass ampoule（3ml）.

4-Clinical Particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

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

4.3 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.

4.4 Special warning 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.

4.5 Interaction with other medicinal products and other forms of Interactions
(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

4.6 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.

4.7 Effects on ability to drive and use machines
N.A.

4.8 Undesirable 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.

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

5-Pharmacological properties

5.1 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.

5.2 Pharmacokinetics

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

5.3 Preclinical safety data
N.A

6-Pharmaceutical Particulars

6.1 List of excipients
Propylene glycol,Benzyl alcohol,Anhydrous sodium sulfite,Water for injection

6.2 Incompatibilities
The stability of the drug product demonstrated that there was no compatibility problem between drug substance and excipients materials or between drug substance and packaging materials.

6.3 Shelf life
36months

6.4 Special precautions for storage
Shading and airtight storage.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Ampoules Made of Low Borosilicate Glass Tubing.

6.6 Special precautions for disposal

N.A.

7-**Name Of Manufacturer&Marketing Authorization Holder** :

7.1 Manufacturer:
Anhui Chengshi Phamaceutical Co., Ltd.
No. 5068 Huaishang road,Bengbu,Anhui province, China
E-mail:csyy2827111@163.com

7.2 Marketing Authorization Holder:
GLOBAL YOUNG PHARMA LIMITED
AGARA BABA PUPA, ROAD 5 (HOUSE NO.3) OFF ODO-ONA ELEWVE, NEW GARAGE, IBADAN OYO STATE
Email: youngpharmareg@gmail.com

158*78*17mm


Global Young
For I.M. USE
10 Ampoules x 3ml
DICLOFENAC INJECTION
Diclofenac Sodium injection 75mg/3ml
NAFDAC Reg. No.:
Each ampoule contains: Diclofenac Sodium 75mg
Marketed by:
Global Young Pharma Limited.
Agara Baba Pupa, Road 5 (House NO.3) Off Odo-Ona
Elewve, New Garage, Ibadan Oyo State, Nigeria
Manufactured by:
Anhui Chengshi Pharmaceutical Co.,Ltd
No.5068 Huaishang Road,Bengbu,Anhui province,China
DICLOFENAC INJECTION
Diclofenac Sodium injection 75mg/3ml
For I.M. USE
10 Ampoules x 3ml
DICLOFENAC INJECTION
Diclofenac Sodium injection 75mg/3ml
Global Young
For I.M injection
Store away from light in a cool place below 25°C.
KEEP MEDICINES OUT OF REACH OF CHILDREN
Pour des injections i.m.
Conserver dans un endroit sec et frais à l'abri de la lumière
A TENIR HORS DE PORTEE D'D'ENFANTS
Para inyecciones i.m.
Conseryar en un lugar fresco y seco y proteger de luz
MANTENER FUERA DEL ALCANCE DE LOS NINOS
DICLOFENAC INJECTION
Diclofenac Sodiuminection 75mg/3ml
Mfg. Lic. No.:
Batch No.:
Mfa.Date:
Exp. Date:
NAFDAC Reg. No.:

Global Young
DICLOFENAC SODIUM INJECTION

COMPOSITION:
Each 3 ml contains diclofenac sodium 75 mg.

PHARMACOLOGICAL CLASSIFICATION:
A. 3.1 Antirheumaties (Anti-inflammatory Agents)

PHARMACOLOGICAL ACTION:
Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins which are known to be implicated in the pathogenesis of inflammation, pain and fever. Peak plasma levels are obtained ten to twenty two minutes after an intramuscular injection of 75 mg diclofenac sodium. There is at least99% binding to plasma-proteins with Diclofenac Sodium Injection and excretion of metabolites is mainly in the urine.

INDICATIONS:
Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteoarthrosis, painful post-operative and post-traurnatic inflammation and swelling, and dysmenorrhoea.

CONTRA-INDICATIONS:
Diclofenac sodium is contra-indicated in patients with a known hypersensitivity to diclofenac and in patients who respond to aspirin and aspirin-type drugs with sensitivity reactions like asthma, acute rhinitis and urticaria. Diclofenac sodium is absolutely contra-indicated in patients with peptic ulceration or a history of such ulceration, and should be used with caution in patients with renal or hepatic insufficiency.

WARNINGS:
Serious interactions have been reported after the use of high dose methotrexate with diclofenac.

DOSAGE AND DIRECTIONS FOR USE:
The directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site. Only for deep intragluteal injection into the upper outer quadrant. After inserting the needle the plunger should be pulled back to avoid inadvertent intra-arterial injection.
Adults:
One 75 mg/3 mL ampoule daily, intramuscularly into the upper, outer quadrant of the buttocks. (Parenteral administration should be supplemented by oral therapy). In severe or acute conditions this may be increased to two ampoules daily, the injections given one in each buttock, separated by an interval of a few hours.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Gastric or intestinal ulceration with associated bleeding has been reported. Therapy with Diclofenac Sodium Injection should be discontinued immediately in such cases. Skin rashes and gastro-intestinal disturbances may occur. Headache, nervousness, pruritus, tinnitus, insomnia, blurred vision and other ocular reactions, dizziness, oedema, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (eg. bronchospasm) have occurred. Blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with Diclofenac Sodium Injection as blood dyscrasias have been reported. The safe use of Diclofenac Sodium Injection in pregnancy has not been demonstrated. Blood concentrations of lithium are increased when Diclofenac Sodium Injection is administered concommitantly. Diclofenac Sodium Injection should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants, in generally should not be given Diclofenac Sodium injection. Injections of Diclofenac Sodium may cause local pain and irritation; abscesses and local necrosis have been reported, especially in elderly diabetics. Diclofenac Sodium may mask the signs and symptoms of infection due to its pharmacodynamic properties.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "Side-effects and Special Precautions". Treatment is symptomatic and sopportive.

PACKAGING:
3ml x 10 Amps.

STORAGE INSTRUCTIONS:
Store below 30°C. Protect from heat and light.
Keep out of reach of children.

MANUFACTURED BY: **Anhui Chengshi Pharmaceutical Co.,Ltd**
No.5068 Huaishang Road,Bengbu,Anhui province,China

Marketed by: **Global Young Pharma Limited.**
Agara Baba Pupa, Road 5 (House NO.3) Off Odo-Ona Elewve, New Garage,
Ibadan Oyo State, Nigeria