Summary of product characteristics

1. Product Name

DOLO-MEC

Compound Vitamin B and diclofenac sodium tablet

Dosage form: Tablet

2. Quality and Quantitative Composition

Each tablet contains vitamin B1 50mg,Vitamin B6 100mg , vitamin B12 100μg，diclofenac sodium 50mg

Excipient are listed in 6.1

3. Pharmaceutical form visual description of the appearance of the product

A pink film-coated tablets

4. Clinical particulars

4.1 Therapeutic indications

1) For the treatment of clinical and sub-clinical vitamin B deficiency states It is also used for single neuropathy or multiple peripheral neuritis caused by different etiologies.

4.2 Posology and method of administration

Adults (including elderly) and children over 3 years: One to two tablets three times daily.

Children under 3 years: Not recommended.

For oral administration.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

1. Chloramphenicol, cycloserine, ethionamide, hydralazine hydrochloride, immunosuppressive agents including adrenal cortex hormones, cyclophosphamide, cyclosporine, isoniazid, penicillamine and other drugs can antagonize vitamin B6 or Increasing the excretion of vitamin B6 through the kidneys can cause anemia or peripheral neuritis.

2. The combination of levodopa and low-dose vitamin B6 (5mg per day) can antagonize the anti-tremor effect of levodopa. But it has no effect on carbidopa.

4.6 Fertility, pregnancy and lactation

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Toxic effects are unlikely since any excess vitamin B is excreted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Excess vitamin B is readily excreted, therefore no serious problems are anticipated for the administration of vitamin B in this form.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: A11EA

The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

5.2 Pharmacokinetic properties

Vitamin B1 forms thiamine pyrophosphate in the body, which is a necessary coenzyme for carbohydrate metabolism and can maintain the normal functions of the heart, nerves and digestive system. Vitamin B1 can inhibit the activity of

cholinesterase. When it is lacking, the activity of cholinesterase will be enhanced, and the hydrolysis of acetylcholine will be accelerated, causing nerve impulse conduction obstacles and affecting gastrointestinal and myocardial functions. Vitamin B6 is converted into pyridoxal phosphate in red blood cells and acts as a coenzyme on various metabolic functions of protein, carbohydrates and lipids. Vitamin B6 is also involved in the conversion of tryptophan into niacin or 5-hydroxytryptophan. Vitamin B12 participates in methyl conversion and folate metabolism in the body, and promotes the conversion of 5-methyltetrahydrofolate into tetrahydrofolate. When it is lacking, it leads to DNA synthesis obstacles and affects the maturation of red blood cells. This product also promotes the conversion of methylmalonic acid to succinic acid and participates in the tricarboxylic acid cycle. This effect is related to the synthesis of nerve myelin lipids and maintaining the integrity of nerve fibers. The nerve damage of vitamin B12 deficiency may be related to this.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Starch

Microcrystalline cellulose

Sodium Starch Glycolate

Hydroxypropyl Cellulose

5% Hypromellose

Silicon dioxide

Talcum powder

Sodium Starch Glycolate

Magnesium stearate

Flavor

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life

3 years from the date of manufacture.

Shelf-life after dilution/reconstitution

Not applicable.

Shelf-life after first opening

Not applicable.

6.4 Special precautions for storage

Store below 30°C in a dry place.

7. Manufacturer

Jiangxi Xier Kangtai Pharmaceutical Co., Ltd.

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