MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product
MeCure's Diclofenac and Vitamin B1+B6+B12 Tablets
(Diclofenac Sodium 50mg and Vitamin B1+B6+B12)

2. Qualitative and quantitative composition
Each film-coated tablet contains:

Vitamin B1: 50mg

Vitamin B6: 100mg

Vitamin B12: 100mcg

Diclofenac Sodium: 50mg

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Tablet

4. Clinical particulars
4.1 Therapeutic indications
Musculoskeletal and joint disorder, inflammation, pain, neuralgia and neuritis (Neuropathies).

4.2 Posology and method of administration
Adults (including elderly) and children over 3 years of age:
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 authorization 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 Pharmacodynamics 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 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
Tablet Core
Diclofenac Sodium, Vitamin B1, Vitamin B6, Vitamin B12, Lactose, Starch, PVP K30, IPA, Talcum, Croscarmellose Sodium, Magnesium Stearate.
Tablet Coating
Isopropyl Alcohol, Ready Mix Coat (Yellow), Methylene Chloride.

6.2 Incompatibilities
None known.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store in a cool dry place below 30°C and protect from light.

KEEP MEDICINES OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
Aluminium-PVC Blister Pack

Administrative Data

7. Marketing authorisation holder
Me Cure Industries PLC,

Plot 6, Block H,

Oshodi Industrial Scheme,

Oshodi, Lagos,

Nigeria.

8. **Nafdac Registration Number:** B4-4631