

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Comploment 100mg Prolonged – Release Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyridoxine Hydrochloride 100mg.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Yellow, biconvex, film-coated prolonged release tablet, marked 'C' on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Isoniazid-induced peripheral neuritis. Idiopathic sideroblastic anaemia.

4.2 Posology and method of administration

Oral

Adults only: The usual daily dose is 100mg.

Tablets should be swallowed whole and not chewed.

4.3 Contraindications

Hypersensitivity to vitamin B6 or any of the ingredients.

4.4 Special warnings and precautions for use

High doses taken continuously for prolonged periods of time may be associated with the development of sensory neuropathy. The symptoms are generally reversible on withdrawal of pyridoxine.

Do not exceed the stated dose.

Short term use is recommended.

4.5 Interaction with other medicinal products and other forms of interaction

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy in patients with Parkinson's Disease.

4.6 Pregnancy and lactation

Use in pregnancy is not recommended unless considered essential by a physician. In high doses, pyridoxine may interfere with prolactin and should be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Gastric hyperacidity and indigestion may occur at doses above 200mg/day. Nausea and breast tenderness have also been reported.

4.9 Overdose

Ingestion of 20 to 30 tablets may cause headache and will alter the kinetics of levodopa. No treatment is necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Following absorption, pyridoxine is converted into its active forms: pyridoxal phosphate and pyridoxamine phosphate. These compounds act as co-enzymes in the metabolism of amino acids, carbohydrates and lipids. They are involved in transamination of amino acids and the conversion of tryptophan to niacin. Pyridoxine appears to be essential to the synthesis of gamma-aminobutyric acid (GABA) in the central nervous system and in the synthesis of haem.

5.2 Pharmacokinetic properties

Pyridoxine is readily absorbed from the gastrointestinal tract. It is stored mainly in the liver with lesser amounts in muscle and brain. Pyridoxal and pyridoxamine phosphate, the principal forms of the vitamin present in the blood, are highly protein bound. In erythrocytes, pyridoxine is converted to pyridoxamine phosphate. In the liver, pyridoxine is phosphorylated to pyridoxamine phosphate and transaminated to pyridoxal and pyridoxamine which are rapidly phosphorylated. Pyridoxal is oxidised to 4-pyridoxic acid which is excreted in the urine.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Hydrogenated castor oil
Hydroxyethylcellulose
Cetostearyl alcohol
Purified talc
Magnesium stearate

Film Coat:

Hypromellose (5cps)
Hypromellose (15cps)
Macrogol 400

Opaspray M-IF-60716 yellow comprised of:
Hypromellose
Quinoline yellow aluminium lake (E104)
Sunset yellow aluminium lake (E110)
Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep blister in the outer carton.

6.5 Nature and contents of container

Blisters comprised of 250µm PVC coated with 48g/m² PVDC heat sealed to 20 µm hard tempered aluminium foil in cartoned packs containing 28 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special precautions.

7 MARKETING AUTHORISATION HOLDER

Seton Products Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 0618/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 February 1978

Date of last renewal: 06 February 2003