

BECOPLEX IDO

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

BECOPLEX IDO, Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Injection of vitamin B complex, each mL contains:

| | |
|--------------------------|----------|
| Thiamine hydrochloride | 10,0 mg |
| Riboflavin | 2,0 mg |
| Pyridoxine hydrochloride | 5,0 mg |
| Nicotinamide | 100,0 mg |
| Calcium pantothenate | 5,0 mg |

Excipient with known effect:

Antioxidant: Disodium edetate

Preservative: Benzyl alcohol 2 % v/v

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection.

A clear, yellow liquid free from particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitamin B deficiency:

BECOPLEX IDO is indicated as a dietary supplement where a deficiency of vitamins exists (in conditions such as Beri-Beri, Pellagra, stomatitis, glossitis, hyperemesis due to X-ray intoxication, neuritis, neuralgia, polyneuritis [e.g. alcoholic]).
Adjuvant in the treatment with antibiotics and chemotherapeutics.

4.2 Posology and method of administration

Posology

2 mL 2-6 times weekly for 1-2 weeks.

Paediatric population

No data are available.

Method of administration

The injections should be given intramuscularly.

4.3 Contraindications

Hypersensitivity to any of the ingredients (i.e., nicotinamide, thiamine, calcium pantothenate, pyridoxine or riboflavin) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

BECOPLEX IDO is intended for intramuscular injection and should not be administered by any other route.

Symptoms of peripheral sensory neuropathy (paraesthesia) may occur. If such symptoms do occur, the dosage of BECOPLEX IDO should be reviewed and treatment discontinued, if necessary.

Neuropathies have been observed under long-term administration, 6 to 12 months of daily dosages exceeding 50 mg pyridoxine hydrochloride (vitamin B6) as well as in short-term administration (over 2 months) of more than 1 g vitamin B6 per day. The recommended dosage should therefore not be exceeded (see section 4.2)

Potentially serious allergic reactions may occur, during or shortly after, administration of BECOPLEX IDO.

There has been a report of life-threatening eosinophilic pleuropericarditis associated with the use of calcium pantothenate, as contained in BECOPLEX IDO. Treatment must be discontinued should this occur.

Benzyl alcohol

BECOPLEX IDO contains 20 mg benzyl alcohol per 1 mL ampoule.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. The minimum amount of benzyl alcohol at which toxicity may occur is not known, with an increased risk in young children due to accumulation.

Large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis") and therefore, BECOPLEX IDO should not be used if you are pregnant or during breastfeeding (see section 4.6).

High volumes should be used with caution and only if necessary, especially in patients with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

4.5 Interaction with other medicines and other forms of interaction

Thiamine hydrochloride:

Thiamine is inactivated by 5-fluorouracil as the latter competitively inhibits the phosphorylation of thiamine to thiamine pyrophosphate.

Loop diuretics, such as furosemide, that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy, thus, lowering the thiamine level.

Beverages containing sulphites (e.g. red wine) enhance thiamine degradation.

Pyridoxine hydrochloride:

Pyridoxine reduces the effects of levodopa, but this does not occur if a dopa decarboxylase inhibitor is also given.

Pyridoxine reduces the activity of altretamine.

Pyridoxine has also been reported to decrease serum concentrations of phenobarbitone and phenytoin.

Concurrent administration of pyridoxine antagonists (such as isoniazid (INH), hydralazine, D-penicillamine, cycloserine and oral contraceptives) may increase the pyridoxine requirement.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Becoplex IDO in pregnancy has not been established.

BECOPLEX IDO should not be used during pregnancy.

Breastfeeding

The safety of Becoplex IDO in lactation has not been established.

BECOPLEX IDO should not be used during breastfeeding.

Fertility

Vitamin B6 (pyridoxine) as contained in Becoplex IDO is associated with damage to spermatogenesis in rats.

4.7 Effects on ability to drive and use machines

Patients should not drive or operate any machinery before they know how they are affected by BECOPLEX IDO.

4.8 Undesirable effects

b) Tabulated summary of adverse reactions

| | |
|--|--|
| Immune system disorders <i>Less frequent:</i> | Hypersensitivity reactions such as sweating, tachycardia and skin reactions like itching, rash and urticaria as well as anaphylaxis. |
| Nervous system disorders <i>Frequency unknown:</i> | Peripheral sensory neuropathy (see section 4.4) |
| Skin and subcutaneous tissue disorders <i>Less frequent:</i> | Eczematous skin alterations and a benign form of acne. |
| Gastrointestinal disorders <i>Frequency unknown:</i> | Nausea, vomiting, diarrhoea and abdominal pain. |
| Renal and urinary disorders <i>Frequency unknown:</i> | Bright yellow discolouration of urine. |
| General disorders and administration site conditions <i>Frequency unknown:</i> | Injection-site reactions, including pain and swelling. |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected **adverse drug reactions to SAHPRA** via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In the event of an overdose, side effects may be exacerbated and exaggerated. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A22.1 Multivitamins and multivitamins with minerals

Pharmacotherapeutic group: ATC code: A11EB

The pharmacological action of the single vitamins is generally known and described in the literature.

Thiamine hydrochloride

Thiamine is a water-soluble vitamin of the vitamin B complex. It is also known as vitamin B1. Thiamine functions as a coenzyme in the oxidative decarboxylation of alpha-ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Thiamine is also important in nerve transmission (independently of coenzyme function).

Riboflavin

Riboflavin is a water-soluble vitamin of the vitamin B complex. It is also known as vitamin B2. Riboflavin functions as a component of two flavin coenzymes, flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). It participates in oxidation – reduction reactions in numerous metabolic pathways and in energy production. Examples include the oxidation of glucose, certain amino acids and fatty acids; reactions with several intermediaries of the Krebs cycle; conversion of pyridoxine to its active coenzyme; and conversion of tryptophan to niacin.

Pyridoxine hydrochloride

Pyridoxine is a water-soluble member of the vitamin B complex. Vitamin B6 is a generic term used to describe compounds that exhibit the biological activity of pyridoxine. Pyridoxine is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also involved in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g. the conversion of tryptophan to niacin); and haemoglobin and sphingosine formation.

Nicotinamide

Nicotinamide is a water-soluble vitamin of the vitamin B complex. Nicotinamide functions as a component of two coenzymes, nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate (NADP). These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino acids and purine metabolism.

Calcium Pantothenate

This is the calcium salt of the pantothenic acid (vitamin B5). It is a water-soluble vitamin.

The clinical effect of a combination product like BECOPLEX IDO is generally known through many years of use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (preservative)
Disodium edetate (antioxidant)
Hydrochloric acid (pH adjuster)
Polyoxyl 35 Castor oil (Cremophor EL)
Sodium hydroxide (pH adjuster)
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

To be stored in a refrigerator (2 - 8 °C). Protect from light.

6.5 Nature and contents of container

BECOPLEX IDO is filled into clear, amber, Type I glass vials (12 mL) and sealed with a bromobutyl rubber stopper with aluminium seal.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

BIOTECH LABORATORIES (PTY) LTD
Block K West, Central Park
400 16th Road, Halfway House, Midrand
1685, South Africa

8 .REGISTRATION NUMBER

H2611 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of registration: 06 May 1976

10. DATE OF REVISION OF THE TEXT

30 April 2024