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CLINICAL APPROVAL LETTER: POST REGISTRATION APPLICATIONS

Clinical approval date	29 April 2026
Applicant's cover letter date	21 November 2025
Applicant	Biotech Laboratories (Pty) Ltd.
Proprietary name(s) (including duplicates)	Becoplex IDO
API(s)	Vitamin B Complex
Registration number(s)	H2611
Sequence no	0004

Dear Sir/Madam,

Kindly be informed that the Authority has completed the evaluation of the above-mentioned Professional Information (PI) and Patient Information Leaflet (PIL) variation application.

1. The amendments to the PI and PIL are approved.
2. The PI and PIL be accepted as the currently approved PI and PIL
3. The date of revision reflected on this PI and PIL should be**: 29 April 2026**
4. The final dated version of the above PI and PIL must be submitted via docubridge in a closing sequence using the Sequence Type "Closing sequence" and Sequence Description "Approved " updated PI and PIL within 10 working days.
5. The approved PI and PIL must be uploaded into the SAHPRA repository within 10 working days.

Note to applicant: Amendments to any quality aspects of the medicine within the PI and PIL are subject to P&A unit approval and may only be implemented in the PI if approved by the P&A unit.

Yours Faithfully,

Hitakani Mabunda

H. MABUNDA

ACTING MANAGER: CLINICAL POST-REGISTRATION UNIT

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 mg
Riboflavin	2 mg
Pyridoxine hydrochloride	5 mg
Nicotinamide	100 mg
Calcium pantothenate	5 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 B_6) as well as in short-term administration (over 2 months) of more than 1 g vitamin B_6 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 lactation (see section 4.6). Do not use for more than a week in young children (less than 3 years old). Do not give to newborn baby (up to 4 weeks old).

High volumes should be used with caution and only if necessary, especially in subjects 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:

Alcohol: excessive alcohol intake induces thiamine deficiency.

Furosemide: may increase urinary loss of thiamine; prolonged furosemide therapy may induce thiamine deficiency.

Pyridoxine hydrochloride:

Alcohol: increases turnover of pyridoxine.

Anti-epileptic medicine: enzyme-inducing anti-epileptic medicines (phenytoin, carbamazepine) may cause pyridoxine deficiency.

Cycloserine: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.

Hydralazine: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.

Isoniazid: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.

Levodopa: effects of levodopa are reversed by pyridoxine (even doses as low as 5 mg daily). Pyridoxine supplements should be avoided (see section 4.4).

Oestrogens: (including oral contraceptives) may increase requirement for pyridoxine.

Penicillamine: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.

Theophylline: may increase requirement for pyridoxine.

Riboflavin

Alcohol: excessive alcohol intake induces riboflavin deficiency.

Barbiturates: prolonged use may induce riboflavin deficiency.

Oral contraceptives: prolonged use may induce riboflavin deficiency.

Phenothiazines: may increase the requirement for riboflavin.

Probenecid: reduces gastrointestinal absorption and urinary excretion of riboflavin.

Tricyclic antidepressants: may increase the requirement for riboflavin.

Calcium Pantothenate

Alcohol: excessive alcohol intake may increase requirement for pantothenic acid.

Oral contraceptives: may increase requirement for pantothenic acid.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

BECOPLEX IDO should not be used in pregnancy.

Breastfeeding

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

BECOPLEX IDO should not be used in lactation.

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	
Less frequent:	Hypersensitivity reactions such as sweating, tachycardia

	and skin reactions like itching, rash and urticaria as well as anaphylaxis.
Nervous system disorders	
Frequency unknown:	Peripheral sensory neuropathy (see section 4.4).
Skin and subcutaneous tissue disorders	
Less frequent:	Eczematous skin alterations and a benign form of acne.
Gastrointestinal disorders	
Frequency unknown:	Nausea, vomiting, diarrhoea and abdominal pain.
Renal and urinary disorders	
Frequency unknown:	Bright yellow discolouration of urine.
General disorders and administration site conditions	
Frequency unknown:	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. Health care 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 B_1. 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 B_2. 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 B_5). It is a water-soluble vitamin.

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

5.2 Pharmacokinetic properties

Nicotinamide

Distribution:

Nicotinamide is widely distributed in the body tissues.

Biotransformation:

The main route of metabolism is their conversion to *N*-methylnicotinamide and the 2-pyridone and 4-pyridone derivatives: nicotinuric acid is also formed.

Elimination:

Small amounts of nicotinamide are excreted unchanged in urine after therapeutic doses, however the amount excreted unchanged is increased with larger doses.

Thiamine hydrochloride

Distribution:

Thiamine is transported in the plasma bound to albumin, and stored in the heart, liver, muscle, kidneys and brain. Only small amounts are stored and turnover is relatively high.

Biotransformation:

Thiamine is rapidly converted to its biologically active form, thiamine pyrophosphate (TPP).

Elimination:

Thiamine is eliminated mainly in the urine (as metabolites). Excess beyond requirements is excreted as free thiamine. Thiamine crosses the placenta and is excreted in breast milk.

Calcium Pantothenate

Distribution:

Pantothenic acid is widely distributed in body tissues (particularly in the liver, adrenal glands, heart and kidneys), mainly as coenzyme A.

Elimination:

About 70 % is excreted unchanged in the urine and 30 % in the faeces.

Pyridoxine hydrochloride

Distribution:

Pyridoxine is stored in the liver, muscle and brain. Pyridoxal phosphate is transported in the plasma (bound to albumin) and in erythrocytes (in association with haemoglobin).

Elimination:

Pyridoxine is eliminated primarily in the urine (mainly as metabolites), but excess amounts are excreted largely unchanged. It also appears in breast milk.

Riboflavin

Distribution:

Some circulating riboflavin is loosely associated with plasma albumin, but significant amounts complex with other proteins. Conversion of riboflavin to its coenzymes occur in most tissues (particularly in the liver, heart and kidney).

Elimination:

Riboflavin is excreted primarily in the urine (mostly as metabolites); excess amounts are excreted unchanged. Riboflavin crosses the placenta and is excreted in breast milk.

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

400 16th Road

Block K West, Central Park

Randjespark, Midrand

Gauteng

1685

Tel: +27 (0) 11 848 3050

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

To be allocated

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BECOPLEX IDO, injection.

Thiamine hydrochloride (Vitamin B_1, 10 mg), riboflavin (Vitamin B_2, 2 mg), pyridoxine hydrochloride (Vitamin B_6 5 mg), nicotinamide (Vitamin B_3 100 mg) and calcium pantothenate (Vitamin B_5, 5 mg)

Antioxidant: **Disodium edetate**

Preservative*: Benzyl alcohol 2 % *v/v

Sugar free

Read all of this leaflet carefully before you are given BECOPLEX IDO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BECOPLEX IDO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BECOPLEX IDO is and what it is used for

BECOPLEX IDO is a vitamin B complex injection used for:

To replenish your deficiency of Vitamin B complex vitamins.

2. What you need to know before you use BECOPLEX IDO

BECOPLEX IDO should not be administered to you:

- if you are hypersensitive (allergic) to nicotinamide, thiamine, calcium pantothenate, pyridoxine or riboflavin, contained in this injection or any of the other ingredients of BECOPLEX IDO (listed in section 6).

Warnings and precautions

Special care should be taken with BECOPLEX IDO:

- BECOPLEX IDO should be injected into a muscle.
- The recommended dosage should not be exceeded.
- If symptoms such as numbness and tingling of your hands and feet; sharp jabbing or burning pain, extreme sensitivity to touch, lack of coordination or muscle weakness occurs, treatment with BECOPLEX IDO should be stopped.
- Serious allergic reactions may occur during, or shortly after being injected with BECOPLEX IDO (see section 4 Possible side effects).
- A case of life-threatening eosinophilic pleuropericarditis (inflammation in the tissues surrounding the lungs (pleura) and the heart (pericardium) and it involves white blood cells called eosinophils) associated with the use of pantothenic acid as in BECOPLEX IDO, has been reported. If you experience chest pain and difficulty breathing, fever, cough or tiredness related to pleurisy and fluid build-up, please contact your doctor.

Other medicines and BECOPLEX IDO

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Alcohol,
- Furosemide: used to treat water retention,
- Phenytoin, carbamazepine: used in the treatment of convulsions,
- Barbiturates (e.g., phenobarbital (phenobarbitone)): used as sedatives,
- Cycloserine: medicines used to treat a bacterial infection,
- Hydralazine: used to reduce blood pressure,
- Isoniazid: used to treat tuberculosis,
- Oral contraceptives: used to prevent pregnancy,
- Penicillamine: used to treat rheumatoid arthritis, Wilson's disease and cystinurea (stones in the kidney or bladder),
- Theophylline: used to treat asthma, bronchitis, emphysema,
- Levodopa: used to treat Parkinson's disease,
- Phenothiazines: used to treat mental and emotional disorders,
- Probenecid: used to treat gout,
- Tricyclic antidepressants: used to treat depression.

Pregnancy, breastfeeding and fertility

The safety of BECOPLEX IDO in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being administered BECOPLEX IDO.

Vitamin B6 (pyridoxine) in BECOPLEX IDO has been shown to affect sperm production in rats.

Driving and using machines

It is not always possible to predict to what extent BECOPLEX IDO may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or operate machines until you are aware of the measure to which BECOPLEX IDO affects you.

BECOPLEX IDO contains benzyl alcohol

BECOPLEX IDO contains 20 mg benzyl alcohol in each ml which is equivalent to 20 mg/mL.

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.

Do not use for more than a week in young children (less than 3 years old). Do not give to newborn baby (up to 4 weeks old).

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to use BECOPLEX IDO

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself BECOPLEX IDO**.** It will be given to you by a person who is qualified to do so.

Your injection will be given to you into a muscle.

The usual dose of BECOPLEX IDO for adults is 2 mL 2 – 6 times weekly for 1 – 2 weeks.

No data are available in the paediatric population.

Your doctor will tell you how long your treatment with BECOPLEX IDO will last. Do not stop treatment early. If you have the impression that the effect of BECOPLEX IDO is too strong or too weak, tell your doctor or pharmacist.

If you receive more BECOPLEX IDO than you should

Since a healthcare provider will administer BECOPLEX IDO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of BECOPLEX IDO

Do not receive a double dose to make up for forgotten individual doses.

Since a healthcare provider will administer BECOPLEX IDO, it is unlikely that the dose will be missed.

4. Possible side effects

BECOPLEX IDO can have side effects.

Not all side effects reported for BECOPLEX IDO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BECOPLEX IDO, please consult your healthcare provider for advice.

If any of the following happens, stop using BECOPLEX IDO and tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe allergic reaction; you may experience a sudden itchy rash, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), sweating, feeling as if you are going to faint.

These are all very serious side effects. If you have them, you may have had a serious reaction to BECOPLEX IDO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- nausea, vomiting, diarrhoea and abdominal pain
- tingling of your hands and feet; sharp jabbing or burning pain, extreme sensitivity to touch, lack of coordination or muscle weakness
- an acute or chronic non-contagious inflammation of the skin, characterised by redness, itching, discharge, becoming scaly and encrusted, acne
- bright yellow discolouration of urine
- reaction around the injection site, including pain and swelling.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BECOPLEX IDO.

5. How to store BECOPLEX IDO

Store all medicines out of reach of children.

Store at 2 - 8 °C (in a refrigerator) and protect from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BECOPLEX IDO contains:

Each mL of the vitamin B complex injection contains:

Thiamine hydrochloride (Vitamin B_1) 10 mg, riboflavin (Vitamin B_2) 2 mg, pyridoxine hydrochloride (Vitamin B_6) 5 mg, nicotinamide (Vitamin B_3) 100 mg, calcium pantothenate (Vitamin B_5) 5 mg.

The other ingredients are benzyl alcohol 2 % *v/v* (preservative), disodium edetate (antioxidant), hydrochloric acid (pH adjuster), polyoxyl 35 castor oil (Cremophor EL), sodium hydroxide (pH adjuster) and water for injection.

What BECOPLEX IDO looks like and contents of the pack

A clear, yellow liquid free from particles.

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

Holder of Certificate of Registration

BIOTECH LABORATORIES (PTY) LTD

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Tel nr: +27 (0) 11 848 3050

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Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.