

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

BECOPLEX IDO, injection.

Thiamine hydrochloride (Vitamin B₁, 10 mg), riboflavin (Vitamin B₂, 2 mg), pyridoxine hydrochloride (Vitamin B₆ 5 mg), nicotinamide (Vitamin B₃ 100 mg) and calcium pantothenate (Vitamin B₅, 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
2. What you need to know before you use BECOPLEX IDO
3. How to use BECOPLEX IDO
4. Possible side effects
5. How to store BECOPLEX IDO
6. Contents of the pack and other information

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 cystinuria (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 B₁) 10 mg, riboflavin (Vitamin B₂) 2 mg, pyridoxine hydrochloride (Vitamin B₆) 5 mg, nicotinamide (Vitamin B₃) 100 mg, calcium pantothenate (Vitamin B₅) 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

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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.