SCHEDULING STATUS:

S3

NEUROBION AMPOULES

Thiamine hydrochloride (Vitamin B_1)

Pyridoxine hydrochloride (Vitamin B_6)

Cyanocobalamin (Vitamin B_{12})

Solution for Injection

Sugar free

Read all of this leaflet carefully before you start receiving NEUROBION AMPOULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What NEUROBION AMPOULES is and what it is used for
2. What you need to know before you take NEUROBION AMPOULES
3. How to use NEUROBION AMPOULES
4. Possible side effects
5. How to store NEUROBION AMPOULES
6. Contents of the pack and other information

1. What NEUROBION AMPOULES is and what it is used for

NEUROBION AMPOULES is a combination of vitamins and is used for:

- Restoring Vitamin B_1, B_6 and/or B_{12} levels.
- The prevention and treatment of deficiencies in vitamin B_1, B_6 and B_{12}.

NEUROBION AMPOULES assist with the management of neuropathies. (Symptoms of

neuropathies include: tingling, numbness, loss of sensation, burning sensation, loss of balance and co-ordination.)

2. What you need to know before you are given NEUROBION AMPOULES

NEUROBION AMPOULES should not be administered to you:

- If you are hypersensitive to Vitamin B1, Vitamin B6, Vitamin B12, or any of the other ingredients of NEUROBION AMPOULES.
- If you are taking a medicine containing Levodopa which is used for treating Parkinson's disease.
- If you are below the age 14 years.

Warnings and precautions

Special care should be taken with NEUROBION AMPOULES:

You should not use NEUROBION AMPOULES before you have been diagnosed as it may mask neurological symptoms (symptoms that affect your nervous systems such as numbness or tingling in your hands and feet, stiff limbs and may you become irritable, drowsy and confused) caused by a deficiency of Vitamin B_{12}. If a Vitamin B_{12} deficiency is not detected and treated, it could affect your nervous system.

Neurological symptoms are described in the literature following long term intake (6 – 12 months) of more than 50 mg average daily dose of Vitamin $B_{6.}$ You should therefore have regular check ups if you are taking NEUROBION AMPOULES over longer periods of time.

Tell your doctor or healthcare professional before being given the injection if you are taking or have recently taken levodopa (for Parkinson's disease).

Other medicines and NEUROBION AMPOULES

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

You should not use NEUROBION AMPOULES if you also take Levodopa, a medicine used to treat Parkinson's disease, as it will reduce the effectiveness of the Levodopa.

Medicines that may decrease the effectiveness of Vitamin B_6 (one of the ingredients in NEUROBION AMPOULES) include the following:

- isoniazide and cycloserine (medicines used for the treatment of tuberculosis)
- penicillamine (a medicine used to treat rheumatoid arthritis)
- hydralazine (a medicine used to treat high blood pressure and heart failure)

Long-term use of medicines called loop diuretics (water pills) such as furosemide, may reduce the levels of Vitamin B_1 in your blood. Furosemide is used to reduce extra fluid in the body caused by conditions such as heart failure, liver disease, and kidney disease.

Long term use of acid-lowering medicines agents (such as omeprazole, lansoprazole, pantoprazole, cimetidine and ranitidine) may lead to vitamin B_{12} deficiency.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking NEUROBION AMPOULES.

If you use NEUROBION AMPOULES, you should not breast feed your baby.

Driving and using machines

NEUROBION AMPOULES do not affect your ability to drive or operate machinery

3. How to use NEUROBION AMPOULES

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

Neurobion Ampoules are preferably injected into the muscle. In severe cases 1 ampoule daily is given until the acute symptoms subside. For milder cases and follow-up therapy, 2 or 3 ampoules per week are given.

If you receive more NEUROBION AMPOULES than you should:

Since a healthcare professional will administer NEUROBION AMPOULES, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have missed a dose of NEUROBION AMPOULES:

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

4. Possible side effects

NEUROBION AMPOULES can have side effects

Not all side effects reported for NEUROBION AMPOULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEUROBION AMPOULES, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following

- difficulty in breathing
- dizziness

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

Tell your doctor if you notice any of the following:

- sweating
- fast heartbeat
- skin reactions with itching and urticaria (skin rash with red, raised, itchy bumps)
- nausea
- vomiting
- diarrhea
- stomach ache
- acne
- eczema
- injection site reaction (Pain, stinging, tingling, burning, redness and swelling at site of injection)
- Chromaturia ("reddish urine", appearing during the first 8 hours after been given NEUROBION AMPOULES and typically resolves within 48 hours).

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **NEUROBION AMPOULES.**

5. How to store NEUROBION AMPOULES

Store all medicines out of reach and sight of children.

Store between 2 - 8 °C in a refrigerator.

6. Contents of the pack and other information

What NEUROBION AMPOULES contains

The active substances are

- Thiamine hydrochloride (Vitamin B1) 100,0 mg
- Pyridoxine hydrochloride (Vitamin B6) 100,0 mg
- Cyanocobalamin (Vitamin B12) 1,0 mg

The other ingredients are: Potassium cyanide, Sodium hydroxide solution

What NEUROBION AMPOULES looks like and contents of the pack

Clear, red solution with no visible particles.

Boxes of 3 ampoules of 3 ml each.

Holder of Certificate of Registration

P&G South African Trading (Pty) Ltd

10th Floor, Alice Lane Towers, 15 Alice Lane, Sandton, 2196

South Africa

This leaflet was revised on Feb 2023

Reference Number

H2488 (Act 101/1965)

Access to the corresponding Professional Information

Professional Information may be accessed at: www.neurobion.com/en-za

Botswana: (S2) B9306470
Namibia: (NS2) 14/22.1/0262