

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

To be assigned

### NALEO™ SPECTRUM Orange Flavour

#### Nutritional supplement

Contains sugar (Isomaltulose 100 mg per serving, Sucrose 50 mg per serving)

Complementary Medicine: Health Supplement. D.34.12. Multiple substance formulation. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you. NALEO™ SPECTRUM Orange Flavour is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use NALEO™ SPECTRUM Orange Flavour carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NALEO™ SPECTRUM Orange Flavour with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

#### What is in this leaflet

1. What NALEO™ SPECTRUM Orange Flavour is and what it is used for
2. What you need to know before you use NALEO™ SPECTRUM Orange Flavour
3. How to use NALEO™ SPECTRUM Orange Flavour
4. Possible side effects
5. How to store NALEO™ SPECTRUM Orange Flavour
6. Contents of the pack and other information

#### 1. What NALEO™ SPECTRUM Orange Flavour is and what it is used for

NALEO™ SPECTRUM Orange Flavour is a nutritional supplement that maintains and supports brain health.

**Vitamin A** contributes to the maintenance of eyesight, skin, membranes, and immune function, contributes the development and maintenance of night vision, and contributes to the development and maintenance of bones and teeth.

**Vitamin B<sub>1</sub> and B<sub>3</sub>** helps to metabolise carbohydrates, fats, and proteins, and contributes to normal growth and development.

**Vitamin B<sub>2</sub>, B<sub>6</sub> and B<sub>12</sub>** helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation.

**Vitamin B<sub>12</sub>** helps to metabolise carbohydrates, fats, and proteins, and contributes to normal red blood cell formation.

**Vitamin C** helps to metabolise fats and proteins, helps in the development and maintenance of bones, cartilage, teeth and gums, helps in connective tissue formation, and helps in wound healing. An antioxidant for the maintenance of good health.

**Vitamin D** helps in the development and maintenance of bones and teeth and helps in the absorption and use of calcium and phosphorus.

**Vitamin E** is an antioxidant for the maintenance of good health.

**Vitamin H (Biotin)** helps to metabolise carbohydrates, fats, and proteins.

**Vitamin K<sub>1</sub> and K<sub>2</sub>** contributes to the maintenance of normal bones.

**Acetyl-L-Carnitine** helps to support and maintain healthy brain function.

**N-Acetyl-L-Cysteine (NAC)** is a source of amino acids involved in muscle protein synthesis.

**Calcium** contributes to the development and maintenance of bones and teeth.

**Choline** helps to support liver function.

**Chromium** provides support for healthy glucose metabolism and helps the body to metabolise carbohydrates and fats.

**Coenzyme Q-10** is an antioxidant that contributes to the protection of cells from oxidative stress and helps to maintain and support cardiovascular health.

**Folate** helps the body to metabolise proteins and helps to form red blood cells.

**Iodine** contributes to the normal production of the thyroid hormones and normal thyroid function.

**Magnesium** helps to metabolise carbohydrates, fats, and proteins, contributes to the development and maintenance of bones and teeth, contributes to tissue formation, and contributes to the maintenance of normal muscle function.

**Methylsulphonylmethane** is used for joint health, a factor in maintaining joint health, and provides support for healthy joints, joint mobility, and joint comfort.

**Potassium** is a factor in the maintenance of good health.

**Selenium** is an antioxidant for the maintenance of good health.

**Turmeric root extract** is an antioxidant that helps to relieve inflammation.

**Zinc** helps in connective tissue formation, helps to maintain healthy skin, helps the body to metabolise carbohydrates, fats, and proteins, and helps to maintain immune function.

#### 2. What you need to know before you use NALEO™ SPECTRUM Orange Flavour

##### Do not use NALEO™ SPECTRUM Orange Flavour

If you are hypersensitive (allergic) to any of the other ingredients of NALEO™ SPECTRUM Orange Flavour (listed in section 6).

#### Warnings and precautions

Take special care with NALEO™ SPECTRUM Orange Flavour:

- Consult a relevant health care provider before use of inositol if you suspect that you may have insulin resistance, high blood glucose levels or diabetes.
- Methylsulphonylmethane is not to be taken at bedtime.
- Consult a relevant health care provider prior to use of Acetyl L-Carnitine if you are pregnant or breastfeeding, if you have liver disease, kidney disease or a seizure disorder. Acetyl L-Carnitine may cause digestive problems.
- Consult a relevant health care provider prior to use of Turmeric root extract if you are pregnant, are taking antiplatelet medication or blood thinners, have gallstones or a bile duct obstruction, or have stomach ulcers or excess stomach acid.
- Consult a relevant health care provider prior to use of Coenzyme Q10 if you are taking blood pressure medication.

#### Other medicines and NALEO™ SPECTRUM Orange Flavour

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

- Consult a relevant health care provider prior to use if you are taking blood sugar (diabetes) medication. Inositol might lower blood sugar levels.
- Antacid medicines should be taken 2 hours before or after taking NALEO™ SPECTRUM Orange Flavour, as antacids may reduce the absorption of certain vitamins and minerals.
- Acetyl-L-Carnitine may interact with certain medications, such as anticoagulants or thyroid hormones. It's important to consult with your health care provider before combining these medications with Acetyl-L-Carnitine.
- Magnesium may interact with certain antibiotics, bisphosphonates (medications used for osteoporosis), and some medications for high blood pressure or muscle relaxants.
- Calcium can interfere with the absorption of certain medications, such as tetracycline antibiotics and certain thyroid medications. It is generally recommended to take calcium supplements a few hours apart from these medications.
- Zinc might interfere with the absorption of certain antibiotics and medications for rheumatoid arthritis. Zinc may also interact with certain diuretics and decrease the absorption of certain antibiotics.
- Manganese might interact with certain antibiotics, bisphosphonates, and medications for Parkinson's disease.
- Iodine may interact with certain medications used for hyperthyroidism.
- Vitamin A may interact with certain medications for acne, cholesterol-lowering drugs, and medications that affect blood clotting.
- Vitamin D may interact with certain medications used for heart conditions and medications that affect calcium levels.
- Coenzyme Q-10, Vitamin C, Vitamin E and Selenium may interact with certain medications that increase the risk of bleeding, such as anticoagulants. It's important to discuss supplementation with your health care provider if you're taking blood thinners.

#### Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

Safety of NALEO™ SPECTRUM Orange Flavour during pregnancy and breastfeeding has not been established.

#### Driving and using machines

NALEO™ SPECTRUM Orange Flavour will have very little or no effect on your ability to drive or use machines.

#### 3. How to use NALEO™ SPECTRUM Orange Flavour

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

Always use NALEO™ SPECTRUM Orange Flavour exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one (1) flattened scoop of NALEO™ SPECTRUM Orange Flavour dissolved in your favourite food or drink once daily, or as recommended by your health care provider.

After use, store the scoop inside of the container and close the lid of the container tightly. Do not remove desiccant/sachet.

#### If you take more NALEO™ SPECTRUM Orange Flavour than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you.

#### If you forget to use NALEO™ SPECTRUM Orange Flavour

If you forget to use NALEO™ SPECTRUM Orange Flavour, use it as soon as you remember. Take NALEO™ SPECTRUM Orange Flavour at the usual time from then on.

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

#### 4. Possible side effects

NALEO™ SPECTRUM Orange Flavour can have side effects.

Not all side effects reported for NALEO™ SPECTRUM Orange Flavour are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NALEO™ SPECTRUM Orange Flavour, please consult your health care provider for advice.

**If any of the following happens, stop using NALEO™ SPECTRUM Orange Flavour and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
  - rash or itching;
  - fainting.
- These are all very serious side effects. If you have them, you may have had a serious reaction to NALEO™ SPECTRUM Orange Flavour. You may need urgent medical attention or hospitalisation.

#### Tell your doctor if you notice any of the following:

##### Frequent side effects:

- nausea (feeling sick);
- abdominal cramps or stomach pains;
- headache;
- dizziness;
- tiredness;
- light-headedness.

##### Less frequent side effects:

- flatulence or wind;
- diarrhoea;
- loss of appetite.

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

#### Reporting of side effects

You can report side effects to Delfran (Pty) Ltd via qa@delfran.co.za or call (012) 654 3029. 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 NALEO™ SPECTRUM Orange Flavour.

#### 5. How to store NALEO™ SPECTRUM Orange Flavour

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

#### 6. Contents of the pack and other information

##### What NALEO™ SPECTRUM Orange Flavour contains

The active substances in NALEO™ SPECTRUM Orange Flavour are:

Composition	Per serving
Methylsulphonylmethane (MSM)	1469 mg
Ascorbic acid (Vitamin C)	500 mg
Choline bitartrate providing Choline 250 mg	608 mg
Acetyl-L-Carnitine	200 mg
DL-alpha-tocopheryl acetate providing Vitamin E 223.5 I.U.	165 mg
Magnesium citrate providing Magnesium 100 mg	620 mg
Inositol (Myo-inositol)	100 mg
Palatinose™ PST (isomaltulose)	100 mg
Calcium bisglycinate chelate providing Calcium 70 mg	500 mg
Potassium citrate providing Potassium 50 mg	140 mg
Turmeric root extract (95 % curcuminoids)	50 mg
Coenzyme Q-10 (ubidecarenone)	50 mg
N-Acetyl-L-Cysteine (NAC) providing L-Cysteine 45 mg	61 mg
Riboflavin (Vitamin B2)	40 mg
Niacinamide (Vitamin B3)	35 mg
D-Calcium pantothenate providing Pantothenic Acid (Vitamin B5) 30 mg	66 mg
Thiamine mononitrate providing Thiamine (Vitamin B1) 20 mg	22 mg
Pyridoxine hydrochloride providing Pyridoxine (Vitamin B6) 20 mg	25 mg
Zinc oxide providing Zinc 15 mg	19 mg
BioPerine® (Piper nigrum (black pepper) [fruit extract])	2 mg
Vitamin A acetate providing Vitamin A 5000 I.U.	10mg
Manganese amino acid chelate providing Manganese 1 mg	10 mg
6S-5-Methyltetrahydrofolate Calcium providing Folate 500 µg	569 µg
D-Biotin (Vitamin H)	225 µg
Methylcobalamin (Vitamin B12)	100 µg
Potassium iodide providing Iodine 100 µg Potassium 30 µg	130 µg
Ammonium heptamolybdate providing Molybdenum 100 µg	157 µg
Phytonadione (Vitamin K1)	80 µg
Chromium nicotinate providing Chromium 70 µg	700 µg
Selenium amino acid chelate providing Selenium 40 µg	2 mg
Menaquinone (Vitamin K2)	40 µg
Cholecalciferol providing Vitamin D 1000 I.U.	10 mg

Minerals are listed in their elemental and non-elemental forms.

Other ingredients: Orange flavour, Naartjie flavour, Silicon Dioxide, Sucrose.

#### What NALEO™ SPECTRUM Orange Flavour looks like and contents of the pack

A unit carton containing a 250 ml black HDPE bottle. Contents of the container includes a 5 g measuring spoon, a silica gel desiccant and card desiccant and 150 g of orange oral powder for solution of NALEO™ SPECTRUM Orange Flavour.

#### Holder of certificate of registration

Delfran (Pty) Ltd.  
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#### Registration number

To be assigned

#### This leaflet was last revised in July 2024

The Professional Information leaflet is available at <http://www.delfran.co.za/>

