

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

BIOGEN
FOR THE RESULTS YOU WANT

33732 P3

BIOGEN 5-HTP NEURO

(capsules)

COMPOSITION:

Active ingredients:

Each capsule contains:

5-Hydroxy-L-tryptophan (5-HTP) (from *Griffonia simplicifolia* (DC.) Baill. seed extract)

100 mg

Excipients: Calcium carbonate, magnesium stearate, microcrystalline cellulose, silicone dioxide and vegetable capsule (containing carrageenan, hydroxypropyl methylcellulose, potassium acetate and titanium dioxide).

Sugar Free

CATEGORY AND CLASS:

D 34.1 Amino acids

PHARMACOLOGICAL ACTION:

5-HTP is produced in the body from the essential amino acid L-tryptophan and is a precursor to the neurotransmitter serotonin.

INDICATIONS:

5-HTP is a precursor to the neurotransmitter serotonin and may have a positive role to play in improving a feeling of general wellbeing.

CONTRAINDICATIONS:

- Hypersensitivity to **5-HTP** or to any of the inactive ingredients of **BIOGEN 5-HTP NEURO** (see **COMPOSITION**).
- Scleroderma.

WARNINGS AND SPECIAL PRECAUTIONS:

- **General: BIOGEN 5-HTP NEURO** should be discontinued and a healthcare provider contacted if signs of weakness, oral ulcers, abdominal pain accompanied by severe muscle pain or skin changes occur.
- **Surgery: 5-HTP** as contained in **BIOGEN 5-HTP NEURO** might interfere with surgical procedures due to the serotonergic effects. It is recommended to discontinue the use of **BIOGEN 5-HTP NEURO** at least 2 weeks before surgery.
- **Effects on ability to drive and use machines: BIOGEN 5-HTP NEURO** may cause side effects, such as drowsiness, and can affect the ability to drive a vehicle and use machines. Caution is advised before driving a vehicle, operating machinery or performing activities requiring mental alertness, until the effects of **BIOGEN 5-HTP NEURO** are known.

INTERACTIONS:

- **Carbidopa:** Concomitant administration of **BIOGEN 5-HTP NEURO** with carbidopa can increase the risk of serotonergic side effects, such as hypomania, restlessness, rapid speech, anxiety, insomnia and aggressiveness. It might also increase the risk of scleroderma-like skin reactions due to elevated serotonin levels.
- **Serotonergic supplements or medicines:** Concomitant administration of **BIOGEN 5-HTP NEURO** with serotonergic supplements or medicines might increase the risk of serotonergic side effects. Serotonergic supplements or medicines may include L-tryptophan, S-adenosylmethionine, St. John's wort, antidepressants, pain killers, cough and cold medicines containing dextromethorphan, anti-nausea medicines and anti-migraine medicines.

HUMAN REPRODUCTION:

Safety during pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults: Take 1 – 2 capsules daily.

SIDE EFFECTS:

- **Nervous system disorders:** *Less frequent* - Drowsiness.
- **Gastrointestinal disorders:** *Less frequent* - Diarrhoea, nausea, vomiting, abdominal pain.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See SIDE EFFECTS.

In the event of overdosage, treatment should be symptomatic and supportive.

IDENTIFICATION:

White to off-white powder in a size 0 white vegetable capsule.

PRESENTATION:

250 mL white PET bottle with a screw cap, heat seal, sponge and silica.

Pack size: 60 capsules.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from moisture.

Keep in the outer container until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated by SAHPRA upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Phyto OTC Health (Pty) Ltd

49 New Road

Midrand

South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Will be allocated by SAHPRA upon registration.

COMPLEMENTARY MEDICINE:

Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

BIOGEN
FOR THE RESULTS YOU WANT

BIOGEN 5-HTP NEURO

(capsules)

Read all of this leaflet carefully because it contains important information for you.

BIOGEN 5-HTP NEURO is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **BIOGEN 5-HTP NEURO** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BIOGEN 5-HTP NEURO** with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT BIOGEN 5-HTP NEURO CONTAINS:

Active ingredients:

Each capsule contains: 100 mg
5-hydroxy-L-tryptophan (5-HTP)
(from *Griffonia simplicifolia* (DC.) Baill. seed extract)

Other ingredients: Calcium carbonate, magnesium stearate, microcrystalline cellulose, silicone dioxide and vegetable capsule (containing carrageenan, hydroxypropyl methylcellulose, potassium acetate and titanium dioxide).

Sugar Free

2. WHAT BIOGEN 5-HTP NEURO IS USED FOR:

5-HTP is a precursor to the neurotransmitter serotonin and may have a positive role to play in improving general wellbeing..

3. BEFORE YOU TAKE BIOGEN 5-HTP NEURO:

Do not take BIOGEN 5-HTP NEURO:

- If you are hypersensitive (allergic) to 5-HTP or any of the other ingredients of **BIOGEN 5-HTP NEURO** (see **WHAT BIOGEN 5-HTP NEURO CONTAINS**).
- If you have scleroderma (a condition causing thickening of your skin and connective tissues).

Take special care with BIOGEN 5-HTP NEURO:

- If you experience symptoms such as weakness, oral ulcers, abdominal pain accompanied by severe muscle pain or skin changes. You should stop taking **BIOGEN 5-HTP NEURO** and contact your healthcare provider.
- If you are going to have an operation. It is recommended that you stop taking **BIOGEN 5-HTP NEURO** 2 weeks before any surgery.

Taking BIOGEN 5-HTP NEURO with food and drink:

- **BIOGEN 5-HTP NEURO** can be taken with or without food.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **BIOGEN 5-HTP NEURO**.

Driving and using machinery:

BIOGEN 5-HTP NEURO can cause side effects, such as drowsiness, and can affect your ability to drive a vehicle and use machines. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **BIOGEN 5-HTP NEURO** affects you.

Taking other medicines with BIOGEN 5-HTP NEURO:

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

Tell your doctor or pharmacist if you are currently using:

- Carbidopa (used to treat Parkinson's disease or Parkinson-like symptoms, such as shakiness, stiffness, difficulty moving).
- L-Tryptophan, S-adenosylmethionine, St. John's wort (used to treat depression, insomnia and anxiety).
- Antidepressant medicines (used to treat depression).
- Pain killers.
- Cough and cold medicine that contains dextromethorphan.
- Anti-nausea medicines (used to treat nausea and vomiting).
- Anti-migraine medicines (used to treat the effect or intensity of migraines).

4. HOW TO TAKE BIOGEN 5-HTP NEURO:

The usual dose is 1 – 2 capsules daily.

If you have the impression that the effect of **BIOGEN 5-HTP NEURO** is too strong or too weak, tell your doctor or pharmacist.

If you take more BIOGEN 5-HTP NEURO than you should:

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining **BIOGEN 5-HTP NEURO** with you so the doctor will know what you have taken.

5. POSSIBLE SIDE EFFECTS:

BIOGEN 5-HTP NEURO can have side effects.

Not all side effects reported for **BIOGEN 5-HTP NEURO** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **BIOGEN 5-HTP NEURO**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **BIOGEN 5-HTP NEURO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to **BIOGEN 5-HTP NEURO**. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

Less frequent:

- Drowsiness.
- Diarrhoea, nausea (feeling sick), vomiting (being sick), pain in your abdominal area

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

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS:

S0

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:

BIOGEN
FOR THE RESULTS YOU WANT

BIOGEN 5-HTP NEURO

(kapsules)

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

BIOGEN 5-HTP NEURO is beskikbaar sonder 'n dokter se voorskrif, sodat u 'n ligte aandoening kan behandel. U moet **BIOGEN 5-HTP NEURO** niétémín steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie **BIOGEN 5-HTP NEURO** met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies nodig het.

1. WAT BIOGEN 5-HTP NEURO BEVAT:

Aktiewe bestanddele:

Elke kapsule bevat: 100 mg
5-hidroksi-L-tryptofaan (5-HTP)
(vanuit *Griffonia simplicifolia* (DC.) Baill. saadestrank)

Ander bestanddele: Kalsiumkarbonaat, magnesiumstearaat, mikrokristallyne sellulose, silikondioksied en plantaardige kapsule (wat karrageen, hidroksiopropielmetielseellulose, kaliumasetaat en titaandioksied bevat).

Suiker-vry

2. WAARVOOR BIOGEN 5-HTP NEURO GEBRUIK WORD:

5-HTP is 'n voorganger van die neuro-oordragstof serotonien en mag 'n positiewe rol speel in die bevordering van algemene welstand.

3. VOORDAT U BIOGEN 5-HTP NEURO NEEM:

Moenie BIOGEN 5-HTP NEURO neem nie:

- Indien u hipersensitief (allergies) vir 5-HTP of vir enige van die ander bestanddele van **BIOGEN 5-HTP NEURO** is (sien **WAT BIOGEN 5-HTP NEURO BEVAT**).
- Indien u skleroderma het (toestand wat verdikking van u vel en bindweefsel veroorsaak).

Wees versigtig met BIOGEN 5-HTP NEURO:

- Indien u simptome soos swakheid, mondsere, buikpyn met gepaardgaande hewige spierpyn of veranderinge van die vel ondervind. U moet ophou om **BIOGEN 5-HTP NEURO** te neem en u gesondheidsorgverskaffer kontak.
- Indien u 'n operasie moet ondergaan. Dit word aanbeveel dat u 2 weke voor enige chirurgie ophou om **BIOGEN 5-HTP NEURO** te neem.

Die neem van BIOGEN 5-HTP NEURO met kos en drinkgoed:

- **BIOGEN 5-HTP NEURO** kan met of sonder kos geneem word.

Swangerskap en borsvoeding:

- Indien u swanger is of u baba borsvoed, raadpleeg asseblief u gesondheidsorgverskaffer voordat u **BIOGEN 5-HTP NEURO** neem.

Bestuur en die gebruik van masjinerie:

BIOGEN 5-HTP NEURO kan newe-effekte soos lomerigheid veroorsaak, en kan u vermoë om 'n voertuig te bestuur en masjiene te gebruik affekteer. Moenie 'n voertuig bestuur, masjinerie hanteer of enigiets anders doen wat konsentrasie verg totdat u weet hoe **BIOGEN 5-HTP NEURO** u affekteer nie.

Die neem van ander medisyne saam met BIOGEN 5-HTP NEURO:

Sê altyd vir u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in).

Sê vir u dokter of apteker indien u tans die volgende gebruik:

- Karbidopa (gebruik om Parkinson se siekte of parkinsonagtige simptome, soos bewing, spierstyfheid en moeisame beweging, te behandel).
- L-Triptofaan, S-adenosielmetonien, johanneskruid (gebruik om depressie, slaaploosheid en angstigheid te behandel).
- Antidepressante (medisyne gebruik om depressie te behandel).
- Pynstillers.
- Hoes- en verkouemedisyne wat dekstrometorfaan bevat.
- Medisyne teen naarheid (gebruik om naarheid en braking te behandel).
- Anti-migrainemedisyne (gebruik om skeelthoofpyn of die intensiteit daarvan te behandel).

4. HOE OM BIOGEN 5-HTP NEURO TE NEEM:

Die gebruikelike dosis is 1 – 2 kapsules daagliks.

Indien u die indruk kry dat die uitwerking van **BIOGEN 5-HTP NEURO** te sterk of te swak is, sê dit vir u dokter of apteker.

Indien u meer BIOGEN 5-HTP NEURO neem as wat u behoort:

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die houer met die oorblywende **BIOGEN 5-HTP NEURO** saam met u, sodat die dokter kan sien wat u geneem het.

5. MOONTLIKE NEWE-EFFEKTE:

BIOGEN 5-HTP NEURO kan newe-effekte hê.

Nie al die newe-effekte wat vir **BIOGEN 5-HTP NEURO** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid verswak of u enige ongunstige effekte ervaar terwyl **BIOGEN 5-HTP NEURO** geneem word, konsulteer asseblief u gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om **BIOGEN 5-HTP NEURO** te neem en sê onmiddellik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- Uitslag of gejeuk.
- Floutes

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie op **BIOGEN 5-HTP NEURO** gehad het. U mag dringende mediese bystand of hospitalisasie benodig.

Sê so gou as moontlik vir u dokter indien u enige van die volgende opmerk:

Newe-effekte wat minder dikwels voorkom:

- Lomerigheid.
- Diarree, naarheid, braking, pyn in u buikarea

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

6. STORING AND DISPOSING OF BIOGEN 5-HTP NEURO:

- Store at or below 25 °C.
- Protect from moisture.
- Keep in the outer container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

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

7. PRESENTATION OF BIOGEN 5-HTP NEURO:

250 ml white PET bottle with a screw cap, heat seal, sponge and silica.
Pack size: 60 capsules.

8. IDENTIFICATION OF BIOGEN 5-HTP NEURO:

White to off-white powder in a size 0 white vegetable capsule.

9. REGISTRATION NUMBER:

Will be allocated by SAHPRA upon registration.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Phyto OTC Health (Pty) Ltd
49 New Road
Midrand
South Africa

11. DATE OF PUBLICATION:

Will be allocated by SAHPRA upon registration.

12. COMPLEMENTARY MEDICINE:

Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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