

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

[s0]

NUTRIVIVA SERENIPAUSE™ – hard capsule

Active Ingredient	Quantity per capsule	Quantity per serving
Magnesium Biglycinate	125mg	500mg
providing elemental Magnesium	17,63mg	70,5mg
<i>Lepidium meyenii</i> Walp. (Maca Extract)	93,8mg	375mg
[root, NLT 4:1 extract]	375mg	1500mg
Sensoril® <i>Withania somnifera</i> (L.) Dunal (Ashwagandha)	75mg	300mg
[roots and leaves], standardised to Withanolide glycosides ≥10%, Oligosaccharides ≥32%, Withanolide aglycone (as Withaferin A) ≤0.5%		
<i>Panax ginseng</i> C.A.Mey.	75mg	300mg
[root, 25:1 extract standardized to ginsenosides 80% DHE]	1875mg	7500mg
<i>Serenoa repens</i> (Bartram) (Saw Palmetto)	75mg	300mg
[fruit, 15:1 extract standardised to total fatty acid 25% DHE]	1125mg	4500mg
<i>Actaea racemosa</i> (L.) (Black Cohosh)	40mg	160mg
[root, standardized to ≥2.5% triterpene glycosides]	1mg	4mg
Pyridoxine (Vitamin B6)	6,25mg	25mg
Riboflavin 5'-phosphate (Vitamin B2)	0,28mg	1.1mg
Methylcobalamin (Vitamin B12)	25mcg	100mcg

Sugar free

COMPLEMENTARY MEDICINE: Health Supplement – Combination Product

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

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

NUTRIVIVA SERENIPAUSE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use NUTRIVIVA SERENIPAUSE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NUTRIVIVA SERENIPAUSE 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 NUTRIVIVA SERENIPAUSE is and what it is used for.
2. What you need to know before you take NUTRIVIVA SERENIPAUSE.
3. How to take NUTRIVIVA SERENIPAUSE.
4. Possible side effects.
5. How to store NUTRIVIVA SERENIPAUSE.
6. Contents of the pack and other information.

1. What is NUTRIVIVA SERENIPAUSE used for

NUTRIVIVA SERENIPAUSE supports support women's health and wellbeing during life transitions.

What you need to know before you take NUTRIVIVA SERENIPAUSE

Do not take NUTRIVIVA SERENIPAUSE

- If you are hypersensitive (allergic) to Maca Extract; magnesium; Ashwagandha; Panax ginseng; Saw Palmetto; Black cohosh; Vitamin B6; Vitamin B2; Vitamin B12 or any of the other ingredients of NUTRIVIVA SERENIPAUSE (listed in section 6).

Warnings and precautions

Take special care with NUTRIVIVA SERENIPAUSE:

- If you suffer from a hormone-sensitive condition such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids Avoid taking with alcohol or products that cause drowsiness.
- If you are having any surgical procedure done. You should stop taking NUTRIVIVA SERENIPAUSE at least two weeks before an operation.
- If you have an autoimmune disease (a condition in which your body's immune system attacks healthy cells).
- If you have a thyroid disorder.
- Panax ginseng is possibly unsafe when taken for more than 6 months. It might have some hormone-like effects that could be harmful when used long-term.
- If you have a heart condition.

- If you have trouble sleeping (insomnia)
- If you suffer with schizophrenia.
- If you suffer with hypotension (low blood pressure).
- If you suffer with liver disease
- Avoid using a combination of vitamin B6, folate, and vitamin B12 after receiving a coronary stent. This combination may increase the risk of blood vessel narrowing.
- Allergy or sensitivity to cobalt or cobalamin: Do not use vitamin B12 if you have this condition.

Children

Not intended for children younger than 18 years.

Other medicines and NUTRIVIVA SERENIPAUSE

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

Tell your doctor or pharmacist if you are currently taking:

- **Anticoagulants (warfarin):** NUTRIVIVA SERENIPAUSE contains quercetin, which may theoretically increase the effects of anticoagulants.
- **Antiplatelet drugs (aspirin, clopidogrel):** NUTRIVIVA SERENIPAUSE contains quercetin, which may theoretically increase the effects of antiplatelet drugs.
- **Levodopa/carbidopa (Sinemet):** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the effectiveness of levodopa/carbidopa.
- **Benzodiazepines (diazepam, clonazepam):** NUTRIVIVA SERENIPAUSE contains ashwagandha, which may theoretically increase the sedative effects of benzodiazepines.
- **CNS depressants (barbiturates, sedatives):** NUTRIVIVA SERENIPAUSE contains ashwagandha, which may theoretically increase the sedative effects of CNS depressants.
- **Immunosuppressants (cyclosporine, tacrolimus):** NUTRIVIVA SERENIPAUSE contains ashwagandha, which may theoretically reduce the effects of immunosuppressants.
- **Thyroid hormones (levothyroxine):** NUTRIVIVA SERENIPAUSE contains ashwagandha, which may theoretically increase the effects of thyroid hormones.
- **Antidiabetic drugs (insulin, metformin, sulfonylureas):** NUTRIVIVA SERENIPAUSE contains ashwagandha and Panax ginseng, which may theoretically increase the risk of hypoglycaemia.

- **Antihypertensive drugs (ACE inhibitors, beta-blockers):** NUTRIVIVA SERENIPAUSE contains ashwagandha and vitamin B6, which may theoretically increase the effects of antihypertensive drugs.
- **Hepatotoxic drugs (acetaminophen, statins):** NUTRIVIVA SERENIPAUSE contains ashwagandha and black cohosh, which may theoretically increase the risk of liver damage.
- **Cisplatin (Platinol-AQ):** NUTRIVIVA SERENIPAUSE contains black cohosh, which may theoretically reduce the effects of cisplatin.
- **CYP2D6 substrate drugs (codeine, tamoxifen):** NUTRIVIVA SERENIPAUSE contains black cohosh and Panax ginseng, which may theoretically alter the effects of these drugs.
- **Estrogens (hormone replacement therapy, oral contraceptives):** NUTRIVIVA SERENIPAUSE contains black cohosh and saw palmetto, which may theoretically alter the effects of Estrogens.
- **Serotonergic drugs (SSRIs, SNRIs):** NUTRIVIVA SERENIPAUSE contains black cohosh, which may theoretically increase the risk of serotonin-related side effects.
- **Aminoglycoside antibiotics (gentamicin, tobramycin):** NUTRIVIVA SERENIPAUSE contains magnesium, which may theoretically increase the risk of neuromuscular weakness.
- **Bisphosphonates (alendronate, risedronate):** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the absorption of bisphosphonates.
- **Calcium channel blockers (nifedipine, amlodipine):** NUTRIVIVA SERENIPAUSE contains magnesium and Panax ginseng, which may theoretically increase the effects of calcium channel blockers.
- **Potassium-sparing diuretics (spironolactone, amiloride):** NUTRIVIVA SERENIPAUSE contains magnesium, which may theoretically increase magnesium levels.
- **Quinolone antibiotics (ciprofloxacin, levofloxacin):** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the absorption of quinolones.
- **Tetracycline antibiotics (doxycycline, tetracycline):** NUTRIVIVA SERENIPAUSE contains magnesium and riboflavin, which may reduce the absorption or potency of tetracyclines.
- **Digoxin:** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the absorption of digoxin.
- **Antacids (aluminium hydroxide, calcium carbonate):** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the laxative effect of magnesium.
- **Skeletal muscle relaxants (rocuronium, vecuronium):** NUTRIVIVA SERENIPAUSE contains magnesium, which may theoretically increase the effects of skeletal muscle relaxants.
- **Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy):** NUTRIVIVA SERENIPAUSE contains magnesium, which may reduce the absorption of bictegravir/emtricitabine/tenofovir alafenamide.

- **Ketamine:** NUTRIVIVA SERENIPAUSE contains magnesium, which may theoretically increase the effects of ketamine.
- **Caffeine:** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically increase the stimulant effects of caffeine.
- **Insulin:** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically increase the risk of hypoglycaemia.
- **MAOIs (phenelzine):** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically interfere with MAOI therapy.
- **QT interval-prolonging drugs (amiodarone, sotalol):** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically increase the risk of QT prolongation.
- **Raltegravir (Isentress):** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically increase the risk of liver toxicity.
- **CYP3A4 substrate drugs (midazolam, imatinib):** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically alter the levels of drugs metabolized by CYP3A4.
- **Selegiline:** NUTRIVIVA SERENIPAUSE contains Panax ginseng, which may theoretically alter the effects of selegiline.
- **Amiodarone:** NUTRIVIVA SERENIPAUSE contains vitamin B6, which may theoretically increase photosensitivity caused by amiodarone.
- **Phenobarbital:** NUTRIVIVA SERENIPAUSE contains vitamin B6, which may reduce the effects of phenobarbital.
- **Phenytoin:** NUTRIVIVA SERENIPAUSE contains vitamin B6, which may reduce the effects of phenytoin.
- **Levodopa (alone):** NUTRIVIVA SERENIPAUSE contains vitamin B6, which may increase the metabolism of levodopa.
- **Antibiotics** (medicines used in the treatment of infections). The ingredients in NUTRIVIVA SERENIPAUSE may change the effect of antibiotics.
- **Antacids** might reduce the laxative effects of magnesium. People taking magnesium as a laxative might require a higher dose
- **Bisphosphonates:** The use of magnesium in conjunction with bisphosphonates may contribute to reduced absorption of bisphosphonates.
- **Gabapentin:** The use of magnesium in conjunction with gabapentin might decrease how much gabapentin the body absorbs. This might decrease the effects of gabapentin. Take gabapentin at least 2 hours before, or 4 to 6 hours after, taking magnesium as in NUTRIVIVA SERENIPAUSE
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- **Antihypertensive medicines** (used to treat high blood pressure) or supplements with a blood pressure-lowering effect.
- **Digoxin** (used in the treatment of various heart conditions)
- **Antidiabetic drugs** (*used to control blood sugar levels in diabetes*): By increasing blood sugar, inositol nicotinate might decrease the effectiveness of diabetes medications. Monitor your blood sugar closely. The dose of your diabetes medication might need to be changed.
- **Sedatives or tranquilisers**, also known as central nervous system (CNS) depressants, such as barbiturates and benzodiazepines (used to treat anxiety, panic attacks, seizures/convulsions and insomnia or trouble sleeping), or supplements with sedative properties.
- **Immunosuppressant medicines** (used to treat autoimmune disorders such as multiple sclerosis (MS), systemic lupus erythematosus (SLE) or rheumatoid arthritis (RA)).
- **Thyroid hormones** (used to treat conditions of the thyroid).
- **Stimulant drugs** that speed up the nervous system.
- **Oestrogen**
- **Fexofenadine** used to treat seasonal allergies
- **Medication that is changed by the liver.** NUTRIVIVA SERENIPAUSE might change how quickly the liver breaks down these medications. This could change the effects and side effects of these medications.
- **Monoamine oxidase inhibitors** (medicines used for depression); Taking NUTRIVIVA SERENIPAUSE with MAOIs might increase the risk for certain side effects, such as anxiousness, headache, restlessness, and insomnia.
- **QT interval- prolonging drugs** (medicines that can cause irregular heartbeat) or supplements that might cause an irregular heartbeat;
- **Anticoagulant/ anti-platelet medicines** (medications used to slow blood clotting) or supplements that influence blood clotting;
- **Contraceptives** (Birth control medicines)
- **Medications used for lowering cholesterol (Statins)**
- **Cisplatin (Platinol-AQ) medication used in the treatment of advanced cancers.** There is some concern that black cohosh might decrease how well cisplatin works for cancer.
- **Organic anion-transporting polypeptide substrates**
- **Serotonergic drugs** used to increase a brain chemical called serotonin
- **Amiodarone (Cordarone) (used to treat arrhythmia).** Amiodarone might increase sensitivity to sunlight. Taking vitamin B6 along with amiodarone might increase the chances of sunburn, blistering, or rashes on areas of skin exposed to sunlight. Be sure to wear sunblock and protective clothing when spending time in the sun.
- **Levodopa (used to treat Parkinsons Disease).** Vitamin B6 can increase how quickly the body breaks down and gets rid of levodopa. But this is only a problem if you are taking levodopa alone. Most people take levodopa along

with carbidopa. Carbidopa prevents this interaction from occurring. If you are taking levodopa without carbidopa, do not take vitamin B6.

- **Phenobarbital (Luminal).** Vitamin B6 might increase how quickly the body breaks down phenobarbital. This could decrease the effects of phenobarbital.
- **Phenytoin (Dilantin).** Vitamin B6 might increase how quickly the body breaks down phenytoin. Taking vitamin B6 along with phenytoin might decrease the effects of phenytoin and increase the risk of seizures. Do not take large doses of vitamin B6 if you are taking phenytoin.

Pregnancy, breastfeeding and fertility

Safety in fertility, pregnancy and lactation 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 health care provider for advice before taking this medicine.

Driving and using machines

NUTRIVIVA SERENIPAUSE may cause drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness.

3. How to take NUTRIVIVA SERENIPAUSE

Do not share your medicines with any other person.

Always take NUTRIVIVA SERENIPAUSE 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.

Adults: The usual dose is 4 capsules daily.

Children: Not intended for children younger than 18 years.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you take more NUTRIVIVA SERENIPAUSE 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.

If you forget to take NUTRIVIVA SERENIPAUSE

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

4. Possible side effects

NUTRIVIVA SERENIPAUSE can have side effects.

Not all side effects reported for NUTRIVIVA SERENIPAUSE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking NUTRIVIVA SERENIPAUSE, please consult your health care provider for advice.

If any of the following happens, stop taking NUTRIVIVA SERENIPAUSE and tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of the 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 NUTRIVIVA SERENIPAUSE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea (loose, watery stools),
- nausea (feeling sick),
- vomiting (being sick)
- gastrointestinal disturbances
- stomach pain,
- insomnia,
- headache,
- constipation,
- decreased libido,
- dizziness,
- fatigue,
- rhinitis (Irritation and swelling of the mucous membrane in the nose.),

Side effect with unknown frequency:

- decreased appetite,
- abdominal distension or bloating,
- hypotension,
- hypertension,

- amenorrhea,
- vertigo,
- hypertension (increased blood pressure),
- postural hypotension,
- tachycardia
- bradycardia,
- skin reactions,
- impotence in males,
- muscle weakness,
- back pain,
- increased risk of bleeding.

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 or 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 NUTRIVIVA SERENIPAUSE.

5. How to store NUTRIVIVA SERENIPAUSE.

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place.

Protect from moisture and light.

6. Contents of the pack and other information.

What is found in NUTRIVIVA SERENIPAUSE

Active Ingredient	Quantity per capsule	Quantity per serving	% NRV per 4 capsules (serving size and maximum daily dose)
Magnesium Biglycinate	125mg	500mg	
providing elemental Magnesium	17,63mg	70,5mg	22.7%
<i>Lepidium meyenii</i> Walp. (Maca Extract)	93,8mg	375mg	*

[root, NLT 4:1 extract]	375mg	1500mg	*
Sensoril® <i>Withania somnifera</i> (L.) Dunal (Ashwagandha)	75mg	300mg	*
[roots and leaves], standardised to Withanolide glycosides ≥10%, Oligosaccharides ≥32%, Withanolide aglycone (as Withaferin A) ≤0.5%			*
<i>Panax ginseng</i> C.A.Mey.	75mg	300mg	*
[root , 25:1 extract standardized to ginsenosides 80% DHE]	1875mg	7500mg	*
<i>Serenoa repens</i> (Bartram) (Saw Palmetto)	75mg	300mg	*
[fruit , 15:1 extract standardised to total fatty acid 25% DHE]	1125mg	4500mg	*
<i>Actaea racemosa</i> (L.) (Black Cohosh)	40mg	160mg	*
[root, standardized to ≥2.5% triterpene glycosides]	1mg	4mg	*
Pyridoxine (Vitamin B6)	6,25mg	25mg	1923%
Riboflavin 5'-phosphate (Vitamin B2)	0,28mg	1.1mg	91.70%
Methylcobalamin (Vitamin B12)	25mcg	100mcg	4167%

The other ingredients are the hypromellose capsules and microcrystalline cellulose.

What NUTRIVIVA SERENIPAUSE looks like and contents of the pack

Clear capsules containing a brown powder.

120 capsules, packed in an appropriately labelled amber glass bottle with a metal lid.

Holder of Certificate of Registration

Nutriviva (Pty) Ltd

Unit 2 Nguni Business Park

1 Nguni Way

Waterfall

3610

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This leaflet was revised in

October 2025.

Registration

To be allocated by SAHPRA.