

RAGE TESTO ARMOUR**PROFESSIONAL INFORMATION****D 33.7 Combination product. Complementary medicine.**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: **1. NAME OF THE MEDICINE****BIOGEN RAGE TESTO ARMOUR****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains	Per capsule	Per daily dose	%NRV*
<i>Eurycoma longifolia</i> Jack (Tongkat Ali) [Root, 200:1 extract providing 6.67 g DHE]	100,00 mg	400,00 mg	
<i>Panax ginseng</i> C.A. (Panax Ginseng) [Root, 5:1 extract providing 500,00 mg DHE]	100,00 mg	400,00 mg	
Magnesium (as Magnesium aspartate and Magnesium oxide)	62,50 mg	250,00 mg	15 %
D-Aspartic acid	50,00 mg	200,00 mg	
<i>Tribulus terrestris</i> (Tribulus terrestris) [Herb, 13:1-15:1 extract standardised to 45 % saponins providing 1.7 g - 1.9 g DHE]	35,00 mg	140,00 mg	
<i>Withania somnifera</i> (L.) Dunal (Ashwaganda) [Root, 15:1 extract providing 0.5 g DHE]	36,00 mg	144,00 mg	
Zinc (as Zinc Mono-methionine)	10,22 mg	40,88 mg	16 %
Pyridoxine (Vitamin B ₆) (from Pyridoxine hydrochloride)	3,00 mg	12,00 mg	176 %
Pantothenic Acid (Vitamin B ₅) (from calcium D-pantothenate)	1,25 mg	5,00 mg	25 %
BioPerine® <i>Piper nigrum</i> L. (Black Pepper) [Fruit, 50:1 extract standardised to 95 % piperine providing 83,5 mg DHE]	1,25 mg	5,00 mg	

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bovine gelatine capsules

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

BIOGEN RAGE TESTO ARMOUR, a combination of herbals, vitamins and minerals that increases levels of Testosterone, dehydroepiandrosterone (DHEA) and dihydrotestosterone that has a mechanism of action on improved exercise performance and sexual health.

4.2 Posology and method of administration

Adults: 16 years and older:
Take 4 (four) capsules daily with meals, or as recommended by your healthcare provider. Use continuously for 6-8 weeks followed by a 2-4 week break.

Elderly:

No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

Patient with impaired renal and/or liver function:

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

Children and adolescents:

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

4.3 Contraindications

- If you have a hypersensitivity to Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine® or any of the excipients listed in 6.1.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Do not use this product if you have hypertension or liver deficiency.
- Contraindicated in patients with prostate cancer.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN RAGE TESTO ARMOUR.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Consult a healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you have diabetes.
- Consult a healthcare provider prior to use in case of qI or blood deficiency.
- Ashwaganda can cause drowsiness in some patients.
- The use of Ashwaganda in patients with diabetes may cause blood sugar levels to go too low, therefore monitor your blood sugar closely.
- Ashwaganda may interfere with medications used to treat high blood pressure. Patients should use Ashwaganda cautiously if they take medication for treating high blood pressure.
- Ashwaganda can irritate the gastrointestinal (GI) tract. Patients are advised to discuss dosage requirements with their relevant healthcare provider.
- Patients with "Auto-immune diseases" such as multiple sclerosis (MS), lupus (systemic lupus erythematosus, SLE), rheumatoid arthritis (RA), are advised to avoid using ashwaganda or discuss dosage requirements with their relevant healthcare provider.
- Ashwaganda may slow down the central nervous system. It is advised to discontinue use at least 2 weeks before a scheduled surgery.
- Ashwaganda might increase thyroid hormone levels. Ashwaganda should be used cautiously or avoided if patients have a thyroid condition or take thyroid hormone medications.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

No specific drug interaction studies have been performed on BIOGEN RAGE TESTO ARMOUR, however, the pharmacokinetic properties of Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine® have been summarized.

Interactions with Medicines

- Taking Panax ginseng with antidiabetics drugs might increase the risk of hypoglycemia, Panax ginseng might decrease blood glucose levels and it is advised that blood glucose levels are monitored closely.
- Caution is advised when taking Panax ginseng with caffeine, concomitant use might increase the risk of stimulant effects.
- Panax ginseng might decrease levels of drugs metabolized by CYP1A1, increase levels of drugs metabolized by CYP2D6 and increase or decrease levels of drugs metabolized by CYP3A4.
- Concomitant use of large amounts of Panax ginseng might interfere with hormone replacement therapy, decrease blood levels of oral lefexidine, reduce effects of furosemide, increase the effects and adverse effects of imatinib, and interfere with immunosuppressive therapy.
- Panax ginseng in combination with insulin might increase the risk of hypoglycemia.
- Panax ginseng with stimulant drugs might increase the risk of adverse stimulant effects.
- Tribulus as in BIOGEN RAGE TESTO ARMOUR may interact with other medicines administered concurrently, particularly those with similar or opposing effects, should also be considered.
- Tribulus can inhibit angiotensin-converting enzyme (ACE). Concurrently administering tribulus with other ACE inhibitors might have additive effects. Monitor blood pressure and potassium levels.
- Tribulus can enhance the blood glucose-lowering effects of hypoglycemic drugs. Monitor blood glucose levels closely.
- Tribulus can lower blood pressure by inhibiting angiotensin-converting enzyme. Concurrently administering tribulus with antihypertensive drugs might have additive blood pressure lowering effects and increase the chance of hypotension.
- Tribulus may have diuretic properties. Due to these potential diuretic effects, tribulus might reduce excretion and increase levels of lithium. The dose of lithium might need to be decreased.
- Tribulus may have lower blood glucose levels. Tribulus might have additive effects when used with other herbs and supplements that also lower glucose levels. This might increase the risk of hypoglycemia.
- Tribulus can lower blood pressure. Combining Tribulus with other herbs or supplements with hypotensive effects might increase the risk of hypotension.
- Tongkat Ali can reduce the levels and clinical effects of propranolol and patients are advised to discuss an appropriate dosing schedule with their healthcare provider.
- Magnesium can bind with certain medications, preventing their full absorption. If you are taking a tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), separate the time of the dose from the time of the magnesium supplement dose by at least 2 to 3 hours.
- Ashwaganda might lower blood pressure. Combining Ashwaganda with other herbs and supplements that also lower blood pressure might cause lowered blood pressure. Some herbs and supplements of this type include andrographis, cassein peptides, Cat's Claw, coenzyme Q-10, fish oil, L-arginine, lycium, Stinging Nettle.
- Ashwaganda can act like a sedative. Using it along with other herbs and supplements to treat sleeplessness might cause interference and can result in excessive sleepiness. Some of these include: 5-HTP, Calamus, California Poppy, Catnip, Hops (*Humulus lupulus*), Jamaican Dogwood, Kava, St. John's Wort, Skulcap, Valerian and Yerba Mansa.
- If you are taking a bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), or a quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), ask your doctor or pharmacist about how long you should wait between doses and for finding a dosing schedule that will work with all your medications.
- Concomitant use of aminoglycosid antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Zinc and Amiloride can modestly reduce zinc excretion and increase zinc levels, decrease cephalaxin levels by chelating with cephalaxin in the gut and preventing its absorption.
- Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.
- Zinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5 - 1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.
- Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.
- Vitamin B₆ might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B₆ may reduce the levels and clinical effects of phenobarbital and phenytoin.

Interactions with Diseases/Impairments

- Panax ginseng might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Panax ginseng may stimulate immune function.
- Panax ginseng might increase bleeding; patients are advised to avoid in cases of hemorrhage or thrombosis. Panax ginseng has been reported to decrease blood coagulation.
- Panax ginseng might increase adverse cardiovascular effects; caution is advised in patients with cardiac conditions.
- Panax ginseng might increase the development of hormone-sensitive tumors; avoid in patients with hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, and uterine fibroids.
- Panax ginseng might interfere with immunosuppressive therapy; avoid use. Panax ginseng might have immune system stimulating properties.
- Panax ginseng might worsen insomnia; use with caution. High doses of ginseng have been associated with insomnia.
- Panax ginseng might worsen some symptoms; use with caution. High doses of ginseng have been associated with insomnia and agitation in people with schizophrenia.
- Tribulus as in BIOGEN RAGE TESTO ARMOUR might reduce blood glucose levels. Combined use might increase the risk for hypoglycemia, especially in patients on insulin or oral hypoglycemic medications. Dose adjustments for diabetes medications may be necessary.
- Tribulus as in BIOGEN RAGE TESTO ARMOUR might affect blood glucose levels and blood pressure. Therefore Tribulus might interfere with blood glucose and blood pressure control during and after surgical procedures.
- Ashwaganda might have immunostimulatory effects. Caution is advised in patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others (see section 4.4).
- Ashwaganda can have sedative effects. Ashwaganda might cause additive CNS depression when combined with anesthesia and other medications during and after surgical procedures. Patients should discontinue ashwaganda at least 2 weeks before elective surgical procedures.
- Ashwaganda might exacerbate hyperthyroidism by increasing thyroid hormone levels; use with caution in patients with hyperthyroidism or those being treated with thyroid hormones.
- Patients are advised to discontinue BIOGEN RAGE TESTO ARMOUR at least 2 weeks before elective surgical procedures (see section 4.4).
- BIOGEN RAGE TESTO ARMOUR and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Supplemental Vitamin B₆ at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of BIOGEN RAGE TESTO ARMOUR in pregnancy and lactation has not been established.

4.7 Effect on ability to drive and use machines

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN RAGE TESTO ARMOUR does not affect their performance.

4.8 Undesirable effects

Orally, Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine® is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:
Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine®

Less Frequent: Tribulus can cause abdominal pain, cramping, nausea, vomiting, diarrhea, and constipation. Transient GI problems including irritation of gastric mucosa and gastric reflux, and heartburn have been associated with consumption of tribulus. Black Pepper can cause dyspepsia.

Nervous system disorders:

Frequent: headache, paresthesia, and somnolence. Tribulus may cause general excitation and insomnia. Panax ginseng may cause insomnia, headache and vertigo.

Endocrine:

Frequency unknown: Tongkat Ali might increase testosterone levels, if testosterone levels are increased beyond the normal range, there is risk of testosterone-related side effects which could include acne, insulin resistance, hepatotoxicity, and others.

Metabolism and nutrition disorders:

Less frequent: hypercalcemia (particularly in patients with renal impairment or after high dosages), alkalosis.

Musculoskeletal:

Frequency unknown: breast soreness or enlargement.

Cardiovascular:

Less Frequent: Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Dermatologic:

Less Frequent: Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Description of selected adverse reactions

BIOGEN RAGE TESTO ARMOUR may cause several adverse reactions, such as gastrointestinal disturbances, such as, digestive disorders, and constipation.

Pediatric population

BIOGEN RAGE TESTO ARMOUR is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

Other special populations

Patients with Renal Impairment: Magnesium is contraindicated in patients with severe renal impairment (see Section 4.3). There is no dose adjustment necessary in patients with mild to moderate renal impairment. No clinical data are available concerning the effects of BIOGEN RAGE TESTO ARMOUR on other special populations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Side effects listed in section 4.8.

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

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Mechanism of action:

Panax Ginseng: The mechanism of action of Panax ginseng is likely related to its ginsenoside constituents. The ginsenoside Rb1 has been suggested to exert its memory effects by minimizing the inhibitory effects of beta-amylloid peptides, which are thought to play a role in memory degeneration. The neuroprotective effects of Panax ginseng may play a role in the improved performance in these systems.

Tribulus: Research suggests that tribulus can improve sexual dysfunction in males and females and erectile dysfunction in males. These effects may be due to changes in hormone levels.

Tongkat Ali: The peptides are thought to activate 17-alpha-hydroxylase/17,20-lyase, resulting in increased metabolism of pregnenolone and 17-OH-pregnenolone to dehydroepiandrosterone (DHEA) and metabolism of progesterone and 17-OH-progesterone to 4-androstenedione and testosterone. Increases muscular strength.

Black pepper/BioPerine®: is a patented, standardised extract from black pepper containing 95% piperine (a bioavailability enhancer for nutrients). Used in combination with other ingredients it may enhance the uptake and utilisation of the natural actives increasing the bioavailability of supplemented nutrients through increased absorption.

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PATIENT INFORMATION LEAFLETSCHEDULING STATUS: **[S0]****PRODUCT NAME**

BIOGEN RAGE TESTO ARMOUR

Each capsule contains:

Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine.

Sugar free.

COMPLEMENTARY MEDICINE: D 33.7 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.

BIOGEN RAGE TESTO ARMOUR is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN RAGE TESTO ARMOUR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN RAGE TESTO ARMOUR with any other person.
- Ask you healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What BIOGEN RAGE TESTO ARMOUR is and what it is used for

BIOGEN RAGE TESTO ARMOUR is a combination of herbs, vitamins and minerals that increases levels of Testosterone, dehydroepiandrosterone (DHEA) and dihydrotestosterone that has a mechanism of action on improved exercise performance and sexual health.

2. What you need to know before you take BIOGEN RAGE TESTO ARMOUR

Do not take BIOGEN RAGE TESTO ARMOUR:

- If you have a hypersensitivity (Allergy) to Tongkat ali, Panax ginseng, Magnesium, D-aspartic acid, Tribulus terrestris, Ashwagandha, Zinc, Vitamin B₆, Vitamin B₅ and BioPerine or any of the excipients listed in 6.1.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Do not use this product if you have hypotension or liver deficiency.
- Contraindicated in patients with prostate cancer.

Warnings and precautions

Special care should be taken with BIOGEN RAGE TESTO ARMOUR.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Consult a healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you have diabetes.
- Consult a healthcare provider prior to use in case of qi or blood deficiency.
- The use of Ashwagandha in patients with diabetes may cause blood sugar levels to go too low, therefore monitor your blood sugar closely.
- Ashwagandha may interfere with medications used to treat high blood pressure. Patients should use Ashwagandha cautiously if they take medication for treating high blood pressure.
- Ashwagandha can irritate the gastrointestinal (GI) tract. Patients are advised to discuss dosage requirements with their relevant healthcare provider.
- Patients with "Auto-immune diseases" such as multiple sclerosis (MS), lupus (systemic lupus erythematosus, SLE), rheumatoid arthritis (RA), are advised to avoid using ashwagandha or discuss dosage requirements with their relevant healthcare provider.
- Ashwagandha may slow down the central nervous system. It is advised to discontinue use at least 2 weeks before a scheduled surgery.
- Ashwagandha might increase thyroid hormone levels. Ashwagandha should be used cautiously or avoided if patients have a thyroid condition or take thyroid hormone medications.

Children and adolescents

BIOGEN RAGE TESTO ARMOUR is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN RAGE TESTO ARMOUR

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

It is advised to consult your doctor if you want to take BIOGEN RAGE TESTO ARMOUR combined with other medicines or treatments such as:

- Decreasing Panax ginseng with antidiabetes drugs might increase the risk of hypoglycemia, Panax ginseng might decrease blood glucose levels and it is advised that blood glucose levels are monitored closely.
- Caution is advised when taking Panax ginseng with caffeine, concomitant use might increase the risk of stimulant effects.
- Panax ginseng might decrease levels of drugs metabolized by CYP1A1, increase levels of drugs metabolized by CYP2D6 and increase or decrease levels of drugs metabolized by CYP3A4.
- Concomitant use of large amounts of Panax ginseng might interfere with hormone replacement therapy, decrease blood levels of oral fenofenadine, reduce effects of furosemide, increase the effects and adverse effects of imatinib, and interfere with immunosuppressive therapy.
- Patients with "Auto-immune diseases" such as multiple sclerosis (MS), lupus (systemic lupus erythematosus, SLE), rheumatoid arthritis (RA), are advised to avoid using ashwagandha or discuss dosage requirements with their relevant healthcare provider.
- Ashwagandha may slow down the central nervous system. It is advised to discontinue use at least 2 weeks before a scheduled surgery.
- Ashwagandha might increase thyroid hormone levels. Ashwagandha should be used cautiously or avoided if patients have a thyroid condition or take thyroid hormone medications.
- Tongkat Ali can reduce the levels and clinical effects of propranolol and patients are advised to discuss an appropriate dosing schedule with their healthcare provider.
- Magnesium can bind with certain medications, preventing their full absorption. If you are taking a tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), separate the time of the dose from the time of the magnesium supplement dose by at least 2 to 3 hours.
- Ashwagandha might lower blood pressure. Combining Ashwagandha with other herbs and supplements that also lower blood pressure might cause lowered blood pressure. Some herbs and supplements of this type include andrographis, casen peptides, Cat's Claw, coenzyme Q-10, fish oil, L-arginine, lycium, Stinging Nettle.
- Ashwagandha can act like a sedative. Using it along with other herbs and supplements to treat sleeplessness might cause interference and result in excessive sleepiness. Some of these include: 5-HTP, Calamus, California Poppy, Catnip, Hops (Humulus lupulus), Jamaican Dogwood, Kava, St. John's Wort, Valerian and Yerba Mansa
- If you are taking a bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), or a quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), ask your doctor or pharmacist about how long you should wait between doses and for finding a dosage schedule that will work with all your medications.
- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Zinc and Amiloride might modestly reduce zinc excretion and increase zinc levels, decrease cephalexin levels by chelating with cephalexin in the gut and preventing its absorption.
- Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.
- Zinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5-1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.
- Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.
- Vitamin B₆ might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B₆ may reduce the levels and clinical effects of phenobarbital and phenytoin.

Other Diseases/Impairments and BIOGEN RAGE TESTO ARMOUR

- Panax ginseng might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Panax ginseng may stimulate immune function.
- Panax ginseng might increase bleeding; patients are advised to avoid in cases of hemorrhage or thrombosis. Panax ginseng has been reported to decrease blood coagulation.
- Panax ginseng might increase adverse cardiovascular effects; caution is advised in patients with cardiac conditions.
- Panax ginseng might increase the development of hormone-sensitive tumors; avoid in patients with hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, and uterine fibroids.
- Panax ginseng might interfere with immunosuppressive therapy; avoid use. Panax ginseng might have immune system stimulating properties.
- Panax ginseng might worsen insomnia; use with caution. High doses of ginseng have been associated with insomnia and agitation in people with schizophrenia.
- Tribulus as in BIOGEN RAGE TESTO ARMOUR might reduce blood glucose levels. Combined use might increase the risk for hypoglycemia, especially in patients on insulin or oral hypoglycemic medications. Dose adjustments for diabetes medications may be necessary.
- Tribulus as in BIOGEN RAGE TESTO ARMOUR might affect blood glucose levels and blood pressure. Therefore Tribulus might interfere with blood glucose and blood pressure control during and after surgical procedures.
- Ashwagandha might have immunostimulatory effects. Caution is advised in patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others (see section 4.4).
- Ashwagandha can have sedative effects. Ashwagandha might cause additive CNS depression when combined with anesthesia and other medications during and after surgical procedures. Patients should discontinue ashwagandha at least 2 weeks before elective surgical procedures.
- Ashwagandha might exacerbate hyperthyroidism by increasing thyroid hormone levels; use with caution in patients with hyperthyroidism or those being treated with thyroid hormones.
- Patients are advised to discontinue BIOGEN RAGE TESTO ARMOUR at least 2 weeks before elective surgical procedures (see section 4.4).
- Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Supplemental Vitamin B₆ at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.

RAGE TESTO ARMOUR with food and drink

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing/suggesting BIOGEN RAGE TESTO ARMOUR.
- Taking magnesium-containing supplements with food may reduce the risk of diarrhea.

Pregnancy, breastfeeding and fertility

The safety and efficacy of BIOGEN RAGE TESTO ARMOUR in pregnancy and lactation has not been established.

Driving and using machinery

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN RAGE TESTO ARMOUR does not affect their performance.

3. How to take BIOGEN RAGE TESTO ARMOUR

Do not share your medicines with any other person.

Always take BIOGEN RAGE TESTO ARMOUR 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: 18 years and older:

Take 4 (four) capsules daily with meals, or as recommended by your healthcare provider. Use continuously for 6-8 weeks followed by a 2-4 week break.

Elderly:

No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating elderly, healthy patients.

Patient with impaired renal and/or liver function:

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

Children and adolescents:

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

If you take more BIOGEN RAGE TESTO ARMOUR than you should

No known information. 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 BIOGEN RAGE TESTO ARMOUR with you so the doctor will know what you have taken.

If you forget to take BIOGEN RAGE TESTO ARMOUR

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

4. Possible side effects

BIOGEN RAGE TESTO ARMOUR can have side effects.

Not all side effects reported for BIOGEN RAGE TESTO ARMOUR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN RAGE TESTO ARMOUR, please consult your healthcare provider for advice.

Side effects associated;

Less frequent: Tribulus can cause abdominal pain, cramping, nausea, vomiting, diarrhea, and constipation. Transient GI problems including irritation of gastric mucosa and gastric reflux, and heartburn have been associated with consumption of tribulus. Black Pepper can cause dyspepsia.

Frequent: headache, paresthesia, and somnolence. Tribulus may cause general excitation and insomnia. Panax ginseng can cause decreased appetite, diarrhea, abdominal pain, and nausea.

Frequency unknown: Panax ginseng may cause insomnia, headache and vertigo. Tongkat Ali might increase testosterone levels, but testosterone levels are increased beyond the normal range, there is risk of testosterone-related side effects which could include acne, insulin resistance, hepatotoxicity, and others.

Less frequent: hypercalcemia (particularly in patients with renal impairment or after high dosages), alkalosis.

Frequency unknown: breast soreness or enlargement. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Should your general health worsen or if you experience any untoward effects while BIOGEN RAGE TESTO ARMOUR, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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

Reporting of side effectsIf you experience side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index.htm>.

By reporting side effects, you can help provide more information on the safety of BIOGEN RAGE TESTO ARMOUR.

5. How to store BIOGEN RAGE TESTO ARMOUR

- Store at below 25 °C.
- Protect from light and moisture.
- 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).

6. Contents of the pack and other information What BIOGEN RAGE TESTO ARMOUR contains**What BIOGEN RAGE TESTO ARMOUR contains**

Active ingredients per capsule: Tongkat Ali 100.00 mg, Panax ginseng 100.00 mg, Magnesium 62.50 mg, D-Aspartic acid 50.00 mg, Ashwagandha 36.00 mg, Tribulus terrestris 35.00 mg, Zinc 10.22 mg, Vitamin B6 3.00 mg, Vitamin B5 1.25 mg, BioPerine® 1.25 mg

Sugar Free.

The other ingredients are Magnesium stearate and Silicon dioxide.

What BIOGEN RAGE TESTO ARMOUR looks like and contents of the pack

The container is a 250 mL PET container, with a Biogen embossed cap and a tamper evident seal. Packed in a unit carton.

Holder of certificate of registration

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

This leaflet was last revised in June 2022

Registration Number

Will be allocated by SAHPRA upon registration.

PLEASE CHECK CAREFULLY

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

PASIENLTINLIGTINGSBLADSKEDULERINGSTATUS: **[S0]****PRODUKNAAM**

BIOGEN RAGE TESTO ARMOUR

Elke kapsule bevat:

Tongkat ali, Panax ginseng, Magnesium, D-asparaginsuur, Tribulus terrestris, Ashwaganda, Sink, Vitaminen B₆, Vitaminen B₅ en BioPerine.

Suikervry.

KOMPLEMTER MEDISYNE: D 33.7 Kombinasieproduk.

Hierdie ongegeregisteerde medisyne is beskikbaar sonder 'n dokter se voorskrif, sodat u gesondheid kan onderhou. U moet BIOGEN RAGE TESTO ARMOUR niteman steeds versigtig neem om die beste resultate te verkry.

Les hierdie inligtingsblad noukerig deur want dit bevat inligting wat belangrik is vir u.

BIOGEN RAGE TESTO ARMOUR is beskikbaar sonder enige drukstof, sodat u gesondheid kan onderhou. U moet BIOGEN RAGE TESTO ARMOUR niteman steeds versigtig neem om die beste resultate te verkry.

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