

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL

FORM - **INSINASE®**, 90 Tablets

COMPOSITION

Each three (3) tablets of **INSINASE®** contain the following actives:

Tetrahydro Iso-Alpha Acids	450 mg
Indian Gum Arabic Tree (Acacia nilotica) [Bark and heartwood 5,5:1 extract]	90 mg

Inactive Ingredients coating [hydroxypropylcellulose, hypromellose, medium-chain triglycerides, and sodium copper chlorophyllin (colour)], croscarmellose sodium, magnesium stearate (vegetable) microcrystalline cellulose, silica and sodium starch glycolate.

This product is suitable for Vegetarians and is non-GMO. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

INSINASE® is formulated with a unique blend of plant-derived extracts, developed to support general metabolic health. This formula, produced using the **ExpresSyn®** Process, features compounds such as tetrahydro iso-alpha acids and Acacia nilotica for balanced wellness support.

Ingredients	Uses for ingredient
Tetrahydro Iso-Alpha Acids	Used for their anti-inflammatory, antioxidant, antimicrobial, and anxiolytic properties
Indian Gum Arabic Tree (Acacia nilotica)	Used for its anti-inflammatory, antimicrobial, antioxidant, liver-protective, wound healing properties.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **INSINASE®** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take three (3) tablets daily or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.
Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Hormone-Sensitive Conditions (e.g., breast cancer, uterine cancer, ovarian cancer, endometriosis, fibroids), Liver Disease (e.g., cirrhosis, hepatitis), Kidney Disease (e.g., chronic kidney disease), Diabetes, Gastrointestinal Disorders (e.g., Crohn's disease, ulcerative colitis), Heart Conditions (e.g., hypertension, heart failure), Hypertension (High Blood Pressure), Liver Disease (e.g., cirrhosis, hepatitis), Cardiovascular Diseases (e.g., heart failure, coronary artery disease), Autoimmune Conditions (e.g., rheumatoid arthritis, lupus). If you are taking the following medication, please consult with your healthcare professional before taking: Sedatives and Central Nervous System Depressants, Hormonal Medications, Anticoagulants and Antiplatelet Drugs, Antidiabetic Medication, Antihypertensive Medication, Immunosuppressants, Liver-Acting Medication. If any of the following happens, stop using **INSINASE®** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat).

These are all very serious effects. If you have them, you may have had a serious reaction to **INSINASE®**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting.
- These are all very serious effects. If you have them, you may have had a serious reaction to **INSINASE®**. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.
- Keep this leaflet. You may need to read it again.
 - Do not share medication with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must consult a doctor should your condition worsen or does not improve.
- DO NOT USE THIS PRODUCT:**
- If you are hypersensitive (allergic) to any of the ingredients listed.
 - Do not accept this package if seals are broken.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C. Protect from direct sunlight and heat. Store in the original bottle. Keep the bottle tightly closed. Replace the protective cap after each use. Do not use after the expiry date stated on the bottle. Do not use **INSINASE®** if you notice visible signs of deterioration.

IDENTIFICATION

Green, oval, coated tablet.

PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

REGISTRATION NUMBER - To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by: Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

Document reference: INSIN.PI.V1 12-24

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

INSINASE[®], 90 Tablette

SAMESTELING

Elke drie (3) tablette van INSINASE[®] bevat die volgende aktiewe stowwe:

Tetrahydro Iso-Alfa-sure	450 mg
Indiese Arabiese gom (Acacia nilotica) [Bas en kernhout 5,5:1 uittreksel]	90 mg

Onaktiewe bestanddele: deklaag [hidroksipropylselulose, hipromellose, mediumketting trigliseriede, en natriumkoperchlorofillien (kleur)], croscarmellose-natrium, magnesiumstearaat (groente) Mikrokrystalynse sellulose, silika en natriumstyselglukolaat.

Hierdie produk is geskik vir vegetariërs en is nie-GGO. (Suikervry)

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

INSINASE[®] is geformuleer met 'n unieke mengsel van plant-afgeleide uittreksels, ontwikkel om algemene metaboliese gesondheid te ondersteun. Hierdie formule, vervaardig met behulp van die Expressyn-proses[®], kenmerke verbindings soos tetrahydro iso-alfa sure en Acacia nilotica vir gebalanseerde welstandsondersteuning.

Bestanddele	Gebruik vir bestanddeel
Tetrahydro Iso-Alfa-sure	Word gebruik vir hul anti-inflammatoriese, antioksidante, antimikrobiëse en angswerende eienskappe
Indiese Arabiese gom (Acacia nilotica)	Word gebruik vir sy anti-inflammatoriese, antimikrobiëse, antioksidante, lewerbeskerende, wondgenesende eienskappe.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie INSINASE[®] neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem daagliks drie (3) kapsules of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hormoonsensitiewe toestande (bv. borskanker, baarmoederkanker, eierstokkanker, endometriose, fibroïede), lewersiekte (bv. sirroose, hepatitis), niersiekte (bv. chroniese niersiekte), diabetes, gastro-intestinale afwykings (bv. Crohn se siekte, useratiewe kolitis), harttoestande (bv. hipertensie, hartversaking), hipertensie (hoë bloeddruk), Lewersiekte (bv. sirroose, hepatitis), kardiovaskulêre siektes (bv. hartversaking, koronêre hartsiekte), auto-immuun toestande (bv. ramatoïede artritis, lupus). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Kalmeer medisyne en sentrale senuweestelseldepressante, hormonale medisyne, antikoagulant en bloedplaatjie-medisyne, anti-diabetiese medisyne, antihipertensiewe medisyne, immuunonderdrukkers, lewerwerkende medisyne. As enige van die volgende gebeur, hou op om INSINASE[®] te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op INSINASE[®] gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-efekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking,
- Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op INSINASE[®] gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-efekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOESING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN

Sien nuwe-efekte.
Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.
Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie. Moenie INSINASE[®] gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Groen, ovaal, bedekte tablet.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension, Sandton, 2146, Tel: 011- 802-8101