

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

INSINASE[®], 90 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **INSINASE[®]** is available without a doctor's prescription.
- Nevertheless, you still need to use **INSINASE[®]** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **INSINASE[®]** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **INSINASE[®]** is and what it is used for.
- What you need to know before you take **INSINASE[®]**.
- How to take **INSINASE[®]**.
- Possible side effects.
- How to store **INSINASE[®]**.
- Contents of the pack and other information.

WHAT INSINASE[®] CONTAINS

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

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

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)

WHAT INSINASE[®] IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE INSINASE[®]

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **INSINASE[®]** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **INSINASE[®]** may affect you.

TAKING OTHER MEDICINES WITH INSINASE[®]

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

Document Reference: INSIN.PIL.CMP.12-24



HOW TO TAKE INSINASE[®]

Do not share medicines prescribed for you with any other person. Always take **INSINASE[®]** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

Directions for use:

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

IF YOU TAKE MORE INSINASE[®] THAN YOU SHOULD

In the event of overdosage, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE INSINASE[®]

Do not take a double dose to make up for a missed dose.

POSSIBLE SIDE EFFECTS

INSINASE[®] may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **INSINASE[®]** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "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 **INSINASE[®]**.

STORAGE AND DISPOSING OF INSINASE[®]

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

Do not use after the expiry date stated on the bottle.

Do not use **INSINASE[®]** if you notice visible signs of deterioration.

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

PRESENTATION OF INSINASE[®]

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

IDENTIFICATION OF INSINASE[®]

Green, oval, coated tablet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

19 December 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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Sandton, 2146
Tel: 011-802-8101



PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS ⁵⁰

Kategorie D: Komplementêre medisyne.
Dissipline: Dissiplinespesifiek
33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

INSINASE[®], 90 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **INSINASE[®]** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **INSINASE[®]** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **INSINASE[®]** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **INSINASE[®]** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **INSINASE[®]** neem.
- Hoe om **INSINASE[®]** te neem.
- Moontlike nuwe-effekte.
- Hoe om **INSINASE[®]** te bêre.
- Inhoud van die pak en ander inligting

WATTER INSINASE[®] BEVAT

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

Tetrahydro Iso-Alfa-sure	450 mg
Indiese Arabiese gom (Acacia nilotica)	90 mg

[Bas en kernhout 5,5:1 uittreksel]

Onaktiewe bestanddele: deklaag [hidroksipropylselulose, hipromellose, mediumketting trigliseriede, en natriumkoperchlorofillien (kleur)], croscarmellose-natrium, magnesiumstearaat (groente) Mikrokrystalynne selulose, silika en natriumstyselglikolaat.

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

WAT IS INSINASE[®] KAPSULES EN WAARVOOR WORD DIT GEBRUIK

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 ExpressSyn-proses[®], kenmerke verbindings soos tetrahydro iso-alfa sure en Acacia nilotica vir gebalanseerde welstandsondersteuning.

VOORDAT JY INSINASE[®] NEEM

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

BESTUUR EN GEBRUIK VAN MASJINE

Dit is nie altyd moontlik om te voorspel in watter mate **INSINASE[®]** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, sel, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **INSINASE[®]** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET INSINASE[®]

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

SWANERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of blye om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

HOE OM INSINASE[®] TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **INSINASE[®]** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:

Volwassenes: Neem daaglik drie (3) tablette of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER **INSINASE[®]** NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGET OM **INSINASE[®]** TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

MOONTLIKE NUWE-EFFEKTE

INSINASE[®] kan nuwe-effekte hê.

Indien jy enige van die volgende tegniese 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, ulseratiewe kolitis), harttoestande (bv. hipertensie, hartversaking), hipertensie (hoë bloeddruk), Lewersiekte (bv. sirroose, hepatitis), kardiovaskulêre siektes (bv. hartversaking, koronêre hartsiekte), outo-immuun toestande (bv. rumatoïede artritis, lupus). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Kalmeer medisyne en sentrale senuweestelseldepresante, hormonale medisyne, antikoagulant en bloedplaatjie-medisyne, antidiabetiese medisyne, antihypertensiewe 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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

- naarheid / braking.

Nie alle nuwe-effekte en interaksies wat vir **INSINASE[®]** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **INSINASE[®]**.

HOE OM INSINASE[®] TE BEREË

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN INSINASE[®]

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

IDENTIFIKASIE VAN INSINASE[®]

Groen, ovaal, bedekte tablet.

REGISTRASIE NUMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 Desember 2024

NAAM EN ADRES VAN REGISTRASIEHOUDER

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