

PATIENT INFORMATION LEAFLET**Scheduling status:****[S0]****PRESSURE-EEZE® FORTE Tablets***Rauvolfia serpentina* (L.) Benth. ex Kurz (Indian snakeroot).

Contains sugar: lactose 39,10mg/tablet.

Contains preservatives: potassium sorbate: 0,13 % m/m; sodium benzoate 0,05 % m/m.

• Complementary Medicine: D33.5 Discipline-Specific Traditional Claims – Unani Medicine.

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

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

Pressure-Eeze® Forte Tablets are only available on prescription, or from an authorised prescriber.

- For a diagnosis or if symptoms persist or worsen consult a relevant medical practitioner.
- Consult a medical practitioner prior to use if diagnosed or suspected to suffer from high blood pressure levels.
- Keep this leaflet. You may need to read it again.
- Do not share Pressure-Eeze® Forte Tablets with any other person.
- Ask your healthcare provider or pharmacist if your need more information or advice.

WHAT IS IN THIS LEAFLET

1. What Pressure-Eeze® Forte Tablets is and what it is used for.
2. What you need to know before you take Pressure-Eeze® Forte Tablets.
3. How to take Pressure-Eeze® Forte Tablets.
4. Possible side effects.
5. How to store Pressure-Eeze® Forte Tablets.
6. Contents of the pack and other information.

1. What Pressure-Eeze® Forte Tablets are and what it is used for

Pressure-Eeze® Forte Tablets is a herbal medicine, based on Unani-Tibb principles, which can assist the body to help regulate moderate to high blood pressure levels.

For a diagnosis or if symptoms persist, consult a medical practitioner.

Efficacy of support may vary between users.

2. What you need to know before you take Pressure-Eeze® Forte Tablets**Do not take Pressure-Eeze® Forte Tablets:**

- If you are hypersensitive (allergic) to reserpine or yohimbine or to any other ingredient of Pressure-Eeze® Forte Tablets (listed in section 6).
- If you are taking antipsychotics (for schizophrenia), beta-blockers (for high blood pressure or irregular heartbeat), digoxin (for heart failure) or levodopa/carbidopa (for Parkinson's disease) (see **Other medicines and Pressure-Eeze® Forte Tablets**).
- If you have Parkinson's disease or a history of depression.
- If you have peptic ulcers or ulcerative colitis.
- If you have pheochromocytoma (a tumour in the adrenal glands which causes dangerously high blood pressure).
- If you have systemic lupus erythematosus (lupus) as Indian snakeroot can worsen symptoms.
- If you are receiving electroconvulsive therapy.
- If you have a heart or kidney disorder.
- If you are pregnant or breastfeeding (see section on **pregnancy and breastfeeding**).

Warnings and precautions

Tell your doctor if you are not sure about any of the information below:

- Contains lactose/fructose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pressure-Eeze® Forte Tablets.
- Pressure-Eeze® Forte Tablets contains lactose and Indian snakeroot which can affect the control of your blood sugar if you have diabetes mellitus.
- Consult a healthcare provider or doctor prior to use if you have asthma or a gallbladder disorder.
- Stop use at least 7 days before starting electroconvulsive therapy.
- Stop use at least 2 weeks before planned surgical procedures due the influence of this product on bleeding time, blood sugar levels, blood pressure and sedative effects.
- Have your blood pressure checked regularly and/or consult a healthcare provider or doctor if your symptoms persist or worsen.

Porphyria: Safety has not been established.**Other medicines and Pressure-Eeze® Forte Tablets**

Products containing herbal ingredients may interact with some medication. Always tell your healthcare provider if you are taking any other medicine, including complementary and/or traditional medicine.

Before using Pressure-Eeze® Forte Tablets, consult your doctor, pharmacist or healthcare provider if you are taking:

- Alcohol, barbiturates or other sedatives, as Indian snakeroot can increase the calming and sleep-inducing effects of these medicines.
- Blood thinners (anticoagulant or antiplatelet medication) e.g., warfarin, as Indian snakeroot can have an additive effect with these medicines and increase the risk of bleeding or bruising.
- Medication for depression (monoamine oxidase inhibitors and tricyclic antidepressants), as Indian snakeroot can have an additive effect or worsen the side effects of these medicines.
- Medication for diabetes, as Pressure-Eeze® Forte Tablets can interfere with the control of blood sugar levels.
- Medication for high blood pressure (including diuretics [water tablets]), as Indian snakeroot can have an additive effect with these medicines and can increase the risk of low blood pressure.
- Medication for schizophrenia, as Indian snakeroot can increase the effects and side effects of these medicines.
- Beta-blockers (for high blood pressure or irregular heartbeat), as Indian snakeroot can increase the risk of low blood pressure or a slow heart rate.
- Digoxin (for heart failure), as Indian snakeroot can increase the risk of a slow heart rate.
- Levodopa/carbidopa (for Parkinson's disease), as Indian snakeroot can reduce the effectiveness of these medicines.
- Stimulants (e.g., ephedrine, caffeine), as Indian snakeroot can increase the side effects of stimulants.

Taking Pressure-Eeze® Forte Tablets with food and drink

You should take Pressure-Eeze® Forte Tablets after a meal, with a glass of water. There is no known interaction between contents of Pressure-Eeze® Forte Tablets and food and drink.

Pregnancy and breastfeeding

- Do not take Pressure-Eeze® Forte Tablets while you are pregnant or breastfeeding as it contains reserpine alkaloids which pass through the placenta to your baby and are also found in breastmilk.
- If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before taking this product.

Driving and using machinery

Pressure-Eeze® Forte Tablets may affect your ability to drive or use machinery. If you think you are affected, you should not drive or operate machinery until you feel better.

3. How to take Pressure-Eeze® Forte Tablets

Do not share medicines with any other person.

Always take Pressure-Eeze® Forte Tablets exactly as described in this leaflet or as your medical practitioner has instructed you. You should check with your doctor or pharmacist if you are unsure of the correct dose.

Usual dose for adults 18 years and older:

Take one (1) tablet twice daily, after meals with a glass of water, or as prescribed by your doctor.

If you take more Pressure-Eeze® Forte Tablets than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Pressure-Eeze® Forte Tablets

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Pressure-Eeze® Forte Tablets

If you intend to discontinue the use of Pressure-Eeze® Forte Tablets, it is not advisable to stop using this product abruptly. Consult a healthcare professional for advice on how to gradually decrease the dose.

4. Possible side effects

Pressure-Eeze® Forte Tablets can have side effects.

Not all side effects reported for Pressure-Eeze® Forte Tablets are included in this leaflet. Should your general health worsen, or if you experience any undesired effects while taking this product, please consult your healthcare provider for advice.

Like all medicines and supplements, Pressure-Eeze® Forte Tablets can cause side effects although not everybody gets them.

If any of the following happens, stop taking Pressure-Eeze® Forte Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

Tell your doctor or pharmacist if you notice any of the following:*Frequency not known:*

- Drowsiness, depression, headache, nightmares, sedation.
- Low heart rate, chest pain.
- Low blood pressure (symptoms include light headedness, dizziness, blurred vision, general weakness, confusion, fainting).
- Nasal congestion, shortness of breath.
- Abdominal pain, increased or decreased appetite, loose stools, nausea, vomiting.

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

Reporting of side effectsIf you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"Adverse Drug Reactions and Quality Problem Reporting Form"**, found online under SAHPRA's publications:https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of Pressure-Eeze® Forte Tablets.**5. How to store Pressure-Eeze® Forte Tablets**

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until required for use.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medication to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of pack and other information that Pressure-Eeze® Forte Tablets contains

Active ingredients	Per tablet	Per maximum daily dose (2 tablets)
<i>Rauvolfia serpentina</i> (L.) Benth. ex Kurz (Indian snakeroot/Sanskrit – Sarpagandha) [root, extract]	127,07 mg	254,13 mg

Other ingredients: calcium phosphate, polyvinylpyrrolidone K30, talc, zea mays.

Pressure-Eeze® Forte Tablets contains sugar: lactose 39,10 mg/tablet.

Pressure-Eeze® Forte Tablets contains preservatives: potassium sorbate: 0,13 % m/m; sodium benzoate 0,05 % m/m.

What Pressure-Eeze® Forte Tablets looks like and contents of the pack

Pressure-Eeze® Forte Tablets are light brown, film coated, biconvex, circular tablets.

Pressure-Eeze® Forte Tablets is available as 60 tablets in a white, high density polyethylene securitainer that includes a patient information leaflet with a tamper-evident, white snap-on cap.

Holder of Certificate of Registration

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This leaflet was last revised

October 2022

Date of registration

To be allocated

Registration number

To be allocated

Professional InformationProfessional Information for Pressure-Eeze® Forte Tablets can be obtained from the Nativa website (www.nativa.co.za).

PASIËNTINLIGTINGSBROSJURE**Skeduleringstatus:****[S0]****PRESSURE-EEZE® FORTE Tablets (tablette)***Rauvolfia serpentina* (L.) Benth. ex Kurz (Indiese rauvolfia-wortel).

Bevat suiker: laktose 39,10 mg/tablet.

Bevat preserveermiddels: kaliumsorbaat: 0,13 % m/m, natriumbensoaat 0,05 % m/m.

• Komplementêre Medisyne: D33.5 Dissipiënte-spesifiek. Tradisionele Indikasies – Unani Medisyne.

• Hierdie medisyne is nie deur die SAHPRA geregistreer of geëvalueer vir kwaliteit, veiligheid of voorgestelde gebruik nie.

Lees alles op hierdie brosjure noukeurig deur want dit bevat belangrike inligting.

- Pressure-Eeze® Forte Tablets is slegs op voorskrif beskikbaar, of van 'n gemagtigde voorskrywer.
- Raadpleeg 'n mediese praktisyner vir 'n diagnose of indien die simptome voortduur of vererger.
- Raadpleeg u geneesheer voor gebruik indien u gediagnoseer is, of vermoed dat u aan hoë bloeddrukvlakke ly.
- Hou hierdie brosjure. U sal dit dalk weer wil lees.
- Moet nie Pressure-Eeze® Forte Tablets met enige ander persoon deel nie.
- Indien u verdere inligting of raad verlang, vra asseblief u gesondheidsorgverskaffer of apteker.

WAT IS IN HIERDIE BROSJURE

1. Wat Pressure-Eeze® Forte Tablets is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u Pressure-Eeze® Forte Tablets neem.
3. Hoe om Pressure-Eeze® Forte Tablets te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Pressure-Eeze® Forte Tablets te bewaar.
6. Inhoud van die verpakking en ander inligting.

1. Wat Pressure-Eeze® Forte Tablets is en waarvoor dit gebruik word

Pressure-Eeze® Forte Tablets is 'n kruimiddel, gebaseer op Unani-Tibb beginsels, wat die liggaam kan help om matige- tot hoë bloeddrukvlakke te reguleer.

Vir a diagnose of indien simptome voortduur, raadpleeg 'n mediese praktisyner.

Doeltreffendheid van ondersteuning kan tussen verbruikers verskil.

2. Wat u moet weet voordat u Pressure-Eeze® Forte Tablets neem**Pressure-Eeze® Forte Tablets moet nie gebruik word:**

- Indien u hipersensitief (allergies) is vir reserpien of johimbien of vir enige ander bestanddeel in Pressure-Eeze® Forte Tablets (gelys in afdeling 6).
- Indien u antipsigotika (vir skisofrenie), beta-blokkers (vir hoë bloeddruk of onreëlmatige hartklop), digoksin (vir hartversaking) of levodopa/karbidopa (vir Parkinson se siekte) neem (sien **Ander medikasie en Pressure-Eeze® Forte Tablets**).
- Indien u Parkinson se siekte of 'n geskiedenis van depressie het.
- Indien u peptiese ulkuse of sweervormende dikdermontsteking het.
- Indien u feochromosoom ('n tumor in die binnere klier wat gevaarlike hoë bloeddruk veroorsaak) het.
- Indien u sistemiese lupus eritematose (lupus) het, aangesien Indiese rauvolfia-wortel die simptome kan vererger.
- Indien u elektrokonvulsiewe terapie ondergaan.
- Indien u 'n hart- of nierversuering het.
- Indien u swanger is of borsvoed (lees afdeling oor **Swangerskap en borsvoeding**).

Waarskuwings en voorsorgmaatreëls

Raadpleeg u dokter indien u onseker is van enige van onderstaande inligting:

- Bevat laktose/fruktose. Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sekere suikers het, moet u eers u dokter raadpleeg voordat u Pressure-Eeze® Forte Tablets gebruik.
- Pressure-Eeze® Forte Tablets bevat laktose en Indiese rauvolfia-wortel wat 'n effek op u bloedsuikervlakke kan hê indien u diabetes mellitus het.
- Raadpleeg 'n gesondheidsorgverskaffer of dokter voor gebruik indien u asma of 'n galblaasversteuring het.
- Staak gebruik ten minste 7 dae voor die begin van elektrokonvulsiewe terapie.
- Staak gebruik ten minste 2 weke voor beplande chirurgiese prosedures weens die effek van die produk op bloedingstyd, bloedglukosevlakke, bloeddruk en sederende effekte.
- Laat u bloeddruk gereeld geneem word en/of raadpleeg u gesondheidsorgverskaffer of dokter indien u simptome nie verbeter nie of erger raak.

Porfirie: Veiligheid is nog nie vasgestel nie.**Ander medikasie en Pressure-Eeze® Forte Tablets**

Produkte wat kruiebestanddele bevat mag dalk interaksies met sommige medikasie hê. Lig altyd u gesondheidsorgverskaffer in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre- of tradisionele-medisyne.

Raadpleeg u dokter, apteker of gesondheidsorgverskaffer voor u Pressure-Eeze® Forte Tablets gebruik indien u die volgende medisyne neem:

- Alkohol, barbiturate of ander kalmeermiddels, aangesien Indiese rauvolfia-wortel die kalmerende en slaap induserende effekte van die middels kan versterk.
- Bloedverdunners (antistollings - of antiplaatjie-medikasie) bv. warfarin, aangesien Indiese rauvolfia-wortel 'n bykomende effek kan hê met die middels en kan die risiko van bloeding of kneusing verhoog.
- Medikasie vir depressie (monoamienoksidasie inhibeerders of trisikliese antidepressante), aangesien Indiese rauvolfia-wortel 'n bykomende effek kan hê of die nuwe-effekte van die middels kan vererger.
- Medikasie vir diabetes, aangesien Pressure-Eeze® Forte Tablets kan inmeng met die beheer van bloedsuikervlakke.
- Medikasie vir hoë bloeddruk, aangesien Indiese rauvolfia-wortel 'n bykomende effek kan hê met die middels en kan die risiko van lae bloeddruk verhoog.
- Medikasie vir skisofrenie, aangesien Indiese rauvolfia-wortel die effekte en nuwe-effekte van die middels kan versterk.
- Beta-blokkers (vir hoë bloeddruk of onreëlmatige hartklop), aangesien Indiese rauvolfia-wortel die risiko van lae bloeddruk en 'n verlaagde harttempo kan verhoog.
- Digoksin (vir hartversaking), aangesien Indiese rauvolfia-wortel die risiko van 'n verlaagde harttempo kan verhoog.
- Levodopa/karbidopa (vir Parkinson se siekte), aangesien Indiese rauvolfia-wortel die effektiwiteit van die middels kan verlaag.
- Stimulante (bv. efedrien, kafeïene), aangesien Indiese rauvolfia-wortel die nuwe-effekte van die middels kan versterk.

Neem van Pressure-Eeze® Forte Tablets saam met eet- en drinkgoed

Neem Pressure-Eeze® Forte Tablets na 'n maaltyd, met 'n glas water. Daar is geen bekende interaksie tussen die inhoud van Pressure-Eeze® Forte Tablets en eet- en drinkgoed nie.

Swangerskap en borsvoeding

- Moet nie Pressure-Eeze® Forte Tablets gebruik terwyl u swanger is of borsvoed nie aangesien dit reserpien alkalioiede bevat wat die plasenta kan deurdring en is ook in borsmelk uitgeskei.
- Indien u swanger is, u baba borsvoed, dink dat u is swanger of beplan om swanger te raak, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie produk neem.

Bestuur en die gebruik van masjinerie

Pressure-Eeze® Forte Tablets kan moontlik u vermoë om te bestuur of masjinerie te bedryf beïnvloed.

Indien u vermoed dat u vermoëns aangetas is, moet u nie bestuur of masjinerie bedryf voordat u beter voel nie.

3. Hoe om Pressure-Eeze® Forte Tablets te neem

Moet nie u medisyne met enige ander persoon deel nie.

Neem Pressure-Eeze® Forte Tablets presies soos voorgeskryf in hierdie brosjure of soos u mediese praktisyner u aanbeveel het. Vra u dokter of apteker wat die aanbevole dosis is indien u onseker is.

Die gewone dosis vir volwassenes 18 jaar en ouer:

Neem een (1) tablet tweemaal daaglik, na ete met 'n glas water, of soos aanbeveel deur u dokter.

Indien u meer Pressure-Eeze® Forte Tablets geneem het as wat u moes

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet het om Pressure-Eeze® Forte Tablets te neem

Neem die dosis wat oorgeslaan is, sodra u daarvan onthou. Moenie 'n dubbele dosis neem om vir die vergete individuele dosis te vergoed nie.

Wanneer u ophou om Pressure-Eeze® Forte Tablets te gebruik

Indien u van plan is om op te hou om Pressure-Eeze® Forte Tablets te gebruik, is dit nie raadsaam om die produk onmiddellik te staak nie. Raadpleeg 'n gesondheidsorgverskaffer vir advies hoe om die dosis geleidelik te verminder.

4. Moontlike nuwe-effekte

Pressure-Eeze® Forte Tablets kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir Pressure-Eeze® Forte Tablets is in hierdie brosjure ingesluit nie. Indien u algemene gesondheid agteruitgaan, of indien u ongewenste effekte ondervind

terwyl u hierdie produk neem, raadpleeg u gesondheidsorgverskaffer vir raad.

Soos alle medisyne en aanvullings, kan Pressure-Eeze® Forte Tablets nuwe-effekte hê, hoewel nie almal dit kry nie.

Indien een van die volgende nuwe-effekte voorkom, hou op om Pressure-Eeze® Forte Tablets te gebruik en raadpleeg u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:

Allergiese reaksies soos: veluitslag, knoppe (vel bultjies), jeukerigheid, swelling van die gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.

Vertel u dokter of apteker indien u enige van die volgende waarneem:*Frekwensie nie-bekend:*

- Lomerigheid, depressie, hoofpyn, nagmerries, sedasie.
- Verlaagde harttempo, borspyn.
- Lae bloeddruk (simptome sluit in lighoofdigheid, duiseligheid, versteurde visie, algemene swaakheid, narsing, floute).
- Nasale kongestie, kortasem.
- Buikpyn, verhoogde of verminderde eetlus, los stoelgang, naarheid, braking.

Indien u enige nuwe-effekte wat nie in hierdie brosjure genoem word nie ondervind, lig asseblief u dokter of apteker in.

Rapportering van nuwe-effekte

Praat met u dokter, apteker of verpleegster indien u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "Adverse Drug Reactions and Quality Problem Reporting Form", wat aanlyn beskikbaar is onder SAHPRA se publikasies:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. Deur

nuwe-effekte aan te meld, kan u help om meer inligting rakende die veiligheid van Pressure-Eeze® Forte Tablets te verskaf.

5. Hoe om Pressure-Eeze® Forte Tablets te bewaar

- BEWAAR ALLE MEDISYNE BINNE DIE BEREIK VAN KINDERS.
- Bewaar in 'n droë plek by of benede 25 °C.
- Beskerm teen lig en vogtigheid.
- Hou in die oorspronklike verpakking totdat u die tablette moet neem.
- Moet nie hierdie produk ná die vervaldatum op die verpakking gebruik nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting wat Pressure-Eeze® Forte Tablets bevat

Aktiewe bestanddele	Per tablet	Per maksimum daaglikse dosis (2 tablette)
<i>Rauvolfia serpentina</i> (L.) Benth. ex Kurz (Indiese rauvolfia/Sanskrit – Sarjagandha) [wortel, uittreksel]	127,07 mg	254,13 mg

Ander bestanddele: kalsiumfosfaat, polivinilpirolidoon K30, talk, zea may.

Pressure-Eeze® Forte Tablets bevat suiker: laktose 39,10 mg/tablet.

Pressure-Eeze® Forte Tablets bevat preserveermiddels: kaliumsorbaat: 0,13 % m/m,

natriumbensoaat 0,05 % m/m.

Hoe Pressure-Eeze® Forte Tablets lyk en die inhoud van die verpakking

Pressure-Eeze® Forte Tablets is ligte bruin, filmbedekte, biconvekse, ronde tablette.

Pressure-Eeze® Forte Tablets is beskikbaar as 60 tablette in 'n wit, plastiek houër met 'n

peuter-sigare, skroefdoop wat 'n pasiëntinligtingsbrosjure insluit.

Houer van Sertifikaat van Registrasie

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Webwerf: www.nativa.co.za

Hierdie brosjure was laas hersien

Oktober 2022

Datum van registrasie

Moet toegeken word

Registrasienumer

Moet toegeken word

Professionele InligtingProfessionele Inligting vir Pressure-Eeze® Forte Tablets kan verkry word op die Nativa webwerf (www.nativa.co.za).