

SCHEDULING STATUS

S0

erex™ 1 HOUR BEFORE capsule

Tribulus terrestris L., *Eurycoma longifolia* (tongkat ali), *Ptychopetalum olacoides* Benth. (muira puama),
Panax ginseng C.A.Mey (panax ginseng), taurine.
 Sugar free.

COMPLEMENTARY MEDICINE: 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.

erex™ 1 HOUR BEFORE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use erex™ 1 HOUR BEFORE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What erex™ 1 HOUR BEFORE is and what it is used for.
2. What you need to know before you take erex™ 1 HOUR BEFORE.
3. How to take erex™ 1 HOUR BEFORE.
4. Possible side effects.
5. How to store erex™ 1 HOUR BEFORE.
6. Contents of the pack and other information.

1. What erex™ 1 HOUR BEFORE is and what it is used for

erex™ 1 HOUR BEFORE might support sexual excitation in men by increasing energy and stamina during intimacy.

2. What you need to know before you take erex™ 1 HOUR BEFORE

Do not take erex™ 1 HOUR BEFORE:

- if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of erex™ 1 HOUR BEFORE (see **What erex™ 1 HOUR BEFORE contains**);
- if you are pregnant or breastfeeding your baby;
- if you suffer from haemorrhage or thrombosis;
- if you suffer from hypotension;
- if you suffer from any liver disorders.

Warnings and precautions

erex™ 1 HOUR BEFORE is intended for use in adults only.

Take special care with erex™ 1 HOUR BEFORE:

- if you suffer from any prostate conditions or have prostate cancer;
- if you suffer from any immune system disease;
- if you have undergone an organ transplant, as it might interfere with immunosuppressive therapy;
- if you suffer from any heart condition or low blood pressure;
- if you have diabetes, as it might reduce blood glucose (blood sugar) levels;
- if you suffer from insomnia (sleeplessness);
- if you are having any surgical procedure done. You should stop taking erex™ 1 HOUR BEFORE two weeks before an operation.

Other medicines and erex™ 1 HOUR BEFORE

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

Tell your doctor or pharmacist if you are currently using:

- ACE inhibitors and other anti-hypertensives (medication to treat high blood pressure). **erex™ 1 HOUR BEFORE** might enhance the hypotensive effect of these medicines;
- Propranolol (medicine to treat heart conditions);
- QT interval-prolonging medicine. **erex™ 1 HOUR BEFORE** could increase the risk of having abnormal heartbeats;
- Antidiabetic medicine (medicine to treat diabetes). **erex™ 1 HOUR BEFORE** might enhance the glucose (sugar) lowering effect of this medicine;
- Lithium (medication to treat bipolar and major depressive disorders). Using **erex™ 1 HOUR BEFORE** with this medication might reduce the excretion of lithium and increase levels of lithium;
- Immunosuppressants (medicines that lower the body's ability to reject a transplanted organ), as **erex™ 1 HOUR BEFORE** might interfere with immunosuppressive therapy.

erex™ 1 HOUR BEFORE with food, drink and alcohol

See section 3 (**How to take erex™ 1 HOUR BEFORE**).

Pregnancy, breastfeeding and fertility

erex™ 1 HOUR BEFORE is not intended for use by women.

erex™ 1 HOUR BEFORE is not safe during pregnancy and breastfeeding. Do not use **erex™ 1 HOUR BEFORE** during pregnancy and breastfeeding.

Driving and using machines

erex™ 1 HOUR BEFORE should not have an effect on your ability to drive or use machines. You should not drive or operate machines until you know how you react to **erex™ 1 HOUR BEFORE**.

3. How to take erex™ 1 HOUR BEFORE

Do not share your medicines with any other person.

Always take **erex™ 1 HOUR BEFORE** 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.

The usual dose is:

Adults: Take 1 capsule one hour before sexual encounter/intimacy. To achieve desired effect, sexual stimulation is required.

If you have the impression that the effect of **erex™ 1 HOUR BEFORE** is too strong or too weak, tell your doctor or pharmacist.

For oral use only.

Do not exceed the recommended dosage.

Most effective as part of a healthy diet and lifestyle.

erex™ 1 HOUR BEFORE can be taken with or without food.

If you take more erex™ 1 HOUR BEFORE than you should

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

Take this leaflet and the rest of the remaining **erex™ 1 HOUR BEFORE** with you so the doctor will know what you have taken.

4. Possible side effects

erex™ 1 HOUR BEFORE can have side effects.

Not all side effects reported for **erex™ 1 HOUR BEFORE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **erex™ 1 HOUR BEFORE**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **erex™ 1 HOUR BEFORE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to **erex™ 1 HOUR BEFORE**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring with an unknown frequency:

- anaphylaxis;
- anxiety;
- euphoria;
- mania;
- insomnia (difficulty falling and staying asleep);
- headaches;
- heart palpitations (changes in the way your heart beats);
- hypertension or hypotension;
- restlessness;
- nausea (feeling sick) or vomiting (being sick);
- abdominal cramps or stomach pains;
- diarrhoea (runny, loose stool);
- Stevens-Johnson syndrome (A rare, serious disorder of the skin and mucous membranes).

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. You can also report side effects to SAHPRA via the “**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 **erex™ 1 HOUR BEFORE**.

5. How to store **erex™ 1 HOUR BEFORE**

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the blister strip in the outer carton.
- Keep the carton closed.
- Do not use after the expiry date stated on the carton.
- 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 **erex™ 1 HOUR BEFORE** contains

Each capsule contains:

The active substances are:

<i>Tribulus terrestris</i> L.	6 250 mg
[fruit, 50:1 extract providing 125 mg of dried herb equivalent]	
<i>Eurycoma longifolia</i> (Tongkat ali)	500 mg
[root, 100:1 extract providing 50 mg of dried herb equivalent]	
<i>Ptychopetalum olacoides</i> Benth. (Muiru Puama)	100 mg
[stem and leaf, 4:1 extract providing 25 mg of dried herb equivalent]	
<i>Panax ginseng</i> C.A.Mey (Panax ginseng)	50 mg
[stem and leaf, 5:1 extract providing 10 mg of dried herb equivalent]	
Taurine	50 mg

The other ingredients are magnesium stearate (E470b) and microcrystalline cellulose (E460).

Sugar free.

What erex™ 1 HOUR BEFORE looks like and contents of the pack

4 light blue capsules in a blister. Packed inside an outer carton.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

0157

info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for erex™ 1 HOUR BEFORE is available on <https://www.brunel.co.za/erex/> or can be requested from the contact details above.

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SKEDULERINGSSTATUS

S0

erex™ 1 HOUR BEFORE kapsule

Tribulus terrestris L., *Eurycoma longifolia* (tongkat ali), *Ptychopetalum olacoides* Benth. (muira puama),
Panax ginseng C.A.Mey (panax ginseng), tourien.
Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

erex™ 1 HOUR BEFORE is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy erex™ 1 HOUR BEFORE versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat erex™ 1 HOUR BEFORE is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy erex™ 1 HOUR BEFORE neem.
3. Hoe om erex™ 1 HOUR BEFORE te neem.
4. Moontlike nuwe-effekte.
5. Hoe om erex™ 1 HOUR BEFORE te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat erex™ 1 HOUR BEFORE is, en waarvoor dit gebruik word

erex™ 1 HOUR BEFORE kan help om seksuele opwinding in mans te ondersteun, deur energie en stamina te verhoog gedurende intimiteit.

2. Wat jy moet weet voordat jy erex™ 1 HOUR BEFORE neem**Moet nie erex™ 1 HOUR BEFORE neem:**

- indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van erex™ 1 HOUR BEFORE nie (sien **Wat erex™ 1 HOUR BEFORE bevat**);
- indien jy swanger is of jou baba borsvoed;
- indien jy aan bloeding of trombose ly;
- indien jy aan lae bloeddruk ly;
- indien jy aan enige lewersiektes ly.

Waarskuwings en voorsorgmaatreëls

erex™ 1 HOUR BEFORE is slegs bedoel vir gebruik in volwassenes.

Wees versigtig met erex™ 1 HOUR BEFORE:

- indien jy aan enige prostaatprobleme ly of prostaatkanker het;
- indien jy aan enige siekte van die immuunstelsel ly;
- indien jy 'n orgaanoorplanting ondergaan het, want dit kan inmeng met immuunonderdrukkingsterapie;
- indien jy aan enige harttoestand of lae bloeddruk ly;
- indien jy diabetes het, want dit kan bloedglukose- (bloedsuiker-) vlakke verlaag;
- indien jy aan slapeloosheid ly;
- indien jy enige chirurgiese prosedure gaan ondergaan. Jy moet twee weke voor 'n operasie ophou om erex™ 1 HOUR BEFORE te neem.

Ander medisyne en erex™ 1 HOUR BEFORE

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- AOE-inhibeerders en ander anti-hipertensiewe middels (medikasie om hoë bloeddruk te behandel). erex™ 1 HOUR BEFORE kan moontlik die hipotensiewe effek van hierdie medisyne verhoog;
- Propranolol (medisyne om hartsiektes te behandel);
- Medisyne wat die QT-interval verleng. erex™ 1 HOUR BEFORE kan die risiko van abnormale hartklop verhoog;
- Antidiabetiese medisyne (medisyne vir die behandeling van diabetes). erex™ 1 HOUR BEFORE kan die glukose- (suiker-)verlagende effek van hierdie medisyne verhoog;
- Litium (medikasie vir die behandeling van bipolêre en major depressiewe steurings). Gebruik van erex™ 1 HOUR BEFORE met hierdie medikasie kan die uitskeiding van litium verminder en litiumvlakke verhoog;
- Immuunonderdrukkers (medisyne wat die liggaam se vermoë verminder om 'n oorgeplante orgaan te verwerp), aangesien erex™ 1 HOUR BEFORE met immuunonderdrukkende terapie kan inmeng.

erex™ 1 HOUR BEFORE met eet- en drinkgoed en alkohol

Sien afdeling 3 (**Hoe om erex™ 1 HOUR BEFORE te neem**).

Swangerskap, borsvoeding en vrugbaarheid

erex™ 1 HOUR BEFORE is nie geskik vir gebruik deur vroue nie.

erex™ 1 HOUR BEFORE is nie veilig vir gebruik tydens swangerskap en borsvoeding nie. Moet nie erex™ 1 HOUR BEFORE gebruik as jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene

erex™ 1 HOUR BEFORE behoort nie jou vermoë om te bestuur of om masjiene te gebruik te beïnvloed nie. Moet nie bestuur of masjiene gebruik voordat jy weet hoe jy op erex™ 1 HOUR BEFORE reageer nie.

3. Hoe om erex™ 1 HOUR BEFORE te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem erex™ 1 HOUR BEFORE altyd presies soos aangedui in hierdie inligtingsblad, of soos wat jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Volwassenes: Neem 1 kapsule, een uur voor seksuele omgang/intimiteit. Om die gewenste effek te bereik, is seksuele stimulasie nodig.

Indien jy die indruk kry dat die uitwerking van erex™ 1 HOUR BEFORE te sterk of te swak is, bespreek dit met jou dokter of apteker.

Slegs vir orale gebruik.

Moet nie die aanbevole dosis oorskry nie.

Mees effektief as deel van 'n gesonde dieet en leefstyl.

erex™ 1 HOUR BEFORE kan met of sonder kos geneem word.

As jy meer erex™ 1 HOUR BEFORE neem as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende erex™ 1 HOUR BEFORE saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike nuwe-effekte

erex™ 1 HOUR BEFORE kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir erex™ 1 HOUR BEFORE gerapporteer is, word in hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy

erex™ 1 HOUR BEFORE neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om erex™ 1 HOUR BEFORE te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op erex™ 1 HOUR BEFORE gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat met 'n onbekende frekwensie voorkom:

- anafilakse;
- angstigheid;
- euforie;
- manie;
- slapeloosheid (sukkel om aan die slaap te raak en aan die slaap te bly);
- hoofpyne;
- hartkloppings (veranderinge in die manier waarop jou hart klop);
- hoë- of laebloeddruk;
- rusteloosheid;
- naarheid of braking;
- maagkrampe of maagpyn;
- diarree (loperige, los stoelgang);
- Stevens-Johnson-sindroom ('n seldsame, ernstige afwyking van die vel en slymvliese).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn **by SAHPRA se publikasies** beskikbaar is: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van erex™ 1 HOUR BEFORE te verskaf.

5. Hoe om erex™ 1 HOUR BEFORE te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C.
- Hou die stulpstrook in die buitenste karton.
- Hou die karton toe.
- Moet nie gebruik na die vervaldatum soos aangedui op die karton nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie die ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat erex™ 1 HOUR BEFORE bevat

Elke kapsule bevat:

Die aktiewe bestanddele is:

<i>Tribulus terrestris</i> L.	6 250 mg
[vrug, 50:1 ekstrak lewer 125 mg gedroogde kruie-ekwivalent]	
<i>Eurycoma longifolia</i> (Tongkat ali)	500 mg
[wortel, 100:1 ekstrak lewer 50 mg gedroogde kruie-ekwivalent]	
<i>Ptychopetalum olacoides</i> Benth. (Muir Puama)	100 mg
[stam en blaar, 4:1 ekstrak lewer 25 mg gedroogde kruie-ekwivalent]	
<i>Panax ginseng</i> C.A.Mey (Panax ginseng)	50 mg
[stam en blaar, 5:1 ekstrak lewer 10 mg gedroogde kruie-ekwivalent]	
Tourien	50 mg

Die ander bestanddele is magnesiumstearaat (E470b) en mikrokristallyne sellulose (E460).
Suikervry.

Hoe erex™ FOR WOMEN DROPS lyk en die inhoud van die verpakking

4 lig blou kapsules in 'n stulpstrook. Verpak binne 'n buitenste karton.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur die SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur die SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir erex™ 1 HOUR BEFORE is beskikbaar by <https://www.brunel.co.za/erex/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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