PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S0

elev8TM film coated tablets
Sceletium tortuosum (L.) N.E. Br. (Kanna).
Sugar free.

COMPLEMENTARY MEDICINE: OTHER HERBAL MEDICINES
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
elev8TM is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use elev8TM 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 elev8TM is and what it is used for.
2. What you need to know before you take elev8TM.
3. How to take elev8TM.
4. Possible side effects.
5. How to store elev8TM.
6. Contents of the pack and other information.

1. What elev8TM is and what it is used for
elev8TM assists in coping with stress, irritability, emotional strain, mood fluctuations and might support cognitive function in adults.

2. What you need to know before you take elev8TM
Do not take elev8TM:
- if you are hypersensitive (allergic) to *Sceletium tortuosum* (L.) N.E. Br. or any of the other ingredients of elev8TM (see **What elev8TM contains**);
- if you are taking psychiatric medicine, including medicine to stabilise your moods, antidepressants or anti-anxiety medicine.

Warnings and precautions
None known.

Other medicines and elev8TM
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

elev8TM with food, drink and alcohol
See section 3 (**How to take elev8TM**).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.
Safety and efficacy of elev8TM during pregnancy and breastfeeding have not been established. Do not use this medicine if you are pregnant or breastfeeding your baby.

Driving and using machines
elev8TM might make you feel drowsy. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how elev8TM affects you.

3. How to take elev8TM

Do not share your medicines with any other person.
Always take elev8TM 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 and children from 12 years of age: 1 – 2 tablets in the morning with a glass of water.

If you have the impression that the effect of elev8TM is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.
elev8TM can be taken with or without food.
elev8TM should not be taken with alcohol.

If you take more elev8TM 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 elev8TM with you so the doctor will know what you have taken.

If you forget to take elev8TM

- Take the missed dose as soon as you remember.
- Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

elev8TM can have side effects.
Not all side effects reported for elev8TM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking elev8TM, please consult your healthcare provider for advice.

If any of the following happens, stop taking elev8TM 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 elev8TM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Side effects occurring less frequently:

- loss of appetite;
- headaches;
- lack of energy or feeling tired;
- stimulation;
- sedation;
- mild diarrhoea (runny, loose stool), mild stomach cramps.

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 elev8TM.

5. How to store elev8TM

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store the blister strips in the carton.
- Protect from light and moisture.

- Do not store in the bathroom.
- Do not use after the expiry date printed on the carton or blister strip.
- 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 elev8TM contains

Each film coated tablet contains 25 mg Zembrin®, equivalent to:

Sceletium tortuosum (L.) N.E. Br. (Kanna) ……………….………..…..… 50 mg
[above ground herb, providing 100 µg mesembrine-type alkaloids]

The other ingredients are calcium phosphate dibasic dihidrate, coating [containing castor oil (E1503), polyvinyl alcohol-polyethylene glycol-*graft*-copolymer, Quinoline Yellow aluminium lake (E104), shellac (E904), talcum, titanium dioxide (E172)], croscarmellose sodium (E468), magnesium stearate (E572), microcrystalline cellulose (E460 (i)), polyvinyl pyrrolidone (E1201), vinylpyrrolidone-vinyl acetate copolymer.

What elev8TM looks like and contents of the pack

Yellow, round, convex, unscored film coated tablet.
PVDC/aluminium blister strip containing 10 tablets, packed in boxes of 10, 30, 60 and 90.

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 elev8TM is available on https://www.brunel.co.za/elev8/ or can be requested from the contact details above.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
S0

elev8TM filmbedekte tablette
Sceletium tortuosum (L.) N.E. Br. (Kanna).
Suikervry.

KOMPLEMENTÊRE MEDISYNE: ANDER KRUIEMEDISYNE
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.
elev8TM is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy elev8TM 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 elev8TM is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy elev8TM neem.
3. Hoe om elev8TM te neem.
4. Moontlike newe-effekte.
5. Hoe om elev8TM te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat elev8TM is, en waarvoor dit gebruik word
elev8TM help om stres, prikkelbaarheid, emosionele spanning en gemoedskommelinge te hanteer en mag kognitiewe funksie in volwassenes ondersteun.

2. Wat jy moet weet voordat jy elev8TM neem
Moet nie elev8TM neem:
- indien jy hipersensitief (allergies) is vir *Sceletium tortuosum* (L.) N.E. Br. of vir enige van die ander bestanddele van elev8TM nie (sien **Wat elev8TM bevat**);
- indien jy psigiatriese medisyne neem, insluitende medisyne om jou gemoedstoestand te stabiliseer, antidepressante of medisyne vir angstigheid.

Waarskuwings en voorsorgmaatreëls
Geen bekend nie.

Ander medisyne en elev8TM
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

elev8TM met eet-, drinkgoed en alkohol
Sien afdeling 3 (**Hoe om elev8TM te neem**).

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy die medisyne neem. Die veiligheid en effektiwiteit van elev8TM tydens swangerskap en borsvoeding is nie vasgestel nie. Moet nie hierdie medisyne gebruik as jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene
elev8TM mag jou lomerig laat voel. Moet nie 'n voertuig bestuur, masjinerie hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe elev8TM jou affekteer nie.

3. Hoe om elev8TM te neem

Moet nie jou medisyne met enige ander persoon deel nie.
Neem elev8TM altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Volwassenes and kinders vanaf 12-jarige ouderdom: 1 – 2 tablette soggens, met 'n glas water.

Indien jy die indruk kry dat die uitwerking van elev8TM te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.
elev8TM kan met of sonder kos geneem word.
elev8TM moet nie saam met alkohol geneem word nie.

As jy meer elev8TM 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 elev8TM saam met jou sodat die dokter kan sien wat jy geneem het.

As jy vergeet om elev8TM te neem

- Neem die dosis wat jy oorgeslaan het sodra jy onthou.
- Moet nie 'n dubbele dosis neem om vir die vergete individuele dosis op te maak nie.

4. Moontlike newe-effekte

elev8TM kan newe-effekte hê.
Nie alle newe-effekte wat vir elev8TM gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy elev8TM neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om elev8TM 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 en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op elev8TM gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat minder gereeld voorkom:

- aptytverlies;
- hoofpyn;
- gebrek aan energie of gevoel van moegheid;
- stimulasie;
- sedasie;
- geringe diaree (lopende, los stoelgang), ligte maagkrampe.

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: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van elev8TM te verskaf.

5. Hoe om elev8TM te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C.
- Stoor die stulpstrokies in die karton.
- Beskerm teen direkte sonlig en vog.

- Moet nie in die badkamer stoor nie.
- Moet nie gebruik word na die vervaldatum wat op die karton of stulpstrokie gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat elev8™ bevat

Elke filmbedekte tablet bevat 25 mg Zembrin®, gelykstaande aan:

Sceletium tortuosum (L.) N.E. Br. (Kanna) .... 50 mg
[bogrondse dele van krui, lewer 100 µg mesembrien-tipe alkaloïede]

Die ander bestanddele is kalsiumfosfaat dibasiese dihidraat, filmlagie [bevattende kasterolie (E1503), polivinielalkohol-poliëtileenglikol-*gehegte*-kopolimeer, Quinoline Yellow aluminiumlak (E104), skilferlak (E904), talkum, titaandioksied, (E172)], natriumkroskarmellose (E468), magnesiumstearaat (E572), mikrokristallyne sellulose (E460 (i)), polivinielpirrolidoon (E1201), vinielpirrolidoon-vinielasetaat-kopolimeer.

Hoe elev8™ lyk en die inhoud van die verpakking

Geel, ronde, konvekse, filmbedekte tablet sonder 'n middellyn.
PVDC/aluminium stulpstrook wat 10 tablette bevat, verpak in 'n buitenste karton met 10, 30, 60 of 90 tablette.

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 SAHPRA aangedui word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir elev8™ is beskikbaar by https://www.brunel.co.za/elev8/ of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.