

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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elev8™ 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.

elev8™ is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use elev8™ 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 elev8™ is and what it is used for.
2. What you need to know before you take elev8™.
3. How to take elev8™.
4. Possible side effects.
5. How to store elev8™.
6. Contents of the pack and other information.

1. What elev8™ is and what it is used for

elev8™ 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 elev8™

Do not take elev8™:

- if you are hypersensitive (allergic) to *Sceletium tortuosum* (L.) N.E. Br. or any of the other ingredients of elev8™ (see **What elev8™ 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 elev8™

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

elev8™ with food, drink and alcohol

See section 3 (**How to take elev8™**).

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 elev8™ 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

elev8™ might make you feel drowsy. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how elev8™ affects you.

3. How to take elev8™

Do not share your medicines with any other person.

Always take elev8™ 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 elev8™ is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

elev8™ can be taken with or without food.

elev8™ should not be taken with alcohol.

If you take more elev8™ 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 elev8™ with you so the doctor will know what you have taken.

If you forget to take elev8™

- 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

elev8™ can have side effects.

Not all side effects reported for elev8™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking elev8™, please consult your healthcare provider for advice.

If any of the following happens, stop taking elev8™ 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 elev8™. 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 elev8™.

5. How to store elev8™

- 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 elev8™ 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 dihydrate, 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 elev8™ 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

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