PROFESSIONAL INFORMATION FOR elev8™

SCHEDULING STATUS:
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PROPRIETARY NAME AND DOSAGE FORM:
elev8™ tablets

COMPOSITION:
Active Ingredient:
Each **elev8™** tablet contains Zembrin® 25 mg, equivalent to 50 mg *Sceletium tortuosum* above ground herb. Standardised to 100 µg mesembrine-type alkaloids, with:

Mesembrenone + Mesembrenol	.....	Not less than 60% of the four alkaloids by weight.
Mesembrine	……..……	Not more than 20% of the four alkaloids by weight.
Mesembranol	……...	Present.

Inactive Ingredients:
Calcium phosphate dibasic dihydrate, castor oil, croscarmellose sodium, flexicoat lemon yellow, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone, shellac, vinylpyrrolidone-vinyl acetate copolymer. Sugar free.

CATEGORY AND CLASS:
D1.6 Other central nervous system stimulants.

PHARMACOLOGICAL ACTION:
The pharmacological action of a Zembrin® standardised extract, harvested from the *Sceletium tortuosum* plant, have been reported to be dual 5-HT (serotonin) reuptake inhibition and the PDE4 (phosphodiesterase-4) enzyme inhibition.

INDICATIONS:
elev8™ assists in coping with stress, irritability, emotional strain, mood fluctuations and might support cognitive function in adults.

CONTRAINDICATIONS:
Allergies or sensitivity to any of the ingredients (see "**COMPOSITION**" and "**WARNINGS AND SPECIAL PRECAUTIONS**").
Pregnancy or lactation (see "**HUMAN REPRODUCTION**").

WARNINGS AND SPECIAL PRECAUTIONS:
Warnings:
Do not use **elev8™** if you are allergic or sensitive to any of the ingredients (see "**COMPOSITION**" and "**CONTRAINDICATIONS**").
Do not use **elev8™** if you are pregnant or breastfeeding your baby (see "**HUMAN REPRODUCTION**").
Consult a doctor or other healthcare professional if symptoms persist or worsen.
Concurrent use with any psychiatric medication, including mood stabilisers, antidepressants and anti-anxiety medication should be discussed with a registered healthcare professional (see "**INTERACTIONS**").

Effects on ability to drive and use machines:
elev8™ is not likely to affect the ability to drive a vehicle or to operate machines. However, patients must take care until they know how they will react to **elev8™** tablets.

INTERACTIONS:
No known drug interactions have been documented, however, concurrent use with any psychiatric medication including mood stabilisers, antidepressants and anti-anxiety medication should be discussed with a registered healthcare professional (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

HUMAN REPRODUCTION:
elev8™ are not intended for use during pregnancy or lactation.

DOSAGE AND DIRECTIONS FOR USE:
elev8™ tablets are for oral use only.
Dosage: Adults: 1 to 2 tablets in the morning. Consult a doctor or other healthcare professional if symptoms worsen or does not improve within 10 days.
Directions for use:
Adults: Take 1 to 2 tablets in the morning with a glass of water. Not recommended for use in children under the age of 12 years. Do not exceed recommended dosage without consulting your healthcare professional.

SIDE EFFECTS:
Side Effect Profile:
Immune system disorders:
Frequency unknown: Allergic reactions (see "**CONTRAINDICATIONS**") and ("**WARNINGS AND SPECIAL PRECAUTIONS**").
Nervous system disorders:
Frequency unknown: Fatigue
Gastrointestinal disorders:
Frequency unknown: Mild and transient gastrointestinal disorders including nausea, diarrhoea and abdominal pain.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms of Overdosage:
There are no known symptoms of overdose.
In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison control centre.
Treatment of Overdosage:
Treatment should be symptomatic and supportive.

IDENTIFICATION:
Yellow, round, convex, unscored, film coated tablet.

PRESENTATION:
PVC/aluminium blister strip containing 10 tablets, packed in boxes of 10, 30, 60 and 90.

STORAGE INSTRUCTIONS:
Store at or below 25 °C in a cool, dry place, protected from light.
Keep tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
To be allocated upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Brunel Laboratoria (Pty) Ltd
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
To be allocated upon registration.

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COMPLEMENTARY MEDICINE:
Complementary Medicine: Western Herbal Medicine.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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