

Professional Information for TURBO ENERGY

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

TURBO ENERGY CITRUS FUSION powder

TURBO ENERGY BERRY FUSION powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet (10 g) contains:

Potassium chloride	309,6 mg
providing Potassium (elemental)	162 mg
Sodium chloride	120,8 mg
providing Sodium	47,5 mg
Caffeine anhydrous	100 mg
Riboflavin (Vitamin B ₂)	1,5 mg

CONTAINS CAFFEINE (100 mg per sachet).

A cup of instant coffee contains approximately 80 mg of caffeine.

Excipients with known effects:

Contains sugar (TURBO ENERGY CITRUS FUSION 7,4 g fructose per sachet and TURBO

ENERGY BERRY FUSION 7,5 g fructose per sachet).

Contains sweetener (TURBO ENERGY CITRUS FUSION 13 mg sodium saccharin per sachet, TURBO ENERGY BERRY FUSION 8 mg sodium saccharin per sachet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

A fine granule or powder.

TURBO ENERGY CITRUS FUSION has an orange colour and tangy citrus flavour.

TURBO ENERGY BERRY FUSION has a pink colour and a characteristic berry flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TURBO ENERGY is a health supplement that may be used to aid with the constraints of daily tasks. TURBO ENERGY can be used to stay awake and feel energised, to maintain performance during extended (greater than 60 min), high-intensity exercise and support hydration before, during and after exercise.

4.2 Posology and method of administration

Adults: Take one sachet up to three times a day.

Dissolve the content of one 10 g sachet in half a glass of water (125ml) and take it one hour before driving, studying, training, a game or race for alertness and to support hydration and energy levels.

Do not exceed the recommended dosage.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.
- Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Cardiovascular disorders

TURBO ENERGY should be used with caution in patients with cardiovascular disorders such as hypertension. TURBO ENERGY contains caffeine which has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals. If those symptoms occur, patients should stop taking TURBO ENERGY and consult a healthcare provider.

Surgery

TURBO ENERGY may interfere with blood glucose control and may increase the risk of bruising and bleeding during surgical procedures. Patients should be advised to discontinue TURBO ENERGY at least 2 weeks prior to surgical procedures (see section 4.5).

Glaucoma

TURBO ENERGY may temporarily increase intraocular pressure in patients with narrow-angle glaucoma.

Epilepsy

TURBO ENERGY may exacerbate seizure disorders by inhibiting acetylcholinesterase (AChE) and cause cholinergic effects. Caution is advised (see section 4.5).

Liver disorder

TURBO ENERGY may exacerbate liver dysfunction in patients with a liver disorder. Patients should be advised to stop taking TURBO ENERGY and consult a healthcare provider if they

develop symptoms of liver trouble such as yellowing of the skin or eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.

Renal disease

TURBO ENERGY may exacerbate renal dysfunction in patients with renal disease. Patients with detrusor instability (overactive bladder syndrome) should consult a healthcare provider prior to use. Closely monitor serum electrolytes when potassium, as in TURBO ENERGY is used by people with renal dysfunction.

Dehydration

TURBO ENERGY should not be used as a substitute of an oral rehydration solution.

Anxiety disorder

TURBO ENERGY may exacerbate anxiety in patients with anxiety disorders. Use with caution.

Sleep deprivation

TURBO ENERGY should not be taken before bedtime as it may result in sleep deprivation.

TURBO ENERGY is not intended as a substitute for sleep.

Prescription medication

TURBO ENERGY may alter the effectiveness of prescription medicines. A healthcare provider must be consulted if a patient is taking any other medicine or have been diagnosed with a chronic condition.

Paediatric population

TURBO ENERGY is not suitable for children under the age of 18 years.

Sodium

TURBO ENERGY contains 47,5 mg sodium per sachet, equivalent to 2.4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Fructose

TURBO ENERGY contains fructose. Patients with hereditary fructose intolerance (HFI) should not take TURBO ENERGY.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines

TURBO ENERGY may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding (see section 4.4).

Antiseizure medicine

TURBO ENERGY could lower the effect of anticonvulsant medicine due to its caffeine content. Concomitant use of TURBO ENERGY with antiseizure medicine such as carbamazepine, ethosuximide, felbamate, phenytoin and valproate could reduce the effect of the medicine and increase the risk of seizures (see section 4.4).

Antidiabetic medicines

Concomitant use of TURBO ENERGY with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Ephedrine and other stimulants

Concomitant use of TURBO ENERGY with ephedrine or other stimulants such

as bitter orange extract, synephrine, octopamine and ephedra may increase blood pressure and heart rate and potentially increase the risk of serious cardiovascular adverse effects. Caution is advised.

Caffeine-containing products or foods

The use of caffeine-containing products should be limited when taking TURBO ENERGY. Use with other caffeine-containing products or foods may increase the risk of caffeine-related adverse effects. Other natural products which contain caffeine include coffee, tea, cola nut, cocoa, guarana and maté.

Monoamine oxidase inhibitors (MAOIs)

Concomitant use of TURBO ENERGY with MAOIs may increase blood pressure raising effects. Caution is advised.

Potassium-sparing diuretics

Concomitant use of TURBO ENERGY with potassium-sparing diuretics may increase the risk of hyperkalemia. Caution is advised.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. Total caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

Do not use TURBO ENERGY if you are pregnant or lactating (see section 4.3).

4.7 Effects on ability to drive and use machines

TURBO ENERGY is unlikely to affect the ability to drive and use machines. Caution is advised before driving a vehicle or operating machinery until the effects of TURBO ENERGY are known.

4.8 Undesirable effects

TURBO ENERGY is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Psychiatric disorders:

Frequency unknown: anxiety, insomnia.

Nervous system disorders:

Frequency unknown: restlessness, tremors, headache.

Cardiac disorders:

Frequency unknown: arrhythmia.

Gastrointestinal disorders:

Frequency unknown: abdominal pain, belching, diarrhoea, flatulence, nausea, vomiting, gastric irritation.

Renal and urinary disorders:

Frequency unknown: diuresis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of TURBO ENERGY is important. It allows continued monitoring of the benefit/risk balance of TURBO ENERGY. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via **The Med Safety App**, which can be found online on SAHPRA's website www.sahpra.org.za, or downloaded from your mobile phone's app store.

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.12 Multiple substance formulation.

Sodium and potassium supports hydration before, during and after exercise and contribute to the maintenance of normal electrolyte balance in anticipation of extended (greater than 60 min), high intensity exercise.

Fructose is a source of carbohydrates that supports energy production and helps to maintain performance in extended (greater than 60 min), high-intensity exercise.

Caffeine assists to temporarily promotes alertness and wakefulness, relieve fatigue and increase mental activity.

5.2 Pharmacokinetic properties

Following supplementation, riboflavin levels are increased in the blood and excretion is in the urine.

Caffeine is rapidly and almost completely (99 %) absorbed after oral administration. Cytochrome P450 1A2 plays a role in the metabolism of caffeine in the liver. The half-life of caffeine in healthy adults is 1,5 – 10 hours and is excreted in the urine.

Potassium in the body is regulated by the kidneys and distribution in intracellular and extracellular fluid influences serum potassium levels without changing the total body potassium. Potassium is excreted mainly in the urine.

Sodium is absorbed by the small intestines, distributed to extracellular compartments, and is excreted in the urine and sweat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmoisine colour (C069/S)

Citric acid anhydrous

Silicon dioxide

Sodium bicarbonate

Uni-Dri 20

TURBO ENERGY CITRUS FUSION: Orange flavour (J1431)

TURBO ENERGY BERRY FUSION: Berry flavour (F1778/D)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from direct sunlight and moisture.

6.5 Nature and contents of container

TURBO ENERGY is available as CITRUS FUSION or BERRY FUSION flavour.

TURBO ENERGY is available in cartons of 15 or 30 sachets. Each sachet contains 10 g of fine granules or powder.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Loock Pharmaceuticals (Pty) Ltd

Postnet Suite 223

Private Bag X82245

Waterfall Mall

Rustenburg

0300

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

August 2024.