

PROFESSIONAL INFORMATION

Complementary Medicine: Health supplement

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

POTCILYTE, capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Potassium Citrate	1000 mg
providing Potassium (elemental)	127.55 mg

For full list of excipients, see section 6.1.
Sugar free.

3. PHARMACEUTICAL FORM

Size double zero burgundy hard gelatine capsules containing white to off white crystalline powder

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Contributes to normal functioning of the nervous system, normal muscle function and maintenance of normal blood pressure. A factor in the maintenance of good health.

4.2 Posology and method of administration

Posology

~~For adults and children over 12 years of age:~~

Adults: One capsule per day or as prescribed.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to the active ingredients or to the excipients listed in section 6.1.
- Hyperkalaemic patients or underlying conditions that is prone to hyperkalaemia for example chronic renal failure, diabetes mellitus (uncontrolled), adrenal insufficiency, acute dehydration and tissue breakdown due to severe exercise or trauma.
- Patients with delayed gastric emptying, or any obstruction from oesophagus to duodenum.
- Patients with renal insufficiency.
- If you suffer from any disease or condition, consult your doctor before taking any medicine or supplement.

4.4 Special warnings and precautions

POTCILYTE should be used with care in:

- Patients under treatment for congestive cardiac failure or hypertension should not use POTCILYTE capsules except under doctor's supervision.
- Keep out of reach of children.

4.5 Interaction with other medicines and other forms of interaction

POTCILYTE may interact with the following medicines.

- Potassium –sparing diuretics: avoid simultaneous use due to risk of hyperkalaemia
Drugs causing delayed movement through gastrointestinal system for example anti-cholinergic increase gastro-intestinal irritation.
- Always consult your doctor before taking new medicines or supplements.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No fertility data available.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

- Some patients may experience nausea, vomiting and diarrhoea or abdominal discomfort. Use with meals may reduce these symptoms.
- Hyperkalaemia: Patients with decreased potassium excretion can rapidly develop fatal hyperkalaemia and arrest for example: chronic renal failure, cardiac failure or severe myocardial damage.
- Gastro-intestinal lesions: Abdominal pain associated with severe vomiting or gastrointestinal bleeding should raise the suspicion for bowel –perforation or obstruction and needs to be further investigated.
- If you experience any side effects, stop use immediately and consult with your doctor.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of POTCILYTE is important. It allows continued monitoring of the benefit/risk balance of POTCILYTE. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (SAHPRA) via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Hyperkalaemia is rarely symptomatic until very high levels in blood, but is also unlikely at the recommended dosages in patients without risk thereof as discussed in contra-indications. ECG (electrocardiographic) changes appear before late symptoms as muscle weakness, paralysis and cardiac arrest.

Consult an emergency department in case of known over dosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category D Medicine: Health supplement 34.7 Minerals

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Maize Starch
Syloid 244

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.

6.5 Nature and contents of container

White Plastic container with Burgundy cap containing 90 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Endovasions
345 Albert Street
Waterkloof
Pretoria
Gauteng
0145
012 880 4300

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF TEXT

This leaflet was last revised in March 2024.