Patient Information Leaflet

SCHEDULING STATUS: S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

POTASSIUM CHLORIDE UNICORN 600 (tablets) (each tablet contains 600 mg potassium chloride equivalent to approximately 315 mg potassium or 8 mmol K^+ in slow release form).

Read all of this leaflet carefully before you start taking POTASSIUM CHLORIDE UNICORN 600:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT POTASSIUM CHLORIDE UNICORN 600 CONTAINS:

- **The active substance** is potassium chloride.

  Each tablet contains 600 mg potassium chloride equivalent to approximately 315 mg potassium or 8 mmol K^+ in slow release form.

  The other inactive ingredients are acacia spray dried, cetostearyl alcohol, dispersed buff 18016 (iron oxide red, iron oxide yellow, titanium dioxide), gelatin, magnesium stearate, polyethylene glycol (PEG) 8000, sucrose, talc purified, titanium dioxide.

  Contains sugar (sucrose 97 mg per tablet).

2. WHAT POTASSIUM CHLORIDE UNICORN 600 IS USED FOR:

POTASSIUM CHLORIDE UNICORN 600 is used to treat low potassium blood levels. Low potassium blood levels may occur during diuretic or digitalis therapy.

3. BEFORE YOU TAKE POTASSIUM CHLORIDE UNICORN 600:

Do not take POTASSIUM CHLORIDE UNICORN 600:

- If you are hypersensitive (allergic) to potassium chloride or any of the ingredients (see “WHAT **POTASSIUM CHLORIDE UNICORN 600** CONTAINS”).
- If you have kidney failure or if it is difficult to urinate.
- If you suffer from adynamia episodica hereditaria or congenital paramyotonia.
- If you have high potassium blood levels as a result of extensive cell destruction (such as in severe burns, crush syndrome, massive haemolysis, rhabdomyolysis, tumour lysis), untreated Addison's disease, hyporeninaemic hypoaldosteronism, metabolic acidosis and acute dehydration.
- If you suffer from delayed stomach emptying or obstruction or stricture in your intestines.
- If you are taking potassium-sparing diuretics (aldosterone antagonists, triamterene, or amiloride) or ACE inhibitors.
- If you are being treated with intravenous potassium.

Take special care with POTASSIUM CHLORIDE UNICORN 600:

If you become aware of signs of intolerance while under treatment with **POTASSIUM CHLORIDE UNICORN 600** e.g. marked nausea or vomiting, pronounced flatulence, pain in the abdomen, diarrhoea, black or bloodstained stools, you should stop taking the medicine at once and notify your doctor without delay.

Tell your doctor:

- If you suffer from oesophageal stasis, delayed intestinal transit, or intestinal ischaemia due to generalised atherosclerotic vascular disease.
- If you have stomach ulcers.
- If you are taking ACE inhibitors (used in treatment of high blood pressure).

Pregnancy and breastfeeding:

POTASSIUM CHLORIDE UNICORN 600 should be used with caution if you are pregnant. Please consult your doctor, pharmacist or other health care professional for advice. It is not known whether **POTASSIUM CHLORIDE UNICORN 600** is safe during breastfeeding.

Driving and using machinery:

You should drive your motor vehicle or operate dangerous machinery with caution until you know how **POTASSIUM CHLORIDE UNICORN 600** affects you.

Important information about some of the ingredients of POTASSIUM CHLORIDE UNICORN 600:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **POTASSIUM CHLORIDE UNICORN 600.**

POTASSIUM CHLORIDE UNICORN 600 contains sugar (sucrose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with POTASSIUM CHLORIDE UNICORN 600:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **POTASSIUM CHLORIDE UNICORN 600** with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are currently using:

- Medication to treat high blood pressure, such as beta blockers or ACE inhibitors.
- Digitalis glycosides (used for treatment of certain heart conditions).
- Potassium-sparing (spironolactone, amiloride, triamterene) or thiazide diuretics.
- Heparin or cyclosporine.

- Potassium-containing medication such as potassium salts of penicillin.
- Medication (such as antimuscarinics) that delay stomach emptying.
- Non-steroidal anti-inflammatory drugs (NSAIDs) used for treatment of inflammation and pain.
- Laxatives.

You should not take salt substitutes or low-salt milk or food unless approved by your doctor.

4. HOW TO TAKE POTASSIUM CHLORIDE UNICORN 600:

Always take **POTASSIUM CHLORIDE UNICORN 600** exactly as your doctor has instructed you. Your doctor will adapt your dosage according to the cause and seriousness of your condition. You should check with your doctor if you are unsure.

If you have the impression that the effect of **POTASSIUM CHLORIDE UNICORN 600** is too strong or too weak, talk to your doctor or pharmacist.

You should continue taking the tablets until your doctor decides otherwise.

The usual daily dosage is 6 to 12 tablets in divided doses. You should not take more than 2 tablets in a single dose.

Swallow the tablets whole with fluid during meals while you are sitting or standing.
You must drink plenty of fluids during treatment with **POTASSIUM CHLORIDE UNICORN 600**.

If you take more POTASSIUM CHLORIDE UNICORN 600 than you should:

In the event of overdosage, consult your doctor immediately. If the doctor is not available, seek help at the nearest hospital or poison control centre.

If you forget to take POTASSIUM CHLORIDE UNICORN 600:

If you forget to take a dose, take it as soon as possible if you remember it within 2 hours. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS:

POTASSIUM CHLORIDE UNICORN 600 can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, tell your doctor immediately since it may indicate a need for medical attention:

- Irregular or slow heartbeat.
- Confusion, numbness or tingling in hands, feet or lips.
- Shortness of breath or difficult breathing.
- Unexplained tiredness or weakness, weakness or heaviness of legs.
- Continuing stomach pain, cramping or soreness.
- Chest or throat pain, especially if your stools contain fresh or digested blood.

The above mentioned are all serious side-effects and occur less frequently.

The following side-effects may occur frequently, however, you do not have to inform your doctor unless the side-effects continue or are bothersome:

- Diarrhoea
- Nausea and vomiting
- Stomach pain, discomfort or gas
- Less frequently a red, itchy skin rash may occur

6. STORING AND DISPOSING OF POTASSIUM CHLORIDE UNICORN 600:

- Store at or below 25 °C and protect from light and moisture.
- Do not remove the product from the container before use.
- **KEEP ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use the tablets after the expiry date printed on the blisters and containers.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF POTASSIUM CHLORIDE UNICORN 600:

Packs of 30 or 500 tablets in white, polypropylene or high density polyethylene bottles or blisters.

8. IDENTIFICATION OF POTASSIUM CHLORIDE UNICORN 600:

Brownish orange, biconvex, round, polished, sugar-coated tablets.

Diameter approximately 11,5 to 12,5 mm. Thickness approximately 6,5 to 8,1 mm.

9. REGISTRATION NUMBER:

36/24/0176

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd [1]

72 Steel Road

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Kempton Park, 1619

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11. DATE OF PUBLICATION:

Date of registration: 25 November 2005

Date of most recent approval of professional information: 30 November 2016

[1] Company Reg No.: 1990/001979/07