1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

PLENISH-K 600 SR

Tablet

Read all of this leaflet carefully because it contains important information for you

PLENISH-K 600 SR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use PLENISH-K 600 SR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PLENISH-K 600 SR with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT PLENISH-K 600 SR CONTAINS

The active substance is potassium chloride.

The other ingredients are ethylcellulose 7 cps, magnesium stearate, purified talc, stearyl alcohol.

Sugar free

WHAT PLENISH-K 600 SR IS USED FOR

PLENISH-K 600 SR is used as an oral potassium supplementation to treat or prevent low levels of potassium in your body. Potassium supplements may be needed by patients using certain medicines, such as diuretics or digoxin.

BEFORE YOU TAKE PLENISH-K 600 SR

Do not take PLENISH-K 600 SR:

- If you are hypersensitive (allergic) to potassium chloride or any of the other ingredients of PLENISH-K 600 SR tablets.
- If you have ulcers in your bowel or gut.
- If you have been told by your doctor you have kidney failure.
- If you have Addison's disease (which is a condition where your adrenal gland is not producing enough steroids).
- If you have recently suffered from trauma, severe burns, anaemia and muscle cramps and metabolic complications occurring after cancer treatment.
- If you suffer from digestive problems or have difficulty swallowing (due to a narrowing or blockage of your gullet (food pipe) or intestines).
- If you have been told you have metabolic acidosis (a condition caused by increased acid levels in the blood).
- If you are dehydrated (you may feel thirsty with a dry mouth)
- If you have high blood potassium levels (which can cause an abnormal heartbeat).
- If you suffer from a condition called hyporeninaemic hypoaldosteronism (where your body is low on an enzyme called renin and a hormone called aldosterone which normally helps to control your blood pressure).

- If you are taking or being given certain types of diuretics (water tablets); either potassium-sparing diuretics (e.g. triamterene and amiloride) or aldosterone antagonists (e.g. spironolactone and eplerenone).

Take special care with PLENISH-K 600 SR:

- if you have undergone any surgery of the intestine or bowel (e.g. colostomy (an operation to remove part of your bowels or colon).
- if you suffer from any condition which affects your bowel movements.
- if you suffer from heart disease (which may cause chest pain, shortness of breath or ankle swelling).
- if you suffer from kidney problems or if you were told by your doctor that your body has difficulty eliminating potassium (e.g. because of kidney problems). If you suffer from severe kidney impairment. Your dose may need to be adjusted.
- if you have or have ever had a stomach ulcer.
- if you experience severe nausea and vomiting, severe stomach pain or experience gas in your stomach, increased urgency to empty your bowels (diarrhoea) or any bleeding in your stomach or intestines, contact your doctor immediately.

Taking PLENISH-K 600 SR with food and drink

PLENISH-K 600 SR should be swallowed whole with fluid during meals. Drink enough water while on treatment with PLENISH-K 600 SR.

Pregnancy and breastfeeding

The safety of PLENISH-K 600 SR during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking PLENISH-K 600 SR.

Driving and using machinery

PLENISH-K 600 SR may influence your ability to drive. Do not drive, use machinery or perform any tasks that require concentration until you are certain that PLENISH-K 600 SR does not adversely affect your ability to do so safely (see POSSIBLE SIDE EFFECTS).

Taking other medicines with PLENISH-K 600 SR

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

Tell your doctor if you are taking any of the following medicines:

- Potassium-sparing diuretics (e.g. triamterene, amiloride): used in the treatment of high blood pressure or certain heart diseases.
- Aldosterone antagonists (e.g. spironolactone, eplerenone): used in the treatment of high blood pressure or certain heart diseases.
- ACE inhibitors (e.g. lisinopril, captopril, enalapril and other): used in the treatment of high blood pressure.
- Angiotensin-II-receptor-blockers (e.g. valsartan, losartan and others): used in the treatment of high blood pressure.
- Non-steroidal anti-inflammatory medicines (e.g. indomethacin and others): used to relieve pain and inflammation.
- Beta-blockers (e.g. atenolol, propranolol and others): used in the treatment of high blood pressure.
- Direct renin inhibitors (e.g. aliskerin): used in the treatment of high blood pressure.

- Anticholinergics (e.g. atropine): medicines used for a variety of disorders such as stomach cramps, bladder spasms, asthma, motion sickness, muscle spasms, poisoning with certain toxic compounds and as an aid to anaesthesia and after heart attacks.
- Heparin: medicine used to prevent blood clotting.
- Digoxin: medicine used in the treatment of certain heart diseases to help the heartbeat.
- Ciclosporin: Medicine used to control your body's immune system in to order to prevent rejection of a transplanted organ.
- Potassium containing salt substitutes for flavouring food.

HOW TO TAKE PLENISH-K 600 SR

Do not share medicines prescribed for you with any other person.

Always take PLENISH-K 600 SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Swallow the tablets whole with a full glass of water of liquid during meals while sitting upright.

Do not crush, chew or suck the tablet.

The usual dose is for adults is 6 to 12 tablets daily. Not more than 2 tablets should be taken at once. Your doctor or pharmacist will tell you exactly how may tablets of PLENISH-K 600 SR to take.

Your doctor will tell you how long your treatment with PLENISH-K 600 SR will last.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

If you have the impression that the effect of PLENISH-K 600 SR is too strong or too weak, tell your doctor or pharmacist.

If you take more PLENISH-K 600 SR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of PLENISH-K 600 SR

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

PLENISH-K 600 SR can have side effects.

Not all side effects reported for PLENISH-K 600 SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PLENISH-K 600 SR, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking PLENISH-K 600 SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PLENISH-K 600 SR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bleeding from your intestines or stomach;

- obstruction in the stomach or intestines which may result in cramping in your stomach, loss of appetite, constipation, vomiting swelling of the stomach and the inability to pass gas.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported but the frequency is unknown:

- Ulcer in the stomach or intestines;
- feeling or being sick (nausea and vomiting);
- pain and cramps in the stomach;
- diarrhoea;
- skin rash;
- itchy skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF PLENISH-K 600 SR

Store at or below 25 °C.

Protect from moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF PLENISH-K 600 SR

500 tablets are packed in an amber polyvinyl chloride (PVC) jar with a leaflet, rayon and sealed with a white high-density polyethylene crab claw cap.

100 tablets are packed in white polypropylene securitainer with a leaflet, rayon, and sealed with a white low-density polyethylene cap with a tamper evident seal.

60 tablets are packed in 12's in a PVC/PVdC /Alu (silver) blister with five blister strips in a cardboard carton.

60 tablets are packed in 10's in a PVC/PVdC/Alu (silver) blister with six blister strips in a cardboard carton.

28 tablets are packed in a metalized layflat and sealed with a Ziploc.

56 tablets are packed in a metalized layflat and sealed with a Ziploc.

84 tablets are packed in a metalized layflat and sealed with a Ziploc.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF PLENISH-K 600 SR

A round, plain, white to off-white, deep biconvex tablet.

REGISTRATION NUMBER

52/24/0441

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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