PATIENT INFORMATION LEAFLET FOR

ULTIPOT

SCHEDULING STATUS: S2

ULTIPOT (600 mg slow release film coated tablet)

Potassium Chloride

Sugar free

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

ULTIPOT is available without a doctor's prescription. Nevertheless, you still need to use ULTIPOT carefully to get the best results from it.

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

What is in this leaflet

1. What ULTIPOT is and what it is used for
2. What you need to know before you take ULTIPOT
3. How to take ULTIPOT
4. Possible side effects
5. How to store ULTIPOT
6. Contents of the pack and other information.

1. What ULTIPOT is and what it is used for

ULTIPOT (potassium chloride) belongs to a group of medicines called potassium supplements.

ULTIPOT contains potassium and is used to treat or prevent low levels of potassium in your body.

2. What you need to know before you take ULTIPOT

Do not take ULTIPOT:

- if you are hypersensitive (allergic) to potassium chloride or any of the other ingredients of ULTIPOT (listed in **section 6**)
- if you have been told by your doctor you have kidney failure
- if you have been told by your doctor you have severe liver diseases
- if you have been told by your doctor you have gastrointestinal ulceration
- if you have Addison's disease (which is a condition where your adrenal gland is not producing enough steroids)
- if you suffer from digestive problems or have difficulty in swallowing (due to narrowing or blockage of your 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 heat cramps
- 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 rennin and a hormone called aldosterone which normally helps to control your blood pressure)
- if you are taking a potassium sparing diuretic (a specific type of water tablet) e.g. spironolactone or amiloride hydrochloride

- if you are taking other potassium supplements or intravenous potassium.

Warnings and precautions

Take special care with ULTIPOT if you:

- have had an ostomy (an operation to remove part of your bowels)
- suffer from heart disease (which may cause chest pain, shortness of breath or ankle swelling)
- suffer from kidney problems
- suffer from liver problems
- have or have ever had a stomach ulcer
- have recently suffered from severe burns.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take ULTIPOT.

Children and adolescents

Do not give ULTIPOT to children.

Other medicines and ULTIPOT

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

Tell your doctor or pharmacist if you are taking or have taken any of the following medicines as they may interfere with ULTIPOT:

• diuretics (“water tablets”)	for water retention or high blood pressure (if you are taking potassium sparing diuretics, stop taking ULTIPOT, see the section ‘**Do not take ULTIPOT**’)
• ACE inhibitors or beta-blockers	for high blood pressure or heart problems such as captopril or atenolol
• cyclosporin	for transplants, rheumatic disease or skin complaints
• non steroidal anti-inflammatories (NSAIDs)	for pain relief or rheumatism such as aspirin or naproxen
• heparin	used to thin the blood
• digoxin	for an irregular heartbeat
• anticholinergics	for abdominal or stomach spasms or cramps such as atropine sulphate or hyoscine butylbromide
• penicillin	an antibiotic for treatment of bacterial infections
• lithium	for treatment or prevention of mania or depression in patients with bipolar affective disorder
• antimuscarinics	treatment for patients with overactive bladder (OAB)

ULTIPOT with food, drink and alcohol

You must take your tablets with fluid during a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ULTIPOT.

ULTIPOT is a modified release tablet, which means it takes a long time for the potassium to be released from the tablet core. When you are pregnant your digestive system works more slowly and so ULTIPOT tablets take longer to pass through your system. This could mean you do not receive the correct amount of potassium from your ULTIPOT tablets. Your doctor will only give you ULTIPOT if you really need it.

Driving and using machines

The possible side effects of ULTIPOT such as confusion, irregular heartbeat, shortness of breath, abrupt loss of heart function, breathing and consciousness and nausea (see **section 4**) may affect the patient's ability to drive or operate machinery. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ULTIPOT affects them.

3. How to take ULTIPOT

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

Always take ULTIPOT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual daily dose is 6 to 12 tablets, in divided doses. Not more than 2 tablets (16 mmol) should be given in a single dose. The tablets must be swallowed whole. Do not break the tablets or chew them before swallowing.

Your doctor will tell you how long your treatment with ULTIPOT will last.

If you have the impression that the effect of ULTIPOT is too strong or too weak, tell your doctor or pharmacist.

If you take more ULTIPOT 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 ULTIPOT

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

4. Possible Side Effects

ULTIPOT can have side effects.

Not all side effects reported for ULTIPOT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ULTIPOT, please consult your healthcare provider for advice.

If any of the following happens, stop taking ULTIPOT 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
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ULTIPOT. 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:

- palpitations (irregular heartbeat)

- shortness of breath
- abrupt loss of heart function, breathing and consciousness
- chest or throat pain, especially when swallowing
- blood in your urine
- coughing up blood (however small the amount)
- blood in your vomit
- black stools.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea
- severe sickness (feeling sick or vomiting)
- trapped wind or indigestion
- severe stomach pains
- diarrhoea.

Less frequent side effects:

- fainting or dizziness
- abdominal or stomach pain
- cramping or soreness.

Side effects with unknown frequency:

- confusion
- high blood levels of potassium (which can cause an abnormal heartbeat).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ULTIPOT.

5. How to store ULTIPOT

Store at or below 25 °C. Protect from light and moisture.

Store all medicines out of reach of children.

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).

6. Contents of the pack and other information

What ULTIPOT contains

The active substance is potassium chloride 600 mg equivalent to potassium 315 mg (8 mmol).

The other ingredients are:

Tablet cores - Colloidal silicon dioxide, macrogol 6000, magnesium stearate and stearic acid.

Coating ingredients - Candurin silver lustre, dibutyl phthalate, Eudragrit RL-100, Eudragrit RS-100, iron oxide black, iron oxide yellow, povidone K-25, talc purified and titanium dioxide.

What ULITPOT looks like and contents of the pack

ULITPOT: Pale yellow, oblong, biconvex film-coated tablet.

ULITPOT tablets are available in containers of 30, 100 and 500. The tablets are packed in white plastic containers with white plastic closures.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 2

Junxion Park

10 Elephant Lane

Century City

7441

Customer Care: 080 222 6662

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