

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

ULTIPOT tablets (slow release film coated tablets)

COMPOSITION:

Each tablet contains:
600 mg potassium chloride equivalent to 315 mg potassium (8 mmol) in a slow release film coated tablet.
The other ingredients are:
Tablet: Macrogol, stearic acid, magnesium stearate and silicon dioxide.
Coating ingredients: Povidone K-25, purified talc, titanium dioxide, iron oxide black, iron oxide yellow, candurin silver luster, dibutyl phthalate, ammonium methacrylate copolymer type A and B.

PHARMACOLOGICAL CLASSIFICATION:

A.24 Mineral substitutes, electrolytes

PHARMACOLOGICAL ACTION:

Potassium is an electrolyte in the human body which is involved in intracellular and extracellular physiological processes.

INDICATIONS:

ULTIPOT is indicated for the prophylaxis and treatment of hypokalaemia.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients of **ULTIPOT**, hyperkalaemia, untreated Addison's disease, hyporeninaemia, hypoaldosteronism, metabolic acidosis, heat cramps and acute dehydration.
Severe liver diseases and gastro-intestinal ulceration or obstruction.
Renal insufficiency: Due to the possibility of hyperkalaemia being precipitated, potassium salts should not be administered to those patients treated with potassium-sparing diuretics (aldosterone antagonists, triamterine or amiloride).
Concomitant use of other potassium supplements or intravenous potassium.

WARNINGS:

Hyperkalaemia: Those patients who have impaired potassium excretion, should not be given **ULTIPOT**, since this could precipitate hyperkalaemia and cardiac arrest. Potentially fatal hyperkalaemia can develop rapidly and may be asymptomatic. Patients with diseases or conditions which impair the excretion of potassium, should be monitored very carefully when administering potassium salts, serum potassium concentration should be checked and the necessary dosage adjustments made.

Gastro-intestinal lesions: If a patient develops symptoms of pronounced nausea, severe vomiting, severe abdominal pains or flatulence, diarrhoea or gastro-intestinal bleeding, while using **ULTIPOT**, the preparation should be withdrawn immediately. The above signs and symptoms may be indicative of ulceration or perforation in the gastro-intestinal tract. Those at risk are patients with oesophageal stasis, peptic or gastric ulcerations, delayed intestinal transit or intestinal ischaemia due to atherosclerotic vascular disease.

ACE-inhibitors may cause retention of potassium due to inhibition of aldosterone production, thus, those patients using ACE-inhibitors should be monitored closely upon administration of potassium supplementation (see INTERACTIONS).

INTERACTIONS:

Potassium supplements should be used with caution, in patients receiving medicines that increase serum-potassium-concentrations. These include potassium-sparing diuretics, ACE-inhibitors, and cyclosporin and medicines containing potassium salts, such as penicillin, digoxin, lithium, NSAID's, heparin and beta-blockers.

PREGNANCY AND LACTATION:

The safety of **ULTIPOT** in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

The dosage should be adapted to the cause and the degree of the manifest hypokalaemic state. Depending on the patient's individual requirement, a daily dosage of 6 to 12 tablets, in several divided doses, should be given. Not more than 2 tablets (16 mmol) should be given in a single dose. Tablets should be taken whole, and should not be chewed or broken before swallowing.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Skin and appendages disorders:

Less frequent: Pruritus, skin rash and urticaria.

Musculoskeletal system disorders:

Frequency unknown: Frequency unknown: Paraesthesia of the extremities, muscle weakness, and paralysis.

Gastro-intestinal disorders:

Frequent: Nausea, vomiting, diarrhoea, stomach pain, flatulence.
Less frequent: Abdominal or stomach pain, cramping or soreness
Gastro-intestinal ulceration, chest or throat pain, especially when swallowing. Blood in the urine, blood in vomit, coughing up blood, black stools.

UPT-PI-13/09



PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking ULTIPO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **ULTIPOT** has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

ULTIPOT 600 mg potassium chloride tablets

WHAT ULTIPO

Each tablet contains:
600 mg potassium chloride equivalent to 315 mg potassium (8 mmol) in a slow release film coated tablet.
The other ingredients are:
Tablet: Macrogol, stearic acid, magnesium stearate and silicon dioxide.
Coating ingredients: Povidone K-25, purified talc, titanium dioxide, iron oxide black, iron oxide yellow, candurin silver luster, dibutyl phthalate, ammonium methacrylate copolymer type A and B.

WHAT ULTIPO

ULTIPOT 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.

INSTRUCTIONS BEFORE TAKING ULTIPO

Do not take ULTIPO:

- if you are allergic (hypersensitive) to potassium chloride or any of the ingredients of **ULTIPOT**
- 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 gastro-intestinal ulceration
- 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 severe burns
- 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 hyporeninaemia 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

HOW TO USE ULTIPO:

Take special care with ULTIPO:

Before you take **ULTIPOT** tell your doctor 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.
Do not give **ULTIPOT** to children.

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

Taking ULTIPO with food and drink:

You must take your tablets with fluid during a meal.

PREGNANCY AND BREAST FEEDING:

If you are pregnant or breast feeding your baby while taking **ULTIPOT**, please consult your doctor, pharmacist or other health care professional for advice.

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.

TAKING OTHER MEDICINES WITH ULTIPO:

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

- diuretics for water retention or high blood pressure ("water tablets") (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-inflammatory (NSAIDs) for pain relief or rheumatism such as aspirin or naproxen
• heparin used to thin the blood

Cardiovascular disorders, general:

Less frequent: Hypotension, cardiac dysrhythmias, heart block and cardiac arrest.

Special Precautions:

Caution should be observed when prescribing **ULTIPOT** in the elderly or patients where renal or adrenocortical insufficiency or heart disease is present or a possibility, as the risk of developing hyperkalaemia is increased. Monitoring of serum electrolytes is indicated in these instances, as well as during protracted substitution of potassium.

ULTIPOT tablets should not be prescribed to patients with a history of gastro-intestinal ulceration or obstruction.

Care should be exercised in patients with renal or adrenocortical insufficiency, cardiac disease, acute dehydration, heat cramps, extensive tissue destruction as occurs with severe burns, or in the case of patients receiving potassium sparing diuretics.

The administration of **ULTIPOT** is not advised in those patients suffering from stomas, due to an altered intestinal transit time. **ULTIPOT** should be given with caution to patients receiving medication that may cause hypomagnesaemia. Plasma magnesium levels should be assessed and any necessary corrections made in these patients.

Children:

Safety and efficacy in children has not been established.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Acute over dosage of **ULTIPOT** tablets may cause nausea, vomiting, diarrhoea and abdominal cramps. The stomach should be emptied by gastric lavage.

Untoward effects are mainly cardiovascular, such as hypotension, shock, ventricular dysrhythmias bundle branch block, ventricular fibrillation; and neuromuscular, such as paraesthesia, convulsions, areflexia, flaccid paralysis of striated muscle which may precipitate respiratory paralysis. Elevation of serum potassium concentrations and typical ECG changes are also observed (increased amplitude and peaking of T-wave, disappearance of P-wave, widening of QRS complex, and ST depression). Gastro-intestinal ulceration. Cardiac toxicity may be treated with intravenous administration of calcium salts with ECG monitoring.

Further treatment is symptomatic and supportive.

Hyperkalaemia following chronic over dosage or as a result of interactions: Potassium containing foods, medications and potassium-sparing diuretics must be withdrawn. Serum potassium may be reduced by infusions with glucose and insulin. When treating hyperkalaemia, lowering of the serum potassium concentrations too rapidly can produce digoxin toxicity in patients who have been previously stabilised on digoxin.

IDENTIFICATION:

Pale yellow, oblong, biconvex film-coated tablet.

PRESENTATION:

ULTIPOT tablets are available in containers of 30 and 500. The tablets are packed in white plastic (HDPE) containers.

STORAGE INSTRUCTIONS:

Store at or below 25 °C, in a cool place and protect from light and moisture.

Dispense in moisture proof containers. Keep the container well-closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

35/24/0370

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

MIRREN (PTY) LTD

18 Golden Drive

Morehill

Benoni

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

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- 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.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ULTIPOT** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

INSTRUCTIONS ON HOW TO TAKE ULTIPO:

Do not share medicines prescribed for you with any other person. Always take **ULTIPOT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist 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.

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

Do not exceed the stated dose.

If you take more ULTIPO than you should:

If you accidentally take too many tablets, or someone else takes your medicine, you should tell your doctor or pharmacist at once.

If neither is available, contact the nearest hospital or poison control centre.

Show any left-over medicines or the empty packet to the doctor.

If you forget to take ULTIPO:

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.

SIDE EFFECTS:

ULTIPOT can have side effects.

If you get any of the following tell your doctor or pharmacist immediately as they may tell you to stop taking **ULTIPOT**:

- severe sickness (feeling sick or vomiting)
 - trapped wind or indigestion
 - severe stomach pains
 - diarrhoea.
- Tell your doctor or pharmacist if you think you have any of these or other problems with **ULTIPOT**.
- Other less frequent side effects are:
- high blood levels of potassium (which can cause an abnormal heartbeat)
 - itching and skin rashes (nettle rash)
 - blood in your urine
 - coughing up blood (however small the amount)
 - blood in your vomit
 - black stools.

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty in breathing; swelling of your face, lips, tongue, or throat.

If any of the side effects get worse or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

Not all side effects reported for **ULTIPOT** are included in this leaflet. Should your general health worsen while taking **ULTIPOT**, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Store at or below 25 °C, in a cool place and protect from light and moisture.

Dispense in moisture proof containers. Keep the container well-closed.

Keep all medicines out of the reach and sight of children.

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

Return all unused medicine to your pharmacist.

PRESENTATION:

ULTIPOT tablets are available in containers of 30 and 500. The tablets are packed in white plastic (HDPE) containers.

IDENTIFICATION:

Pale yellow, oblong, biconvex film-coated tablet.

REGISTRATION NUMBER/REFERENCE NUMBER:

35/24/0370

NAME AND ADDRESS OF REGISTRATION HOLDER OF THE CERTIFICATE OF REGISTRATION:

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

19 April 2013

UPT-PI-13/09

SKEDULERINGSTATUS: [S2]

EIENDOMSNAAM EN DOSEERVORM:

ULTIPOT tablette (stadige vrystelling film bedekte tablette)

SAMESTELLING:

Elke tablet bevat: 600 mg kaliumchloried ekwivalent aan 315 mg kalium (8 mmol) in 'n stadige vrystelling film bedekte tablet. Die ander bestanddele is:

Tablet: Makrogol, steariensuur, magnesium stearaat en silikon dioksied.

Bestanddele van film bedekking: Povidone K-25, gesuiwerde talk, titanium dioksied, swart ysteroksied, geel ysteroksied, kandurien silwer glans, dibutiel ftalaat en ammonium metakrilaat, kopolimeer A en B.

FARMAKOLOGIESE KLASSIFIKASIE:

A.24 Minerale vervangings, elektroliete

FARMAKOLOGIESE WERKING:

Kalium is 'n elektroliet in die menslike liggaam wat betrokke is in intrasellulêre en ekstrasellulêre fisiologiese prosesse.

INDIKASIES:

ULTIPOT word gebruik vir die voorkoming en behandeling van hipokalemie.

KONTRA-INDIKASIES:

Hipersensitiwiteit vir enige van die bestanddele van **ULTIPOT**. Hiperkalemie, onbehandelde Addison se siekte, hipo-reninemie, hipo-alдостeronisme, metaboliese asidose, hitte krampe en akute dehidrasie.

Ernstige lewer siekte en gastro-intestinale ulserasie of obstruksie. Nier ontoereikendheid: As gevolg daarvan dat hiperkalemie moontlik kan ontstaan, behoort kaliumlose nie toegedien te word aan pasiënte wat behandel word met kaliumsparende diuretika nie (aldosteron antagonist, triamterien of amiloriet). Gesamtelike gebruik van ander kalium aanvullings of intraveneuse kalium.

WAARSKUWINGS:

Hiperkalemie: Pasiënte met verswakte kalium uitskeiding, behoort nie **ULTIPOT** te neem nie, omdat dit hiperkalemie en hartstilstand kan veroorsaak.

Potensieel fatale hiperkalemie kan vinnig ontwikkel en kan asimptomaties wees. Pasiënte wat siektes of toestande onder lede het, wat die uitskeiding van kalium belemmer, moet baie goed gemonitor word wanneer kaliumlose toegedien word. Serum kaliumkonsentrasies behoort na gegaan te word en die nodige doserings aanpassings moet gemaak te word.

Gastro-intestinale letsel: Wanneer 'n pasiënt simptome van erge naarheid, erge braking, erge abdominale pyn, opgeblaseheid, diarree of gastro-intestinale bloeding ontwikkel terwyl **ULTIPOT** gebruik word, moet die gebruik daarvan dadelik gestaak word. Die bogenoemde tekens en simptome mag dui op ulserasie of perforasie in die gastro-intestinale kanaal. Pasiënte wat 'n risiko loop is die pasiënte met slukderm stasie, peptiese of gastriese ulserasies, vertraagde intestinale deurgang of intestinale iskemie as gevolg van aterosklerotiese vasikulêre siekte. AOE-inhibeerdors moet tensie van kalium tot gevolg hê as gevolg van inhibering van aldosteron produksie, dus moet pasiënte wat AOE-inhibeerdors gebruik, noukeurig gemonitor word wanneer kalium aanvullings toegedien word (sien INTERAKSIES).

INTERAKSIES:

Kalium aanvullings behoort met versigtigheid gebruik te word by pasiënte wat medisyne gebruik wat die serum-kalium-konsentrasies verhoog. Dit sluit middels in soos kalium sparende diuretika, AOE-inhibeerdors, as ook siklosporien en medisyne wat kalium sout bevat soos, penisillien, digokisien, litium, nie-steroidale anti-inflammatoriese middels, heparien en beta-blokkers.

SWANGERSKAP EN BORSVOEDING:

Die veiligheid van **ULTIPOT** tydens swangerskap en borsvoeding is nog nie vasgestel nie.

DOSES EN GEBRUIKSAANWYSINGS:

Die dosis moet aangepas word na aanleiding van die oorsaak en die graad van die bepaalde hipokalemiese toestand. Afhangende van die pasiënt se individuele vereistes behoort 'n daaglikse dosis van 6 tot 12 tablette, in verskeie verdeelde dosisse toegedien te word, nie meer as 2 tablette (16 mmol) moet in 'n enkele dosis geneem word nie. Tablette moet heel in gesluk word en moet nie gekou of gebreek word voordat dit gesluk word nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Vel en aanhangsel steurings:

Minder dikwels: Jeukerigheid, veluitslag, galbulte.

Spier- en skelet sisteem steurings:

Frekwensie onbekend: Parestesie van die ekstremitate, spier swakheid en verlamming.

09/2013
BRITPAK



PASIËNT INLIGTINGSBLAD

Lees die hele blaadjie noukeurig deur voordat u begin om **ULTIPOT** te neem

- Hou hierdie blaadjie. U mag dit nodig vind om dit weer te lees.
- Indien u enige verdere vrae het, vra u dokter of apteker.
- **ULTIPOT** is vir u voorgeskryf. Moet dit nie vir ander mense gee nie. Dit mag skadelik wees vir hulle, al is hulle simptome dieselfde as u's'n.
- Indien enige van die newe effekte ernstig raak, of as u enige newe effekte opmerk wat nie in hierdie blaadjie gelys is nie, vertel asseblief u dokter of apteker.

SKEDULERINGSTATUS: [S2]

EIENDOMSNAAM EN DOSEERVORM:

ULTIPOT 600mg kaliumchloried tablette

WAT ULTIPTOT BEVAT:

Elke tablet bevat: 600 mg kaliumchloried ekwivalent aan 315 mg kalium (8 mmol) in 'n stadige vrystelling film-bedeekte tablet. Die ander bestanddele is:

Tablet: Makrogol, steariensuur, magnesium stearaat en silikon dioksied.

Bestanddele van die film bedekking: Povidone K-25, gesuiwerde talk, titanium dioksied, swart ysteroksied, geel ysteroksied, kandurien silwer glans, dibutiel ftalaat en ammonium metakrilaat, kopolimeer A en B.

WAARVOOR ULTIPTOT GEBRUIK WORD:

ULTIPOT behoort aan 'n groep medisyne wat kalium aanvullings genoem word.

ULTIPOT bevat kalium en word gebruik vir die behandeling of voorkoming van lae kalium vlakke in u liggaam.

INSTRUKSIES VOORDAT ULTIPTOT GEBRUIK WORD:

Moenie ULTIPTOT neem nie indien:

- u allergies (hipersensitief) is vir kalium chloride of enige van die ander bestanddele van **ULTIPOT**
- u dokter u meegedeel het dat u niersiekte het
- u dokter u meegedeel het dat u ernstige lewersiekte het
- u dokter u meegedeel het dat u gastro-intestinale ulkuse het
- u Addison se siekte het (dit is 'n toestand waar u adrenale klier nie genoeg steroïde produseer nie)
- u onlangs gely het aan ernstige brand wonde
- u gely het aan verteringsprobleme of gesukkel het om te sluk (as gevolg van 'n vernouing of verstopping in u slukpyp of ingewande)
- u meegedeel is dat u metaboliese asidose het ('n toestand wat veroorsaak word deur verhoogde suur vlakke in die bloed)
- u gedehidreer is (u mag dors voel met 'n droë mond)
- u hitte krampe het
- u hoë kalium vlakke in u bloed het (wat 'n abnormale hartslag kan veroorsaak)
- u ly aan 'n toestand wat genoem word hiporeninamie hipoaldosteronisme (waar u liggaam lae ensiem vlakke het van die ensiem rennin en die hormoon aldosteron wat gewoonlik help om u bloeddruk te beheer)
- u kalium sparende diuretika gebruik ('n spesifieke tipe watertablet) soos spironolaktone of amiloried hidrochloried
- u ander kalium aanvullings gebruik of intraveneuse kalium ontvang

HOE OM ULTIPTOT TE GEBRUIK:

Neem spesiale voorsorg met ULTIPTOT:

- Voordat u **ULTIPOT** neem vertel aan u dokter as u:
- 'n ostmie gehad het ('n operasie om 'n deel van u derm te verwyder)
 - ly aan hartsiekte (wat borspyn, kort asem of swelling van die enkels tot gevolg kan hê)
 - ly aan nier probleme
 - ly aan lewer probleme
 - 'n maagseer het of gehad het.
- Moenie **ULTIPOT** vir kinders gee nie.
- As enige van bogenoemde op u van toepassing is, raadpleeg u dokter of apteker voordat u **ULTIPOT** neem.
- Gebruik van ULTIPTOT met maaltye en vloeistowwe:**
- U behoort die tablette met vloeistof te sluk gedurende 'n maaltyd.

SWANGERSKAP EN BORSVOEDING:

As u swanger is of u baba borsvoed terwyl u **ULTIPOT** gebruik raadpleeg u dokter, apteker of ander gesondheidsorgkundige.

ULTIPOT is 'n veranderde vrystellings tablet, wat beteken dat dit 'n lang tyd neem vir die kalium om vrystel te word uit die tablet. Wanneer u swanger is werk u verteringsstelsel stadiger en gevolglik neem **ULTIPOT** tablette langer om deur u sisteem te beweeg. Dit kan beteken dat u nie die regte hoeveelheid kalium uit die **ULTIPOT** tablette kry nie. U dokter sal slegs **ULTIPOT** aan u voorskryf as u dit werklik nodig het.

DIE NEEM VAN ANDER MEDISYNE SAAM MET ULTIPTOT:

Vertel u dokter of apteker as u enige van die volgende medisyne neem of gemeen het omdat die medisyne die werking van **ULTIPOT** kan belemmer:

- diuretika ("water tablette") vir water tensie of hoë bloeddruk (as u kalium sparende diuretika neem, staak **ULTIPOT**, sien die afdeling 'Moenie **ULTIPOT** neem nie')
- AOE-inhibeerdors of beta-blokkers vir hoë bloeddruk of hart probleme soos kaptopril of atenolol
- siklosporien vir oorplantings, rumatiëse siektes of vel toestande
- nie steroïde anti-inflammatoriese middels vir pyn verligting of rumatiëke soos aspirien of naproksien

Gastro-intestinale verstourings:

Meer dikwels: Naarheid, braking, diarree, maagpyn, pyn, ongemak of wind (matig).

Minder dikwels: Abdominale of maag pyn, krampe of gevoeligheid. Gastro-intestinale ulserasie, bors of keel pyn, veral wanneer gesluk word. Bloed in die urine, bloed in braking, bloed op hoës, swart stoelgang.

Kardiovaskulêre verstourings, algemeen:

Minder dikwels: Hipotensie, kardiale aritmie, hart blok en hard stilstand.

Spesiale voorsorgmaatreëls:

ULTIPOT moet met versigtigheid toegedien word in bejaarde pasiënte en by pasiënte waar nier, adrenokortikale ontoereikendheid of hart kwale teenwoordig is of waar dit 'n moontlikheid is, omdat die risiko om hiperkalemie te ontwikkel verhoog word. Monitoring van serum elektroliete is nodig in hierdie gevalle, as ook gedurende uitgerekte aanvulling van kalium.

ULTIPOT tablette behoort nie voorgeskryf te word vir pasiënte met 'n geskiedenis van gastro-intestinale ulserasie of obstruksie nie. Versigtigheid moet aan die dag gelê word by pasiënte met nier of adrenokortikale ontoereikendheid, hartsiekte, akute dehidrasie, hitte krampe, uitgebreide weefsel skade soos wat voorkom by erge brandwonde, of in die geval van pasiënte wat kaliumsparende diuretika gebruik.

Die toediening van **ULTIPOT** word nie aanbeveel by pasiënte wat ly aan stomas, as gevolg van die veranderde intestinale deurgang tyd. **ULTIPOT** moet met versigtigheid gegee word vir pasiënte wat medisyne ontvang wat hipomagnesemie tot gevolg kan hê. Plasma magnesium vlakke behoort bepaal te word en die nodige aanpassings moet gemaak word by hierdie pasiënte.

Kinders:

Die veiligheid en effektiwiteit van **ULTIPOT** in kinders is nog nie bevestig nie.

BEKENE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Akute oordosering van **ULTIPOT** tablette mag naarheid, braking, diarree en abdominale krampe tot gevolg hê. Die maag behoort geleidelik te word deur maagspoeling.

Ongewense effekte is hoofsaaklik kardiovaskulêr, soos hipotensie, skok, ventrikulêre disritmie, bondel-tak blok, ventrikulêre fibrillasie, en neuromuskulêr, soos parestesie, konvulsies, arefleksie, verlamming van skelet spiere wat verlamming van die asemhalings spiere kan veroorsaak. Verhoogde serum kalium konsentrasies en kenmerkende EKG veranderinge kan ook waargeneem word (verhoogde omvang en pieke van die T-golf, verdwyning van die P-golf, verwyding van QRS kompleks, en ST onderdrukking). Gastro-intestinale ulserasie. Kardiaal toksisiteit kan behandel word met intraveneuse toediening van kalsium sout met EKG monitoring.

Verdere behandeling is simptome en ondersteunend.

Hiperkalemie as gevolg van 'n kroniese oordosering of as 'n gevolg van medisyne interaksies: Kalium bevattende voedsel, medisyne en kalium- sparende diuretika moet gestaak word. Serum kalium kan verminder word deur infusie met glukose en insulien. Wanneer hiperkalemie behandel word, kan die te vinnige verlag van die serum kalium konsentrasies digitalis toksisiteit in pasiënte veroorsaak wat voorheen gestabiliseer was op digitalis.

IDENTIFIKASIE:

Lig geel langwerpige, bikonvekse, film-bedeekte tablet.

AANBIEDING:

ULTIPOT tablette is beskikbaar in houers van 30 en 500 tablette. Die tablette word verpak in wit plastiek houers.

BERGINGSINSTRUKSIES:

Bewaar by of benede 25 °C, op 'n koel plek en beskerm teen lig en vog. Resepteer in vobbestande houers. Hou die houer dig toe.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

35/24/0370

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT:

MIRREN (PTY) LTD
18 Golden Drive
Morehill
Benoni
South Africa

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- heparien wat gebruik word om bloed dunner te maak
- digokisien vir 'n ongereelde hartklop
- antikolinergika vir abnormale of maag spasmas of krampe soos atropien sulfaat of hiosien butielbromied
- penisillien 'n antibiotika vir die behandeling van bakteriële infeksies
- litium vir die behandeling of voorkoming van manie of depressie in pasiënte met bipolêre affektiewe toestand.

Indien u enige ander medisyne op 'n gereelde grondslag gebruik, insluitend komplementere of tradisionele medisyne, kan die gelyktydige gebruik van **ULTIPOT** saam met die ander medisyne ongewenste interaksies veroorsaak. Raadpleeg u dokter, apteker of ander gesondheidsorgkundige.

INSTRUKSIES HOE OM ULTIPTOT TE GEBRUIK:

Moenie die medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem altyd **ULTIPOT** presies volgens u dokter se instruksies. As u nie seker is nie raadpleeg u dokter of apteker. Die gewone daaglikse dosis is 6 tot 12 tablette, in verdeelde dosisse. Nie meer as 2 tablette (16 mmol) behoort in 'n enkele dosis geneem te word nie. Die tablette moet heel ingesluk word. Moenie die tablette breek of kou voordat dit gesluk word nie.

Indien u onder die indruk is dat die werking van **ULTIPOT** te sterk of te swak is, raadpleeg u dokter of apteker.

Moenie die voorgestelde dosis oorskry nie.

Indien u meer ULTIPTOT neem as wat u behoort:

Indien u per ongeluk te veel tablette neem, of iemand anders neem u medisyne, raadpleeg dadelik u dokter of apteker. Wys enige oorbywende medisyne of die lêer houer vir die dokter. Indien nie een beskikbaar is nie kontak die naaste hospitaal of vergiftigings sentrum.

Indien u vergeet om ULTIPTOT te neem:

As u vergeet om 'n dosering te neem, neem dit so gou moontlik, behalwe as dit amper tyd is vir die volgende dosering. Moenie 'n dubbele dosering neem nie. Gaan dan terug na 'n gebruikskedule. Moenie 'n Dubbele dosis neem nie.

NEWE-EFFEKTE:

ULTIPOT kan newe effekte hê.

Indien u enige van die volgende kry, raadpleeg dadelik u dokter of apteker omdat hulle u kan sê of u die gebruik van **ULTIPOT** moet staak:

- erge naarheid (voel naar of gooi op)
- wind wat vassit of slegte spysvertering
- erge maagpyn
- diarree.

raadpleeg u dokter of apteker indien u dink dat u die probleme het of enige ander probleme met **ULTIPOT** het.

Ander newe-effekte wat minder dikwels voorkom:

- hoë bloed vlakke van kalium (wat abnormale hartklop kan veroorsaak)
- jeukerigheid en veluitslag (netel uitslag)
- bloed in u urine
- hoës bloed op (al is dit baie min)
- bloed in u braaksel
- swart stoelgang.

Kry onmiddellik nood mediese hulp as u enige van die tekens van 'n allergiese reaksie kry: galbulte; moeilik asemhaal; swelling van u gesig, lippe, tong of keel.

Indien enige van die newe-effekte erger word of as u enige newe-effekte oplet wat nie gelys is in hierdie biljet nie raadpleeg u dokter of apteker.

Nie al die newe-effekte wat vir **ULTIPOT** aangemeld is, word in hierdie blaadjie genoem nie. Indien u algemene gesondheid verswak terwyl u **ULTIPOT** gebruik, moet u asseblief u dokter, apteker of ander gesondheidsorgkundige raadpleeg.

BERGINGS- EN VERNIETIGINGSINLIGTING:

Bewaar by of benede 25 °C, op 'n koel plek en beskerm teen lig en vog.

Resepteer in 'n vobbestande houer. Hou die houer dig toe.

Moenie gebruik na die vervaldatum wat op die etiket aangegee word nie.

Moenie alle medisyne buite bereik en sig van kinders.

Neem alle ongebruikte medisyne na 'n aptek vir vernietiging.

AANBIEDING:

ULTIPOT tablette is beskikbaar in houers van 30 en 500. Die tablette word verpak in wit plastiese houers.

IDENTIFIKASIE VAN DIE MEDISYNE:

Lig geel langwerpige, bikonvekse, film-bedeekte tablet.

REGISTRASIENOMMER:

35/24/0370

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