SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

PURESIS (tablet)

COMPOSITION

Each tablet of PURESIS contains 40 mg furosemide.

Excipients:

Magnesium stearate, microcrystalline cellulose, modified cellulose gum, purified talc, starch maize, sodium bicarbonate

Sugar free

CATEGORY AND CLASS

A 18.1 Diuretics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Furosemide exerts its diuretic action by virtue of its saluretic properties. Experimental evidence has proved that furosemide acts by reducing the reabsorption of sodium and water at the levels

of the proximal convoluted tubule, ascending limb of Henle's loop and the distal convoluted tubule.

Pharmacokinetic properties

Furosemide thus acts throughout the tubule, and it is today believed that the action of Furosemide on the Loop of Henle is the most important action on the nephron. In situations where other methods of treatment fail to induce diuresis, it is often possible, with furosemide, to increase the excretion of sodium and water, even when the glomerular filtration rate is markedly impaired.

Furosemide lowers pathologically raised blood pressure levels but does not affect normal values.

With furosemide administration, the onset of action is rapid, usually within half-an-hour. Peak action is usually achieved after 2 hours, and the duration of action of the drug is 4 to 5 hours.

INDICATIONS

(a) Ascites due to cirrhosis of the liver, mechanical obstruction or cardiac failure.

(b) To prevent oliguria from progressing to complete anuria.

(c) Cardiac oedema.

(d) Hypertension of mild to moderate degree.

(e) Oedema occurring during the last three months of pregnancy - pre-eclamptic toxaemia and eclampsia (see WARNINGS AND SPECIAL PRECAUTIONS).

CONTRAINDICATIONS

Patients who exhibit hypersensitivity to furosemide.

In hepatic coma and in states of electrolyte depletion. PURESIS is contraindicated if increasing azotaemia and oliguria treatment of severe progressive renal disease.

Lactating women (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

In pregnancy, PURESIS should be administered with great caution and only in carefully selected cases, for short periods of time (see HUMAN REPRODUCTION).

PURESIS should be used with care in patients with prostatic hypertrophy or impairment of micturition.

PURESIS should be used with caution in patients with impaired hepatic function since it may increase the risk of hepatic encephalopathy. It should be used with caution in patients with renal impairment.

The use of PURESIS in patients suffering from acute forms of porphyria, especially variegate porphyria, and to a lesser extent acute intermittent porphyria and hereditary coproporphyria is contentious, and PURESIS should thus be used with caution in these patients.

Excessive diuresis may result in dehydration and reduction in blood volume, with circulatory

collapse and the possibility of vascular thrombosis and embolism, particularly in elderly patients. The excessive loss of potassium in patients receiving cardiac glycosides may precipitate digitalis toxicity. Care should be taken in patients receiving potassium depleting steroids.

Electrolyte disturbance - Hypokalaemia may be reduced with a potassium-rich diet.

If it already exists before the commencement of treatment - which is particularly likely to occur in cases of cirrhosis - the serum potassium should be restored to normal by potassium supplements and, if necessary, by the administration of sodium and chloride. Because of its strong natriuretic effect, PURESIS may cause a decrease in the sodium levels, particularly when the oedema is corrected rapidly.

Electrolyte depletion may manifest itself by weakness, dizziness, lethargy, leg cramps, anorexia, vomiting and/or mental confusion.

Effects on ability to drive and use machines

Not known.

INTERACTIONS

Concomitant therapy with cephaloridine may result in nephrotoxicity.

PURESIS may enhance the nephrotoxicity of cephalosporin antibiotics such as cephalothin and of aminoglycoside antibiotics.

It can also enhance the ototoxicity of aminoglycoside antibiotics. Concurrent administration of phenytoin or indomethacin may reduce the clinical effects of PURESIS.

PURESIS may enhance the toxicity of digitalis glycosides by depleting serum-potassium concentrations.

It may enhance the neuromuscular blocking action of competitive muscle relaxants, such as tubocurarine.

It may enhance the effects of antihypertensive agents.

The potassium-depleting effect of furosemide may be enhanced by corticosteroids, corticotrophin, or carbenoxolone.

Concomitant administration of PURESIS and lithium is generally not recommended since the association may lead to toxic blood concentrations of lithium.

Blood-glucose concentrations should be monitored in patients taking antidiabetic agents as requirements may change.

HUMAN REPRODUCTION

In pregnancy, PURESIS should be administered with great caution and only in carefully selected cases, for short periods of time.

Lactating women should not use PURESIS (see CONTRAINDICATIONS and WARNINGS AND SPECIAL PRECAUTIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults	Initial dose:	One to three tablets.
	Maintenance dose:	Half to one tablet daily.
	Or:	As prescribed by the physician.

SIDE EFFECTS

(i) Various forms of dermatitis including urticaria and exfoliative dermatitis, pruritus, paraesthesia, blurring of vision, yellow vision, dizziness, pancreatitis, photosensitivity, postural hypotension, headache, nausea, vomiting or diarrhoea may occur.

(ii) Anaemia, leucopenia, aplastic anaemia and thrombocytopenia (with purpura) may occur. Agranulocytosis has occurred.

(iii) Asymptomatic hyperuricaemia can occur and gout may be precipitated.

(iv) Alterations in glucose tolerance tests with abnormalities of the fasting and 2-hour post-prandial sugar has been observed, and cases of precipitation of diabetes mellitus have been reported.

(v) PURESIS may lower the serum calcium levels and cases of tetany have been reported.

Hepatic dysfunction, cholestatic jaundice and paraesthesia have been reported. Tinnitus and deafness may occur in particular during rapid high-dose parenteral furosemide therapy. Deafness may be permanent particularly if furosemide has been given to patients taking ototoxic medication.

PURESIS increases the urinary excretion of calcium. Renal stone formation has been reported when PURESIS has been used to treat preterm infants.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

See SIDE EFFECTS above.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A flat, white to off-white bevel edged bisected tablet engraved F above the bisect and 1 below the bisect. “F/1” on one side and plain on the other side.

PRESENTATION

30 or 250 tablets are packed in a white opaque high density polyethylene container with a white opaque high density polyethylene screw closure with a 3 layered induction seal liner.

30 or 250 tablets are packed in a round amber high density polyethylene plastic container with an amber high density polyethylene screw closure with a 3 layered induction seal liner.

250 tablets are packed in a white polypropylene securitainer with low linear density polyethylene closures.

30 tablets are packed in a red polyvinylchloride/polyvinylidene chloride blister strips sealed with an aluminium foil backing. Blisters are packed into a cardboard outer carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H/18.1/185

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 19 May 1976

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Botswana: B9322745 S2

Namibia: NS2 90/18.1/001160

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SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

PURESIS (tablet)

SAMESTELLING

Elke tablet van PURESIS bevat 40 mg furosemied.

Eksipiënte:

Magnesiumstearaat, mikrokristallyne sellulose, gewysigde sellulose gom, gesuiwerde talk, mieliestysel, natriumbikarbonaat

Suikervry

KATEGORIE EN KLAS

A 18.1 Diuretika

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Furosemied oefen sy diuretiese werking uit vanweë sy saluretiese eienskappe. Eksperimentele bewyse het getoon dat furosemied werksaam is deur herabsorbsie van natrium en water by die vlakke van die proksimale kronkelbuisie, die stygende deel van Henle se lus, en die distale kronkelbuisie te verminder.

Farmakokinetiese eienskappe

Furosemied werk dus regdeur die buisie, en dit word vandag aangeneem dat die werking van furosemied op die Lus van Henle, die mees belangrikste werking op die nefron is. In situasies waar ander metodes van behandeling nie daarin kon slaag om diurese te induseer nie, is dit dikwels moontlik, met furosemied, om die uitskeiding van natrium en water te verhoog, selfs wanneer die glomerulêre filtrasietempo merkbaar ingekort is.

Furosemied verlaag patologies verhoogde bloeddrukvlakke, maar het geen uitwerking op normale waardes nie.

Met toediening van furosemied is die aanvang van werking vinnig, gewoonlik binne ’n halfuur. Piek werking word gewoonlik verkry na 2 ure en die tydperk van werking van die geneesmiddel is 4 tot 5 uur.

INDIKASIES

(a) Askites as gevolg van lewersirrose, meganiese obstruksie of hartversaking.

(b) Om te voorkom dat oligurie oorgaan na algehele anurie.

(c) Kardiale edeem.

(d) Hipertensie van ligte tot matige graad.

(e) Edeem wat voorkom gedurende die laaste drie maande van swangerskap - pre-eklamptiese toksemie en eklampsie (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

KONTRA-INDIKASIES

Pasiënte wat hipersensitiwiteit teenoor furosemied toon.

By hepatiese koma en by gevalle van elektroliet uitputting. PURESIS is teenaangedui indien asotemie en oligurie behandeling van progressiewe renale siekte verhoog word.

Lakterende vrouens (sien MENSLIKE VOORTPLANTING).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Tydens swangerskap, moet PURESIS met groot versigtigheid toegedien word en slegs by noukeurig geselekteerde gevalle, vir kort tydperke (sien MENSLIKE VOORTPLANTING).

PURESIS moet met sorg by pasiënte met prostatiese hipertrofie of inkorting van mikturisie gebruik word.

PURESIS moet met versigtigheid by pasiënte met ingekorte hepatiese funksie gebruik word aangesien dit die risiko van hepatiese ensefalopatie kan verhoog. Dit moet met versigtigheid by pasiënte met renale inkorting gebruik word.

Die gebruik van PURESIS by pasiënte wat aan akute vorms van porfirie ly, veral gevaieerde porphyria, en tot ’n mindere mate akute intermitterende porfirie en oorerflike koproporfirie is omstrede, en PURESIS moet dus met versigtigheid by hierdie pasiënte gebruik word.

Oormatige diurese kan lei tot dehidrasie en verlaging in bloedvolume, met sirkulatoriese ineenstorting en die moontlikheid van vaskulêre trombose en embolisme, veral by bejaarde pasiënte.

Die oormatige verlies van kalium by pasiënte wat hartglikosiede ontvang kan digitalis toksisiteit ontketen. Versigtigheid moet geneem word by pasiënte wat kalium uitputtende steroïde ontvang.

Elektroliet versteuring - Hipokalemie kan met ’n kalium-ryke dieet verminder word.

Indien dit alreeds bestaan voor die aanvang van behandeling - wat veral waarskynlik by gevalle van sirrose sal voorkom - moet die serum kalium herstel word na normaal deur kalium aanvullings en, indien nodig, deur die toediening van natrium en chloried. As gevolg van sy sterk natriuretiese effek, kan PURESIS ’n verlaging in die natrium vlakke veroorsaak, veral wanneer die edeem vinnig reggestel word.

Elektroliet uitputting kan op sigself deur swakheid, duiseligheid, moegheid, krampe in die bene, anoreksie, braking en/of geestelike verwarring openbaar word.

Effekte op die vermoë om te bestuur en masjinerie te gebruik

Onbekend.

INTERAKSIES

Meegaande terapie met kefaloridien kan nefrotoksisiteit tot gevolg hê.

PURESIS kan die nefrotoksisiteit van kefalosporien antibiotika soos kefalotien en van aminoglikosied antibiotika versterk.

Dit kan ook die ototoksisiteit van aminoglikosied antibiotika versterk. Meegaande toediening van fenitoïen of indometasien kan die kliniese effekte van PURESIS verminder.

PURESIS kan die toksisiteit van digitalis glikosiede versterk deur die uitputting van serum-kalium konsentrasies.

Dit kan die neuromuskulêre blokkerende werking van kompeterende spierverslappers, soos tubokurarien versterk.

Dit kan die effek van antihipertensiewe middels versterk.

Die kalium-uitputtende effek van furosemied kan deur kortikosteroïede, kortikotropien, of karbenoksoloon versterk word.

Meegaande toediening van PURESIS en litium word gewoonlik nie aanbeveel nie aangesien dit tot toksiese bloedkonsentrasies van litium kan lei.

Bloed-glukose konsentrasies moet gemoniteer word by pasiënte wat antidiabetiese middels neem aangesien vereistes kan verander.

MENSLIKE VOORTPLANTING

Tydens swangerskap, moet PURESIS tablette met groot versigtigheid toegedien word en slegs by noukeurig geselekteerde gevalle, vir kort tydperke.

Lakterende vrouens moenie PURESIS gebruik nie (sien KONTRA-INDIKASIES en WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes	Aanvangsdosis:	Een tot drie tablette.
	Instandhoudingsdosis:	Half tot een tablet daagliks.
	Of:	Soos deur die geneesheer voorgeskryf.

NEWE-EFFEKTE

(i) Verskeie vorms van dermatitis insluitende urtikarie en eksfoliatiewe dermatitis, pruritus, parestesie, dowwe visie, geel visie, duiseligheid, pankreatitis, fotosensitiwiteit, posturale hipotensie, hoofpyn, naarheid, braking of diarree kan voorkom.

(ii) Anemie, leukopenie, aplastiese anemie en trombositopenie (met purpura) kan voorkom.

Agranulositose het voorgekom.

(iii) Asimptomatiese hiperurisemie kan voorkom en jig kan ontketen word.

(iv) Veranderings in glukose verdraagsaamheidstoetse met abnormaliteite van die vastende en 2-uur na-maaltyd suiker is waargeneem, en gevalle van ontketening van diabetes mellitus is aangemeld.

(v) PURESIS kan die serum kalsiumvlakke verlaag en gevalle van tetanie is aangemeld.

Hepatiese wanfunksie, cholestatiese geelsug en parestesie is aangemeld. Tinnitus en doofheid kan veral voorkom tydens vinnige hoë-dosis parenterale furosemied terapie. Doofheid kan permanent wees veral indien furosemied gegee is aan pasiënte wat ototoksiese medisyne neem.

PURESIS verhoog die urinêre uitskeiding van kalsium. Renale steen vorming is aangemeld wanneer PURESIS gebruik word om premature babas te behandel.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Simptome

Sien NEWE-EFFEKTE hierbo.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

'n Plat, wit tot naaswit afgeskuinste tablet met 'n halveerlyn, gegraveer met 'n F bo die halveerlyn en 1 onder die halveerlyn. "F/1" aan die een kant en gewoon aan die ander kant.

AANBIEDING

30 of 250 tablette word verpak in ’n wit, ondeursigtige hoëdigtheidspoliëtileen houer met ’n wit, ondeursigtige hoëdigtheidspoliëtileen skroefsluiting, met ’n 3 laag induksieseël voering.

30 of 250 tablette word verpak in ’n ronde, amberkleurige hoëdigtheidspoliëtileen plastiese houer, met ’n amberkleurige hoëdigtheidspoliëtileen skroefsluiting, met ’n 3 laag induksieseël voering.

250 tablette word verpak in ’n wit, polipropileen “securitainer” met lae lineêredigtheidspoliëtileen sluitings.

30 tablette word verpak in ’n rooi polivinielchloried/polivinilidienchloried stolpstrokies verseël met ’n aluminiumfoelie rugmateriaal. Stolpstroke word verpak in ’n kartonhouer.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen lig.

Hou in oorspronklike verpakking totdat benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

H/18.1/185

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

Datum van registrasie: 19 Mei 1976

Datum van mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 19 Mei 1976

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