SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

HYPERPHEN-10 (tablet)

HYPERPHEN-50 (tablet)

COMPOSITION

Each tablet of HYPERPHEN-10 contains 10 mg hydralazine hydrochloride.

Excipients:

Colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil, povidone, pregelatinised starch

Sugar free

Each tablet of HYPERPHEN-50 contains 50 mg hydralazine hydrochloride.

Excipients:

Acetylated monoglycerides, carnauba wax, FD and C red 3 (C.I. 45430), hydrogenated vegetable oil, methylated spirit industrial, microcrystalline cellulose, povidone, purified talc, shellac, sodium benzoate, starch maize, sucrose, titanium dioxide (C.I. 77891)

Contains sugar: Sucrose 104,168 mg

CATEGORY AND CLASS

A 7.1.3 Other hypotensives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The major action of hydralazine is direct relaxation of vascular smooth muscle with a greater effect on arterioles than on veins. Therefore, in adequate doses, it decreases arterial blood pressure, diastolic often more than systolic, and peripheral vascular resistance, and increases heart rate, stroke volume, and cardiac output. The preferential dilatation of arterioles minimizes postural hypotension and promotes the increase in cardiac output. The latter may limit the reduction in mean blood pressure produced by the medicine. The peripheral vasodilatation is widespread but not uniform. Glomerular filtration, renal tubular function, and urine volume are not consistently affected; however, in common with many other hypotensive medicines, hydralazine can produce sodium retention and decreased urine volume. Hydralazine usually increases plasma rennin activity. Vascular resistance in the cutaneous and muscle beds may decrease, but this is usually in parallel with the fall in blood pressure and blood flow does not increase.

Effects of hydralazine on organs other than those of cardiovascular system are minor and variable.

INDICATIONS

HYPERPHEN is used to reduce the blood pressure in hypertension.

CONTRAINDICATIONS

HYPERPHEN is contraindicated in patients with tachycardia and should be used with caution in patients with a history of coronary disease.

WARNINGS AND SPECIAL PRECAUTIONS

Chronic administration of HYPERPHEN, particularly in doses of 400 mg or more per day, can produce an acute rheumatoid state. This has been reported in approximately 10 % of patients receiving high doses and a syndrome indistinguishable from disseminated lupus erythematosus develops in smaller percentage. The symptoms regress after HYPERPHEN is discontinued but relatively long-term treatment with adrenocorticosteroids may be required.

Reduced doses of HYPERPHEN should be given to patients who are slow acetylators. Hypotension may occur during anaesthesia in patients being treated with HYPERPHEN.

Excipients

HYPERPHEN-50 contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take HYPERPHEN-50

INTERACTIONS

Adrenaline should not be given to antagonise the hypotensive effects of HYPERPHEN since it enhances the cardiac-accelerating effects.

Caution should be observed if HYPERPHEN is administered concurrently with monoamine oxidase inhibitors or tricyclic antidepressants.

The hypotensive effects of HYPERPHEN may be enhanced by thiazide diuretics and by ß-adrenergic blocking agents which may also diminish the cardiac-accelerating effects.

HUMAN REPRODUCTION

The safety of this preparation in pregnant women has not yet been established.

DOSAGE AND DIRECTIONS FOR USE

The usual oral dose is 100 mg to 200 mg per day, starting with 10 mg or 20 mg two to four times daily; this is increased gradually until the desired effect is obtained or unacceptable side effects develop. The dose should not exceed 300 mg per day.

SIDE EFFECTS

Side effects occurring frequently are tachycardia, palpitations, angina, sweating, severe headache, anorexia, nausea, vomiting, diarrhoea and postural hypotension.

Side effects occurring less frequently are conjunctivitis, lacrimation, chills, fever, vertigo, flushing, dyspnoea, malaise, muscle cramps and nasal congestion. Occasionally hepatitis, local oedema, urinary retention, emotional depression, paralytic ileus, anxiety and tremor occur. Rarely medicine related fever, urticaria, skin rash, polyneuritis, gastro-intestinal haemorrhage, anaemia and pancytopenia occurs and requires termination of therapy.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Tachycardia, palpitations, severe headache, anorexia, nausea, vomiting, postural hypotension, lachrimation, nasal congestion and peripheral neuritis.

Treatment

Empty the stomach by aspiration and lavage. Treatment for tachycardia and relative hypovolaemia may be indicated.

IDENTIFICATION

HYPERPHEN-10: Off-white to pale yellow, round, flat bevelled edge tablet bisected on one side and plain on the other side.

HYPERPHEN-50: Pink sugar-coated, deep biconvex tablet, free from cracking, chipping or peeling.

PRESENTATION

HYPERPHEN-10:

30, 100 or 500 tablets are packed in a white cylindrical polypropylene container with a white low density polyethylene cap, together with a foam or rayon insert and a leaflet.

HYPERPHEN-50:

30, 100 or 500 tablets are packed in a white cylindrical polypropylene container with a white low density polyethylene cap, together with a polyester fibre insert, with or without desiccant and a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from moisture and light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

HYPERPHEN-10: M/7.1.3/39

HYPERPHEN-50: M/7.1.3/40

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: 06 August 1979

Date of the most recent amendment to the professional information as approved by the Authority:

Botswana:	S2
HYPERPHEN-10:	B9322355
HYPERPHEN-50:	B9322360

Namibia:	NS2
HYPERPHEN-10	90/7.1.3/00976
HYPERPHEN-50:	90/7.1.3/00977

Zimbabwe:	P.P.10
HYPERPHEN-50:	92/12.3.1/2608

ZA_HYPETAB_7908_04

SUID AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

HYPERPHEN-10 (tablet)

HYPERPHEN-50 (tablet)

SAMESTELLING

Elke HYPERPHEN-10 tablet bevat 10 mg hidralasienhidrochloried.

Eksipiënte:

Kolloïdale silikondioksied, krospovidoon, gehidrogeneerde plantolie, povidoon, pregelatiniseerde stysel

Suikervry

Elke HYPERPHEN-50 tablet bevat 50 mg hidralasienhidrochloried.

Eksipiënte:

Asetileerde monogliseriede, karnauba was, FD en C rooi 3 (C.I. 45430), gehidrogeneerde plantolie, industriële brandspiritus, mikrokristallyne sellulose, povidoon, gesuiwerde talk, skellak, natriumbensoaat, mieliestysel, sukrose, titaandioksied (C.I. 77891)

Bevat suiker: Sukrose 104,168 mg

KATEGORIE EN KLAS

A 7.1.3 Ander hipotensiewe middels

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Die hoofwerking van hidralasien is direkte verslapping van vaskulêre gladdespier met ’n groter effek op arteriole as op are. Daarom verlaag dit, in voldoende dosisse, arteriële bloeddruk, meer dikwels diastolies as sistolies, en perifere vaskulêre weerstand, en verhoog dit harttempo, slagvolume en kardiale omset. Die voorkeur dilatasie van arteriole minimaliseer posturale hipotensie en bevorder die toename in die kardiale omset. Laasgenoemde kan die vermindering in gemiddelde bloeddruk, wat die medisyne teweegbring, beperk. Die perifere vasodilatasie is wydverspreid maar nie eenvormig nie. Glomerulêre filtrasie, renale tubulêre funksie, en urienvolume word nie konsekwent beïnvloed nie; alhoewel, in gemeen met baie ander hipotensiewe medisyne, kan hidralasien natriumretensie en verminderde urienvolume teweegbring. Hidralasien verhoog gewoontlik plasmarenienaktiwiteit. Vaskulêre weerstand in die kutaneuse en spierbeddens kan verminder, maar dis gewoonlik in ooreenstemming met die bloeddrukverlaging, en bloedvloei wat nie toeneem nie.

Effekte van hidralasien op ander organe as dié van die kardiovaskulêre stelsel is gering en wisselvallig.

INDIKASIES

HYPERPHEN word gebruik om die bloeddruk te verminder by hipertensie.

KONTRA-INDIKASIES

HYPERPHEN is teenaangedui by pasiënte met tagikardie en moet versigtig by pasiënte met ’n geskiedenis van koronêre siekte gebruik word.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Chroniese toediening van HYPERPHEN, veral in dosisse van 400 mg of meer per dag, kan ’n akute rumatoïede toestand veroorsaak. Dit was aangemeld by ongeveer 10 % van pasiënte wat hoë dosisse ontvang en ’n sindroom, ononderskeibaar van verspreide lupus erythematose, ontwikkel by ’n kleiner persentasie. Die simptome neem af nadat HYPERPHEN gestaak word, maar relatiewe langtermynbehandeling met adrenokortikosteroïede kan nodig wees.

Verminderde dosisse van HYPERPHEN moet aan pasiënte, wat stadige asetileerders is, gegee word. Hipotensie kan voorkom gedurende narkose by pasiënte wat met HYPERPHEN behandel word.

Eksipiënte

HYPERPHEN-50 bevat sukrose wat ’n effek op die glisemiese beheer van pasiënte met diabetes mellitus kan hê. Pasiënte met die seldsame oorerflike toestande soos fruktose onverdraagsaamheid, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid moenie HYPERPHEN-50 neem nie.

INTERAKSIES

Adrenalien moenie gegee word om die hipotensiewe effekte van HYPERPHEN te antagoniseer nie aangesien dit die hartversnellende effekte versterk.

Sorg moet geneem word indien HYPERPHEN saam met mono-amienoksidase inhibeerders of trisikliese antidepressante toegedien word.

Die hipotensiewe effekte van HYPERPHEN kan versterk word deur tiasied-diuretika en deur ß-adrenergiese blokkeerders wat ook die hartversnellende effekte kan verminder.

MENSLIKE VOORTPLANTING

Die veiligheid van hierdie preparaat by swanger vrouens is nog nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS

Die gewone mondelikse dosis is 100 mg tot 200 mg per dag, deur met 10 mg of 20 mg twee tot vier keer per dag te begin; dit word geleidelik verhoog totdat die gewenste effek bereik word of onaanvaarbare newe-effekte ontwikkel. Die dosis moenie 300 mg per dag oorskry nie.

NEWE-EFFEKTE

Newe-effekte wat dikwels voorkom is tagikardie, palpitasies, angina, sweet, ernstige hoofpyn, anoreksie, naarheid, braking, diarree en posturale hipotensie.

Newe-effekte wat minder dikwels voorkom is konjunktivitis, lakrimasie, koue rillings, koors, vertigo, blosing, dispnee, malaise, spierkrampe en neusstuwing. Soms vind hepatitis, plaaslike edeem, urienretensie, teneergedruktheid, verlamde ileus, angstigheid en bewing plaas. Medisyne verwante koors, urtikarie, veluitslag, polineuritis, gastroïntestinale bloeding, anemie en pansitopenie kom seldsaam voor en vereis die staking van terapie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Simptome

Tagikardie, hartkloppings, ernstige hoofpyn, anoreksie, naarheid, braking, posturale hipotensie, lakrimasie, neusstuwing en perifere neuritis.

Behandeling

Ledig die maag deur aspirasie en maagspoeling. Behandeling vir tagikardie en relatiewe hipovolemie kan aangedui wees.

IDENTIFIKASIE

HYPERPHEN-10: Naaswit tot liggeel, ronde, plat tablet met afgeskuinste kante, gehalveer aan die een kant en gewoon aan die ander kant.

HYPERPHEN-50: Pienk, suikerbedekte, diep bikonvekse tablet vry van krake, afsplintering of afskilfering.

AANBIEDING

HYPERPHEN-10:

30, 100 of 500 tablette word verpak in ’n wit silindriese polipropileen houer met ’n wit laedigtheidspoliëtileen dop saam met ’n skuim- of rayoninsetsel, en ’n voubiljet.

HYPERPHEN-50:

30, 100 of 500 tablette word verpak in ’n wit, silindriese polipropileen houer met ’n wit laedigtheidspoliëtileen dop saam met ’n poliëster vesel-insetsel met of sonder ’n uitdroogmiddel en ’n voubiljet.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen vog en lig.

Hou in oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

HYPERPHEN-10: M/7.1.3/39

HYPERPHEN-50: M/7.1.3/40

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: 06 Augustus 1979

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 06 Augustus 1979

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