HIDRIST
P1533458

HIDRIST
P1533458

PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK
SKEDULERINGSTATUS
SUID-AFRIKA: S3
NAMIBIË: NS2
EIENDOMSNAAM (en doseervorm):
HIDRIST 8 mg TABLETS (tablet)
HIDRIST 16 mg TABLETS (tablet)
HIDRIST 24 mg TABLETS (tablet)

SAMESTELLING:
HIDRIST 8 mg TABLETS:
Elke onbedekte tablet bevat betahistiendihidrochloried 8mg. Bevat suiker: 6.25 mg mannitol.
HIDRIST 16 mg TABLETS:
Elke onbedekte tablet bevat betahistiendihidrochloried 16 mg. Bevat suiker: 12.5 mg mannitol.
HIDRIST 24 mg TABLETS:
Elke onbedekte tablet bevat betahistiendihidrochloried 24 mg. Bevat suiker: 18.75 mg mannitol.
Die ander onaktiewe farmaseutiese bestanddele van die formulering is mikrokristallyne sellulose, povidoon, krospovidoon, watervrye sitroensuur, kolloïdale watervrye silika, talk en stweariensuur.

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.6 Histamiene

FARMAKOLOGIESE WERKING:
Farmakodinamika:
Die meganisme van werking is nie bekend nie. Farmakologiese toetse in diere het aangedui dat die bloedsirkulasie in die striae vascularis van die binneoor verbeter, waarskynlik as gevolg van 'n verslapping van die prekapillêre sfinkters van die mikrosirkulasie van die binneoor.
Daar is in farmakologiese studies gevind dat betahistien 'n swak H_1- reseptor-agonistiese en aansienlike H_3-antagonistiese eienskappe besit in 1 3 die outonome senusisteem en die sentrale senuweestelsel. Daar is ook gevind dat betahistien 'n dosis-afhanklike inhiberende effek het op spits generasie van neurone in laterale en mediale vestibulêre nukleï. Die belangrikheid van hierdie waarneming met betrekking tot die werking teen Ménière se sindroom of vestibulêre vertigo, bly steeds onduidelik.

Farmakokinetika:
Na orale toediening word betahistien volledig geabsorbeer. Slegs een metaboliet, 2-piridiel-asynsuur wat in die urine uitgeskei word, is bekend.

INDIKASIES:
HIDRIST TABLETS word aangedui vir die simptomatiese behandeling van vertigo geassosieer met Ménière se sindroom.

KONTRA-INDIKASIES:
- Hipersensitiwiteit teen enige van die bestanddele.
- Pasiënte met aktiewe peptiese ulkus.
- Pasiënte met feochromositoom.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
HIDRIST TABLETS behoort met omsigtigheid toegedien te word pasiënte met brongiale asma omdat kliniese intoleransie in 'n relatief klein getal pasiënte aangedui kon word. Omsigtigheid word aanbeveel by pasiënte met 'n geskiedenis van peptiese ulkusse.
Gelyktydige gebruik saam met antihistamiene behoort vermy te word (sien "**INTERAKSIES**").

Effekte op die vermoë om te bestuur en masjinerie te gebruik:
Op die basis van die farmakodinamiese profiel en gerapporteerde nadelige reaksies (sien **"NEWE EFFEKTE"**), het **HIDRIST TABLETS** geen of slegs nietige effekte op die vermoë om te bestuur en masjiene te gebruik.

INTERAKSIES:
Gelyktydige gebruik saam met antihistamiene moet vermy word (Sien "**WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**").

SWANGERSKAP EN LAKTASIE:
Daar is onvoldoende data oor die gebruik van hierdie medisyne tydens swangerskap en laktasie. **HIDRIST TABLETS** behoort dus nie tydens swangerskap en laktasie gebruik te word nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes (insluitend bejaardes): Aanvanklik 16 mg drie keer daagliks wat verkieslik saam met maaltye geneem word.
Onderhoudsdosisse is gewoonlik in die reikwydte van 24 tot 48 mg daagliks, in verdeelde dosisse.

HIDRIST 8 mg TABLETS	HIDRIST 16 mg TABLETS	HIDRIST 24 mg TABLETS
1 - 2 tablette 3 keer/dag	½ - 1 tablet 3 keer/dag	1 tablet 2 keer/dag

Die dosis behoort individueel aangepas te word volgens die reaksie.
Kinders: Geen dosisaanbevelings word vir kinders gemaak nie.

NEWE EFFEKTE:
HIDRIST TABLETS mag die volgende newe effekte veroorsaak:
Immuunsisteemversteurings:
Minder frekwent: Hipersensitiwiteitsreaksies bv. anafilakse.
Senusisteemversteurings:
Minder frekwent: Hoofpyn.
Gastroïntestinale versteurings:
Frekwent: Gastroïntestinale versteurings. Dit kan normaalweg gehanteer word deur die dosis te verminder of deur die dosis gedurende maaltye te neem.
Vel- en onderhuidse weefselversteurings:
Minder frekwent: Hipersensitiwiteitsreaksies van die vel is aangemeld, veral veluitslag, pruritus en urtikarie.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Sien "**NEWE EFFEKTE**". Die mees algemene simptome is naarheid, braking en hoofpyn. Hipotensie mag voorkom. Daar is geen spesifieke teenmiddel nie. Behandeling mag maaglediging deur induksie van emese of deur spoeling, insluit. Verdere behandeling is simptomaties en ondersteunend.
IDENTIFIKASIE:
HIDRIST 8 mg TABLETS:
Wit tot byna wit ronde, plat, onbedekte tablette gedebosseleer met 'X' aan een kant en '87' aan die ander kant.
HIDRIST 16 mg TABLETS:
Wit tot byna wit ronde, onbedekte tablette gedebosseleer met 'X' en 'n breeklyn aan een kant en '88' aan die ander kant.
HIDRIST 24 mg TABLETS:
Wit tot byna wit ronde, onbedekte tablette gedebosseleer met 'X' en 'n breeklyn aan een kant en '89' aan die ander kant.
AANBIEDING:
HIDRIST 8 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakking bevat 10 tablette.
Verpakkingsgrootte: 30s: Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houers met polipropileen sluitstukke met 'n induksie seëlvulsel wat 'n katoenspoel bevat. Elke houer bevat 30 tablette.
Verpakkingsgrootte: 30s - Een HDPE houer bevat 30 tablette.
HIDRIST 16 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakking bevat 10 tablette.
Verpakkingsgrootte: 30s: Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houer met polipropileen sluitstukke met 'n induksie seëlvulsel wat 'n katoenspoel bevat. Elke houer bevat 30 tablette.
Verpakkingsgrootte: 30s - Een HDPE houer bevat 30 tablette.
HIDRIST 24 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakking bevat 10 tablette.
Verpakkingsgrootte: 20s: Elke kartondoos bevat 2 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houers met polipropileen sluitstukke met 'n induksie seëlvulsel wat 'n katoenspoel bevat. Elke houer bevat 20 tablette.
Verpakkingsgrootte: 20s - Een HDPE houer bevat 20 tablette.
BEWARINGSINSTRUKSIES:
Bewaar by of benede 25 °C.
Moenie die stulpverpakkings uit die kartondoos verwyder nie totdat dit benodig word. Hou die houers dig gesluit.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER:
SUID-AFRIKA:
HIDRIST 8 mg TABLETS: 45/5.6/0571
HIDRIST 16 mg TABLETS: 45/5.6/0572
HIDRIST 24 mg TABLETS: 45/5.6/0573
NAMIBIË:
HIDRIST 8 mg TABLETS: 18/5.6/0058
HIDRIST 16 mg TABLETS: 18/5.6/0057
HIDRIST 24 mg TABLETS: 18/5.6/0056
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,
1448, Suid Afrika.
DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:
Datum van registrasie:
6 Maart 2014
Datum van hersiening:
13 Maart 2023

✂ DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSBLAD
SUID-AFRIKA: S3
NAMIBIË: NS2
HIDRIST 8 mg TABLETS (tablet)
HIDRIST 16 mg TABLETS (tablet)
HIDRIST 24 mg TABLETS (tablet)
Betahistiendihidrochloried

Lees die hele brosjure sorgvuldig voordat u begin om HIDRIST TABLETS te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **HIDRIST TABLETS** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT HIDRIST TABLETS BEVAT
Die aktiewe bestanddeel is betahistiendihidrochloried.
HIDRIST 8 mg TABLETS:
Elke onbedekte tablet bevat 8 mg betahistiendihidrochloried. Bevat suiker: 6.25 mg mannitol.
HIDRIST 16 mg TABLET:
Elke onbedekte tablet bevat 16 mg betahistiendihidrochloried. Bevat suiker: 12.5 mg mannitol.
HIDRIST 24 mg TABLETS:
Elke onbedekte tablet bevat 24 mg betahistiendihidrochloried. Bevat suiker: 18.75 mg mannitol.
Die ander onaktiewe farmaseutiese bestanddele van die formulering is mikrokristallyne sellulose, povidoon, krospovidoon, watervrye sitroensuur, kolloïdale watervrye silika, talk en stweariensuur.

2. WAARVOOR HIDRIST TABLETS GEBRUIK WORD
HIDRIST TABLETS word gebruik om vertigo (duiseligheid) wat met Ménière se sindroom geassosieer word, te behandel.
Vertigo is 'n kondisie wat veroorsaak dat lyers daaraan 'n sensasie van rotasie of beweging van hulself of hul omgewing ondervind. **HIDRIST TABLETS** werk deur die bloedvloei in die binne-oor te verbeter. Dit verminder die opbou van druk.

3. VOORDAT U HIDRIST TABLETS NEEM
Moenie HIDRIST TABLETS neem:
- As u hipersensitief (allergies) teen betahistiendihidrochloried of enige van die ander bestanddele van **HIDRIST TABLETS** is.
- As u aan 'n maagulkus ly.
- As u aan feochromositoom ('n tumor van die bynier) ly.

Neem spesiale sorg met HIDRIST TABLETS:
- As u aan asma ly.
- As u al ooit aan 'n maagulkus gely het.

Die neem van HIDRIST TABLETS met voedsel:
- **HIDRIST TABLETS** moet verkieslik saam met maaltye geneem word.

Swangerskap en borsvoeding:
- Die veilige gebruik van **HIDRIST TABLETS** gedurende swangerskap en borsvoeding is nie vasgestel nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte nader voordat u **HIDRIST TABLETS** neem.

Effek op die vermoë om te bestuur of om met masjinerie te werk.
Dit wil nie voorkom asof **HIDRIST TABLETS** 'n persoon slaperig of lomerig maak nie. U kan daarom motor bestuur of met masjinerie werk, indien nodig. Raadpleeg asseblief u dokter of apteker vir advies.

Die neem van ander medisyne saam met HIDRIST TABLETS:
- Moenie **HIDRIST TABLETS** saam met antihistamiene (d.i. medisyne wat vir die behandeling van allergieë gebruik word) neem nie.

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik.
(Dit sluit komplementêre en tradisionele medisyne in).

4. HOE OM HIDRIST TABLETS TE NEEM

Neem altyd **HIDRIST TABLETS** presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **HIDRIST TABLETS** te sterk of te swak is, moet u u dokter of apteker raadpleeg. Moenie medisyne wat aan u voorgeskryf is met enigiemand anders deel nie.

- **Volwassenes (insluitende bejaardes):**
  - **HIDRIST TABLETS** moet verkieslik saam met maaltye geneem word.
  - Die dosis word volgens die indiwiduele pasiënt se respons bereken. Afhangende van die graad van erns van u klagte, sal u dokter die nodige dosis vir die behandeling van u siekte bepaal.
  - Die normale begindosis is 16 mg drie keer per dag.
  - Daarna is die normale dosis 24 – 48 mg daagliks, geneem in verdeelde dosisse.
- **Kinders:**
  - **HIDRIST TABLETS** behoort nie in kinders gebruik te word nie.

As u te veel HIDRIST TABLETS geneem het:
- Die simptome van oordosering sluit naarheid, braking en hoofpyn in. Lae bloeddruk mag voorkom.
- Behandeling kan maaglediging insluit.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

As u vergeet het om HIDRIST TABLETS te neem:
- Moenie die dosis verdubbel om vir die oorgeslane dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE
HIDRIST TABLETS kan newe effekte hê.
Kry onmiddellik nood mediese hulp as u enige van hierdie **tekens van 'n allergiese reaksie toon:**
- Moeite met asemhaling; swelling van u gesig, lippe, tong of keel.
- 'n Rooi veluitslag, ontsteekte jeukerige vel; urtikarie.

Ander newe effekte sluit die volgende in: Hoofpyn, jeuk, urtikarie, geringe maagklagtes soos braking, maagpyn en opgeblaasdheid. Deur **HIDRIST TABLETS** met maaltye te neem of die dosis te verminder kan help om enige maagprobleme te verminder.
Stel u dokter so gou as moontlik in kennis as enige van die bogenoemde newe-effekte erg of kwellend is, of as hulle nie verdwyn nie of as u enige besorgdheid het terwyl u **HIDRIST TABLETS** neem.

Nie al die newe effekte wat vir **HIDRIST TABLETS** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **HIDRIST TABLETS** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN HIDRIST TABLETS
Berg by of benede 25 °C (kamertemperatuur).
Moenie die stolpstrokies uit die karton verwyder tot voor gebruik nie.
Hou die houers dig toe.

Bewaar alle medisyne buite bereik van kinders.

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN HIDRIST TABLETS
HIDRIST 8 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakkings bevat 10 tablette.
Verpakkingsgrootte: 30s - Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houers met polipropileen sluitstukke met 'n induksie seëlvulsel wat a katoenspoel bevat. Elke houer bevat 30 tablette.
Verpakkingsgrootte: 30s - Een HDPE houer bevat 30 tablette.
HIDRIST 16 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakkings bevat 10 tablette.
Verpakkingsgrootte: 30s - Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houers met polipropileen sluitstukke met 'n induksie seëlvulsel wat 'n katoenspoel bevat. Elke houer bevat 30 tablette.
Verpakkingsgrootte: 30s - Een HDPE houer bevat 30 tablette.
HIDRIST 24 mg TABLETS:
1) Stulpverpakking:
Tablette word in stulpverpakkings (bestaande uit OPA/ aluminiumfoelie/ PVC-film en gedrukte aluminiumfoelie) verpak. Elke stulpverpakkings bevat 10 tablette.
Verpakkingsgrootte: 20s - Elke kartondoos bevat 2 stulpverpakkings van 10 tablette elk.
2) HDPE Houer:
Tablette word verpak in 40 ml HDPE houers met polipropileen sluitstukke met 'n induksie seëlvulsel wat a katoenspoel bevat. Elke houer bevat 20 tablette.
Verpakkingsgrootte: 20s - Een HDPE houer bevat 20 tablette.

8. IDENTIFIKASIE VAN HIDRIST TABLETS
HIDRIST 8 mg TABLETS:
Wit tot byna wit ronde, plat, onbedekte tablette met 'X' op die een kant en '87' op die ander kant gedruk.
HIDRIST 16 mg TABLETS:
Wit tot byna wit ronde, onbedekte tablette met 'X' en 'n breeklyn op die een kant en '88' op die ander kant gedruk.
HIDRIST 24 mg TABLETS:
Wit tot byna wit ronde, onbedekte tablette met 'X' en 'n breeklyn op die een kant en '89' op die ander kant gedruk.

9. REGISTRASIENOMMER/VERWYSINGSNOMMER
SUID-AFRIKA:
HIDRIST 8 mg TABLETS: 45/5.6/0571
HIDRIST 16 mg TABLETS: 45/5.6/0572
HIDRIST 24 mg TABLETS: 45/5.6/0573
NAMIBIË:
HIDRIST 8 mg TABLETS: 18/5.6/0058
HIDRIST 16 mg TABLETS: 18/5.6/0057
HIDRIST 24 mg TABLETS: 18/5.6/0056

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,
1448, Suid Afrika.

11. DATUM VAN PUBLIKASIE
Datuum van registrasie:
6 Maart 2014
Datum van hersiening:
13 Maart 2023

PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE
SCHEDULING STATUS
SOUTH AFRICA: S3
NAMIBIA: NS2
PROPRIETARY NAME (and dosage form):
HIDRIST 8 mg TABLETS (tablet)
HIDRIST 16 mg TABLETS (tablet)
HIDRIST 24 mg TABLETS (tablet)
COMPOSITION:
HIDRIST 8 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 8 mg. Contains sugar: 6.25 mg mannitol.
HIDRIST 16 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 16 mg. Contains sugar: 12.5 mg mannitol.
HIDRIST 24 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 24 mg. Contains sugar: 18.75 mg mannitol.
The other inactive pharmaceutical ingredients of the formulation are cellulose microcrystalline, povidone, crospovidone, anhydrous citric acid, colloidal anhydrous silica, talc and stearic acid.
PHARMACOLOGICAL CLASSIFICATION:
A 5.6 Histamine
PHARMACOLOGICAL ACTION:
Pharmacodynamics:
The mechanism of action is not known. Pharmacological testing in animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.
Betahistine was found to have weak H_1 receptor agonistic and considerable H_3 antagonistic properties in the autonomic nervous system and central nervous system in pharmacological studies. Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei. However, the importance of this observation in the action against Ménière's syndrome or vestibular vertigo remains unclear.
Pharmacokinetics:
After oral administration, betahistine is completely absorbed. Only one metabolite, 2-pyridyl-acetic acid, which is excreted in the urine is known.
INDICATIONS:
HIDRIST TABLETS are indicated for the symptomatic treatment of the vertigo associated with Ménière's syndrome.
CONTRA-INDICATIONS:
- Hypersensitivity to any of the ingredients.
- Patients with an active peptic ulcer.
- Patients with phaeochromocytoma.

WARNINGS AND SPECIAL PRECAUTIONS:
HIDRIST TABLETS should be administered with caution to patients with bronchial asthma as clinical intolerance has been shown in relatively few patients. Caution is advised in patients with a history of peptic ulcers.
Concomitant use with anti-histamines should be avoided (see "**INTERACTIONS**").
Effects on the ability to drive and use machines:
On the basis of the pharmacodynamics profile and reported adverse reactions (see "**SIDE EFFECTS**"), **HIDRIST TABLETS** have no or negligible effects on the ability to drive and use machines
INTERACTIONS:
Concomitant use with antihistamines should be avoided (See **"WARNINGS AND SPECIAL PRECAUTIONS"**).
PREGNANCY AND LACTATION:
There is insufficient data on the use of this medicine during pregnancy and lactation. Therefore **HIDRIST TABLETS** should not be used during pregnancy and lactation.
DOSAGE AND DIRECTIONS FOR USE:
Adults (including the elderly): Initially 16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range of 24 to 48 mg daily, in divided doses.

HIDRIST 8 mg TABLETS	HIDRIST 16 mg TABLETS	HIDRIST 24 mg TABLETS
1 – 2 tablets 3 times/day	½ – 1 tablet 3 times/day	1 tablet 2 times/day

The dosage should be individually adapted according to the response.
Children: No dosage recommendations are made for children.
SIDE EFFECTS:
HIDRIST TABLETS may cause the following side effects:
Immune system disorders:
Less frequent: Hypersensitivity reactions e.g. anaphylaxis.
Nervous system disorders:
Less frequent: Headache.
Gastrointestinal disorders:
Frequent: Gastrointestinal disturbances. These can normally be dealt with by lowering the dose or by taking the dose during meals.
Skin and subcutaneous tissue disorders:
Less frequent: Cutaneous hypersensitivity reactions have been reported, in particular rash, pruritis and urticaria.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "**SIDE EFFECTS**". The most common symptoms are nausea, vomiting and headache. Hypotension may occur. There is no specific antidote. Treatment may include stomach emptying by inducing emesis or by lavage. Further treatment is symptomatic and supportive.
IDENTIFICATION:
HIDRIST 8 mg TABLETS:
White to off–white round, flat, uncoated tablets debossed with 'X' on one side and '87' on the other side.
HIDRIST 16 mg TABLETS:
White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '88' on the other side.
HIDRIST 24 mg TABLETS:
White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '89' on the other side.
PRESENTATION:
HIDRIST 8 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminium foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.
Pack size: 30's - One HDPE container contains 30 tablets.
HIDRIST 16 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.
Pack size: 30's - One HDPE container contains 30 tablets.
HIDRIST 24 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 20's – Each carton contains 2 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 20 tablets.
Pack size: 20's - One HDPE container contains 20 tablets.
STORAGE INSTRUCTIONS:
Store at or below 25 °C.
Do not remove the blisters from the carton until required. Keep the containers tightly closed.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER:
SOUTH AFRICA:
HIDRIST 8 mg TABLETS: 45/5.6/0571
HIDRIST 16 mg TABLETS: 45/5.6/0572
HIDRIST 24 mg TABLETS: 45/5.6/0573
NAMIBIA:
HIDRIST 8 mg TABLETS: 18/5.6/0058
HIDRIST 16 mg TABLETS: 18/5.6/0057
HIDRIST 24 mg TABLETS: 18/5.6/0056
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, Johannesburg,
South Africa, 1448
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DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET
SOUTH AFRICA: S3
NAMIBIA: NS2
HIDRIST 8 mg TABLETS (tablet)
HIDRIST 16 mg TABLETS (tablet)
HIDRIST 24 mg TABLETS (tablet)
Betahistine dihydrochloride

Read all of this leaflet carefully before you start taking HIDRIST TABLETS.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **HIDRIST TABLETS** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT HIDRIST TABLETS CONTAIN
The active substance is betahistine dihydrochloride.
HIDRIST 8 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 8 mg. Contains sugar: 6.25 mg mannitol.
HIDRIST 16 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 16 mg. Contains sugar: 12.5 mg mannitol.
HIDRIST 24 mg TABLETS:
Each uncoated tablet contains betahistine dihydrochloride 24 mg. Contains sugar: 18.75 mg mannitol.
The other ingredients of **HIDRIST TABLETS** are cellulose microcrystalline, citric acid, crospovidone, povidone, silica colloidal anhydrous, stearic acid and talc.
2. WHAT HIDRIST TABLETS ARE USED FOR
HIDRIST TABLETS are used to treat vertigo (dizziness) associated with Ménière's syndrome. Vertigo is a condition that causes sufferers to have a sensation of rotation or movement of themselves or their surroundings. **HIDRIST TABLETS** work by improving blood flow in the inner ear. This lowers the build up of pressure.
3. BEFORE YOU TAKE HIDRIST TABLETS
Do not take HIDRIST TABLETS:
- If you are hypersensitive (allergic) to betahistine dihydrochloride, or any of the other ingredients of **HIDRIST TABLETS**.
- If you have a stomach ulcer.
- If you suffer from phaeochromocytoma (a tumour on the adrenal gland).

Take special care with HIDRIST TABLETS:
- If you have asthma.
- If you have ever had a stomach ulcer.

Taking HIDRIST TABLETS with food:
- **HIDRIST TABLETS** are preferably taken with meals.

Pregnancy and Breastfeeding:
- The safe use of **HIDRIST TABLETS** during pregnancy and breatfeeding has not been determined.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **HIDRIST TABLETS.**

Effects on the ability to drive and use machinery
HIDRIST TABLETS do not appear to make one sleepy or drowsy, so you can drive or operate machinery, if necessary. Please consult your doctor or pharmacist for advice.
Taking other medicines with HIDRIST TABLETS:
- Do not take **HIDRIST TABLETS** together with antihistamine medicines i.e. medicines used for the treatment of allergy.

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

4. HOW TO TAKE HIDRIST TABLETS

Always take **HIDRIST TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **HIDRIST TABLETS** is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

- **Adults (including the elderly):**
  - **HIDRIST TABLETS** are preferably taken with meals.
  - Dosage is determined according to the individual patient response. Depending on the severity of your complaints, your doctor will determine the necessary dose for the treatment of your disease.
  - The usual starting dose is 16 mg three times a day.
  - Thereafter, the usual recommended dose is 24 – 48 mg daily, taken in divided doses.
- **Children:**
  - **HIDRIST TABLETS** should not be used in children.

If you take more HIDRIST TABLETS than you should:
- The symptoms of overdose include nausea, vomiting and headache. Low blood pressure may occur.
- Treatment may include emptying the stomach

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

If you forget to take HIDRIST TABLETS:
- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
HIDRIST TABLETS can have side effects.
Get emergency medical help immediately if you have any of these **signs of an allergic reaction:**
- Difficulty breathing; swelling of your face, lips, tongue, or throat.
- A red skin rash, inflamed itchy skin; hives

Other side effects include: Headache, itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking **HIDRIST TABLETS** during meals or lowering the dose can help reduce any stomach problems.
Tell your doctor as soon as possible if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **HIDRIST TABLETS**.

Not all side effects reported for **HIDRIST TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HIDRIST TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF HIDRIST TABLETS
Store at or below 25 °C (room temperature).
Do not remove the blisters from the carton until required for use.
Keep the containers tightly closed.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF HIDRIST TABLETS
HIDRIST 8 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.
Pack size: 30's - One HDPE container contains 30 tablets.
HIDRIST 16 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.
Pack size: 30's - One HDPE container contains 30 tablets.
HIDRIST 24 mg TABLETS:
1) Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
Pack size: 20's – Each carton contains 2 blisters of 10 tablets each.
2) HDPE Container:
Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 20 tablets.
Pack size: 20's - One HDPE container contains 20 tablets.
8. IDENTIFICATION OF HIDRIST TABLETS
HIDRIST 8 mg TABLETS:
White to off–white round, flat, uncoated tablets debossed with 'X' on one side and '87' on the other side.
HIDRIST 16 mg TABLETS:
White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '88' on the other side.
HIDRIST 24 mg TABLETS:
White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '89' on the other side.
9. REGISTRATION NUMBER/REFERENCE NUMBER
SOUTH AFRICA:
HIDRIST 8 mg TABLETS: 45/5.6/0571
HIDRIST 16 mg TABLETS: 45/5.6/0572
HIDRIST 24 mg TABLETS: 45/5.6/0573
NAMIBIA:
HIDRIST 8 mg TABLETS: 18/5.6/0058
HIDRIST 16 mg TABLETS: 18/5.6/0057
HIDRIST 24 mg TABLETS: 18/5.6/0056
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