PROFESSIONAL INFORMATION
SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM
TREVIGO 24 mg TABLETS

COMPOSITION
Each uncoated tablet contains betahistine dihydrochloride 24 mg.
Excipients: Cellulose microcrystalline, mannitol, povidone, crospovidone, anhydrous citric acid, colloidal anhydrous silica, talc, and stearic acid.
Contains mannitol 18,75 mg.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION
A.5.6 Histamine.

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
The mechanism of action is not known. Pharmacological testing in animals has shown that the blood circulation in the stria 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 (CNS) 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.

Pharmacokinetic properties
After oral administration, betahistine is completely absorbed. Only one metabolite, 2-pyridyl-acetic acid which is excreted in the urine, is known.

INDICATIONS
TREVIGO 24 mg TABLETS are indicated for the symptomatic treatment of the vertigo associated with Ménière's syndrome.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients.
Patients with active peptic ulcer.
Patients with pheochromocytoma.

WARNINGS and SPECIAL PRECAUTIONS
TREVIGO 24 mg 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"**), **TREVIGO 24 mg 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"**).

HUMAN REPRODUCTION
There is insufficient data on the use of this medicine during pregnancy and lactation. Therefore **TREVIGO 24 mg 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.

TREVIGO 24 mg TABLETS
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
TREVIGO 24 mg 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, pruritus 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
White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '89' on the other side.

PRESENTATION
Blister Pack
Tablets are packed in blister packs (composed of OPA / aluminium foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
The blisters will be further packed in pre-printed cartons with a package leaflet.
Pack size: 20's – Each carton contains 2 blisters of 10 tablets each.

HDPE Container Pack
Tablets are packed in 40 ml white opaque round HDPE containers with white opaque polypropylene ribbed stock closures with a wad having an induction sealing liner, containing cotton coil.
The HDPE containers will be further packed in pre-printed cartons with a package leaflet.
Pack size: 20's - One HDPE container contains 20 tablets.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Do not remove the blisters from the carton until required for use.
Keep the containers tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
TREVIGO 24 mg TABLETS: 45/5.6/0579

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Novagen Pharma (Pty) Ltd
Office 2, 100 Sovereign Drive
Route 21 Corporate Park
Nellmapius Drive
Irene - Pretoria
South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of Registration: 6 March 2014
Date of latest revision of the text as approved by Council: 6 March 2014
Date of notification with regard to amended Reg. 9 and 10: 16 January 2015

DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET
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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
TREVIGO 24 mg TABLETS
Betahistine dihydrochloride

Read all of this leaflet carefully before you start taking TREVIGO 24 mg TABLETS.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TREVIGO 24 mg 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 TREVIGO 24 mg TABLETS CONTAIN
The active substance is betahistine dihydrochloride.

Each uncoated tablet contains betahistine dihydrochloride 24 mg.
The other ingredients of **TREVIGO 24 mg TABLETS** are cellulose microcrystalline, citric acid, crospovidone, mannitol, povidone, silica colloidal anhydrous, stearic acid and talc.
Contains mannitol 18,75 mg.
Sugar free.

2. WHAT TREVIGO 24 mg TABLETS ARE USED FOR
TREVIGO 24 mg 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. **TREVIGO 24 mg TABLETS** work by improving blood flow in the inner ear. This lowers the build-up of pressure.

3. BEFORE YOU TAKE TREVIGO 24 mg TABLETS
Do not take TREVIGO 24 mg TABLETS:
- If you are hypersensitive (allergic) to betahistine dihydrochloride, or any of the other ingredients of **TREVIGO 24 mg TABLETS**.
- If you have a stomach ulcer.
- If you suffer from pheochromocytoma (a tumour on the adrenal gland).

Take special care with TREVIGO 24 mg TABLETS:
- If you have asthma.
- If you have ever had a stomach ulcer.

Taking TREVIGO 24 mg TABLETS with food and drink:
- **TREVIGO 24 mg TABLETS** are preferably taken with meals.

Pregnancy and Breastfeeding:
- The safe use of **TREVIGO 24 mg TABLETS** during pregnancy and breastfeeding 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 **TREVIGO 24 mg TABLETS**.

Driving and using machinery
TREVIGO 24 mg 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 TREVIGO 24 mg TABLETS:
- Do not take **TREVIGO 24 mg 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 TREVIGO 24 mg TABLETS
Always take **TREVIGO 24 mg 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 **TREVIGO 24 mg 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):**
  - **TREVIGO 24 mg TABLETS** are preferably taken with meals.
  - Dosage is determined according to the individual patient's 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 to 48 mg daily, taken in divided doses.
- **Children:**
  - **TREVIGO 24 mg TABLETS** should not be used in children.

If you take more TREVIGO 24 mg 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 control centre.

If you forget to take a dose of TREVIGO 24 mg TABLETS:
- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
TREVIGO 24 mg 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, mild gastric complaints such as vomiting, stomach pain and bloating. Taking **TREVIGO 24 mg 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 **TREVIGO 24 mg TABLETS**.

Not all side-effects reported for **TREVIGO 24 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TREVIGO 24 mg TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF TREVIGO 24 mg 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.

KEEP ALL MEDICINES OUT OF 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 TREVIGO 24 mg TABLETS
TREVIGO 24 mg TABLETS:
Blister Pack:
Tablets are packed in blister packs (composed of OPA / aluminium foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.
The blisters will be further packed in pre-printed cartons with a package leaflet.
Pack size: 20's – Each carton contains 2 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque round HDPE containers with white opaque polypropylene ribbed stock closures with a wad having an induction sealing liner, containing cotton coil.
The HDPE containers will be further packed in pre-printed cartons with a package leaflet.
Pack size: 20's - One HDPE container contains 20 tablets.

Not all packs and pack sizes are necessarily marketed.

8. IDENTIFICATION OF TREVIGO 24 mg TABLETS
TREVIGO 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
TREVIGO 24 mg TABLETS: 45/5.6/0579

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Novagen Pharma (Pty) Ltd
Office 2, 100 Sovereign Drive
Route 21 Corporate Park
Nellmapius Drive
Irene - Pretoria
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Tel.: +27 (0)12 345 3175

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET
Date of Registration: 6 March 2014
Date of latest revision of the text as approved by Council: 6 March 2014
Date of notification with regard to amended Reg. 9 and 10: 16 January 2015

PROFESSIONELE INLIGTING
SKEDULERINGSTATUS

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EIENDOMSNAAM EN DOSEERVORM
TREVIGO 24 mg TABLETS (Tablette)

SAMESTELLING
Elke onbedekte tablet bevat betahistiendihidrochloried 24 mg.
Eksipiënte: Mikrokristallyne sellulose, mannitol, povidoon, krospovidoon, anhidriese sitroensuur, kolloïdale anhidriese silika, talk en stearіensuur.
Bevat mannitol 18,75 mg
Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
A.5.6 Histamien.

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Die meganisme van werking is nie bekend nie. Farmakologiese toetsing by diere het getoon dat die bloedsirkulasie in die stria-vaskulêre van die binneoor verbeter, waarskynlik deur middel van 'n verslapping van die prekapillêre sfinkters van die mikro-sirkulasie van die binneoor.

Daar is gevind in farmakologiese studies dat betahistien swak H_1-reseptor-agonistiese en aansienlike H_3-antagonistiese eienskappe in die outonome senuweestelsel en Sentrale Senuweestelsel (SSS) het. Betahistien is ook gevind om 'n dosisafhanklike inhiberende effek op spits-generasie van neurone in laterale en mediale vestibulêre kerne te hê. Die belangrikheid van hierdie waarneming in die werking teen Ménière se sindroom of vestibulêre vertigo bly egter onduidelik.

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

INDIKASIES
TREVIGO 24 mg TABLETS word aangedui vir die simptomatiese behandeling van die vertigo wat verband hou met Ménière se sindroom.

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

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS
TREVIGO 24 mg TABLETS moet met omsigtigheid toegedien word aan pasiënte met brongiale asma aangesien kliniese onverdraagsaamheid by relatief min pasiënte aangetoon is. Omsigtigheid word aanbeveel by pasiënte met 'n geskiedenis van peptiese ulkusse.

Gelyktydige gebruik met antihistamiene moet vermy word (sien **"INTERAKSIES"**).

Effekte op die vermoë om te bestuur en masjiene te gebruik
Op grond van die farmakodinamiese profiel en gerapporteerde nadelige reaksies (sien **"NEWE-EFFEKTE"**), het **TREVIGO 24 mg TABLETS** geen of minimale uitwerking op die vermoë om te bestuur en masjiene te gebruik nie.

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

MENSLIKE VOORTPLANTING
Daar is onvoldoende data oor die gebruik van hierdie medisyne tydens swangerskap en laktasie. Daarom moet **TREVIGO 24 mg TABLETS** nie tydens swangerskap en laktasie gebruik word nie.

DOSERING EN GEBRUIKSAANWYSINGS
Volwassenes (insluitend bejaardes): Aanvanklik word 16 mg drie keer daagliks geneem, verkieslik met etes. Instandhoudingsdosisse is gewoonlik tussen 24 en 48 mg per dag, in verdeelde dosisse.

TREVIGO 24 mg TABLETS
1 tablet 2 keer/dag
Die dosering moet individueel aangepas word volgens die reaksie.
Kinders: Geen doseringsaanbevelings word vir kinders gemaak nie.

NEWE-EFFEKTE
TREVIGO 24 mg TABLETS kan die volgende newe-effekte veroorsaak:
Immuunstelselafwykings
Minder dikwels
Hipersensitiwiteitsreaksies, bv. anafilakse

Senuweestelselafwykings
Minder dikwels
Hoofpyn.

Gastroïntestinale afwykings
Dikwels
Gastroïntestinale versteurings. Dit kan normaalweg hanteer word deur die dosis te verlaag of deur die dosis tydens maaltye te neem.

Vel- en subkutane weefselafwykings
Minder dikwels
Kutane hipersensitiwiteitsreaksies is aangemeld, veral uitslag, 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 kan voorkom. Daar is geen spesifieke teenmiddel nie. Behandeling kan maaglediging insluit deur emese of spoeling. Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Wit tot naaswit, ronde, onbedekte tablette, gedruk met 'X' en 'n breeklyn aan die een kant en '89' aan die ander kant.

AANBIEDING
Stolpverpakking
Die tablette word verpak in stolpstroke (saamgestel uit 'n OPA / aluminiumfoelie / PVC laag en gedrukte aluminiumfoelie).
Elke stolpstrook bevat 10 tablette.
Die stolpstroke sal verder verpak word in voorafgedrukte kartonne met 'n verpakkingsbiljet.
Pakgrootte: 20's - Elke karton bevat 2 stolpstroke met 10 tablette elk.

HDPE-houer verpakking
Tablette word verpak in 40 ml wit ondeurskynende ronde HDPE houers met wit ondeurskynende polipropileen geribde sluitings met 'n prop met 'n induksieseëlvoering, wat 'n watteluis bevat.
Die HDPE houers sal verder verpak word in voorafgedrukte kartonne met 'n verpakkingsbiljet.
Pakgrootte: 20's - Een HDPE-houer bevat 20 tablette.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BEWARINGSINSTRUKSIES
Bewaar teen of benede 25 °C.
Moet nie die stolpverpakkings uit die karton verwyder totdat dit benodig word vir gebruik nie.
Hou die houers dig toe.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
TREVIGO 24 mg TABLETS: 45/5.6/0579

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Novagen Pharma (Pty) Ltd
Kantoor 2, Sovereignrylaan 100
Route 21 Corporate Park
Nellmapiusrylaan
Irene - Pretoria
Suid-Afrika

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING
Datum van registrasie: 6 Maart 2014
Datum van laaste hersiening van die teks soos goedgekeur deur die Raad: 6 Maart 2014
Datum van kennisgewing met betrekking tot gewysigde Reg. 9 en 10: 16 Januarie 2015

P1519035

DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSBILJET
SKEDULERINGSTATUS

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EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
TREVIGO 24 mg TABLETS
Betahistiendihidrochloried

Lees die hele pamflet deeglik deur voordat jy TREVIGO 24 mg TABLETS neem.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy nog vrae het, raadpleeg asseblief jou dokter of apteker.
- **TREVIGO 24 mg TABLETS** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

1. WAT TREVIGO 24 mg TABLETS BEVAT
Die aktiewe bestanddeel is betahistiendihidrochloried.
Elke onbedekte tablet bevat betahistiendihidrochloried 24 mg.
Die ander bestanddele van **TREVIGO 24 mg TABLETS** is mikrokristallyne sellulose, sitroensuur, krospovidoon, mannitol, povidoon, kolloïdale anhidriese silika, stearіensuur en talk.
Bevat mannitol 18,75 mg.
Suikervry.

2. WAARVOOR TREVIGO 24 mg TABLETS GEBRUIK WORD
TREVIGO 24 mg TABLETS word gebruik om vertigo (duiseligheid) wat met Ménière se siekte geassosieer word, te behandel. Vertigo is 'n toestand wat veroorsaak dat lyers voel asof hulle, of hulle omgewing, beweeg of in die rondte draai. **TREVIGO 24 mg TABLETS** werk deur die bloedvloei in die binneoor te verbeter. Dit verlaag die opbou van druk.

3. VOORDAT JY TREVIGO 24 mg TABLETS NEEM
Moenie TREVIGO 24 mg TABLETS neem nie:
- As jy hipersensitief (allergies) is vir betahistiendihidrochloried, of vir enige van die ander bestanddele van **TREVIGO 24 mg TABLETS**.
- As jy 'n maagsweer het.
- As jy ly aan feochromositoom ('n gewas op die byniere).

Wees versigtig met TREVIGO 24 mg TABLETS:
- As jy asma het.
- As jy ooit 'n maagsweer gehad het.

Inname van TREVIGO 24 mg TABLETS saam met kos en vloeistof:
- **TREVIGO 24 mg TABLETS** moet verkieslik met ete geneem word.

Swangerskap en borsvoeding:
- Die veilige gebruik van **TREVIGO 24 mg TABLETS** tydens swangerskap en borsvoeding is nie bepaal nie.

Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige voordat jy **TREVIGO 24 mg TABLETS** neem.

Bestuur en gebruik van masjinerie
Dit wil voorkom asof TREVIGO 24 mg TABLETS mens nie vaak of lomerig maak nie, dus kan jy bestuur of masjinerie gebruik indien nodig. Raadpleeg asseblief jou dokter of apteker vir advies.

Die gebruik van ander medisyne saam met TREVIGO 24 mg TABLETS:
- Moenie **TREVIGO 24 mg TABLETS** saam met antihistamien medisyne, dit is medisyne wat vir allergie gebruik word, neem nie.

Lig altyd jou professionele gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

4. HOE OM TREVIGO 24 mg TABLETS TE NEEM
Neem **TREVIGO 24 mg TABLETS** altyd presies soos jou dokter dit vir jou voorgeskryf het. As jy onseker is, vra jou dokter of apteker. Indien jy die indruk kry dat die effek van **TREVIGO 24 mg TABLETS** te sterk of te swak is, bespreek dit met jou dokter of apteker. Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.
- **Volwassenes (bejaardes ingesluit):**
  - **TREVIGO 24 mg TABLETS** moet verkieslik saam met maaltye geneem word.
  - Die dosering hang af van hoe die individuele pasiënt reageer. Afhangende van die erns van jou klagtes, sal jou dokter die nodige dosis vir die behandeling van jou siekte bepaal.
  - Die gewone aanvangsdosis is 16 mg drie keer per dag.
  - Daarna is die gewone aanbevole dosis 24 tot 48 mg daagliks, geneem in verdeelde dosisse.
- **Kinders:**
  - **TREVIGO 24 mg TABLETS** moet nie by kinders gebruik word nie.

Indien jy te veel TREVIGO 24 mg TABLETS geneem het:
- Die simptome van oordosering sluit in naarheid, braking en hoofpyn. Lae bloeddruk kan voorkom.
- Behandeling kan behels dat die maag leeggemaak moet word.

In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet het van 'n dosis TREVIGO 24 mg TABLETS:
- Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE
TREVIGO 24 mg TABLETS kan newe-effekte hê.
Kry dadelik nood mediese hulp as jy enige van die volgende **tekens van 'n allergiese reaksie ervaar:**
- Moeilike asemhaling; geswelde gesig, lippe, tong of keel.
- 'n Rooi veluitslag, ontsteekte vel, netelroos (galbulte).

Ander newe-effekte sluit in: Hoofpyn, ligte maagprobleme soos braking, maagpyn en opgeblasenheid. Indien **TREVIGO 24 mg TABLETS** tydens maaltye geneem word, of die dosis verlaag word, kan dit help om maagprobleme te verminder.

Lig jou dokter so gou moontlik in as enige van die bogenoemde newe-effekte ernstig is, nie wil oorgaan nie, of as jy bekommerd voel terwyl jy **TREVIGO 24 mg TABLETS** neem.

Nie alle newe-effekte wat vir **TREVIGO 24 mg TABLETS** aangemeld is, is by hierdie biljet ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy **TREVIGO 24 mg TABLETS** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige.

6. BEWARING EN WEGDOENING VAN TREVIGO 24 mg TABLETS
Bewaar by of onder 25 °C (kamertemperatuur).
Moenie die stolpstroke uit die kartonhouer haal voordat dit benodig word vir gebruik nie.
Sorg dat die houers dig toe bly.

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

7. AANBIEDING VAN TREVIGO 24 mg TABLETS
Stolpverpakking:
Die tablette word verpak in stolpstroke (saamgestel uit 'n OPA / aluminiumfoelie / PVC laag en gedrukte aluminiumfoelie).
Elke stolpstrook bevat 10 tablette.
Die stolpstroke sal verder verpak word in voorafgedrukte kartonne met 'n verpakkingsbiljet.
Pakgrootte: 20's - Elke karton bevat 2 stolpstroke met 10 tablette elk.

HDPE-houer verpakking:
Tablette word verpak in 40 ml wit ondeurskynende ronde HDPE houers met wit ondeurskynende polipropileen geribde sluitings met 'n induksieseëlvoering, wat 'n watteplуis bevat.
Die HDPE houer sal verder verpak word in voorafgedrukte kartonne met 'n verpakkingsbiljet.
Pakgrootte: 20's - Een HDPE- houer bevat 20 tablette.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

8. IDENTIFIKASIE VAN TREVIGO 24 mg TABLETS
Wit tot naaswit, ronde, onbedekte tablette, gedruk met 'X' en 'n breeklyn aan die een kant en '89' aan die ander kant.

9. REGISTRASIENOMMER
TREVIGO 24 mg TABLETS: 45/5.6/0579

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
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11. DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNTINLIGTINGSBILJET
Datum van registrasie: 6 Maart 2014
Datum van laaste hersiening goedgekeur deur die Raad: 6 Maart 2014
Datum van kennisgewing met betrekking tot gewysigde Reg. 9 en 10: 16 Januarie 2015