Front Side

350 mm

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

NOALZH 10
Memantine hydrochloride 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **NOALZH 10** tablet contains memantine hydrochloride 10 mg
This medicine contains less than 1 mmol sodium (23 mg) per tablet.
NOALZH 10 is sugar-free.
Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet

NOALZH 10:
White to off white, capsule shape, film-coated tablet, debossed with "CL 29" on one side and break line on both the sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Treatment of patients with moderately severe to severe Alzheimer's disease.
Efficacy has not been established beyond 6 months.

4.2 Posology and method of administration
Posology:
Treatment should be initiated and supervised by a medical practitioner experienced in the diagnosis and treatment of Alzheimer's dementia. Therapy should only be started if a caregiver is available who will regularly monitor the intake by the patient. Diagnosis should be made according to current guidelines.
Adults: The maximum daily dose is 20 mg per day. In order to reduce the risk of undesirable effects the maintenance dose is achieved by upward titration of 5 mg per week over the first 3 weeks as follows:
Treatment should be started with 5 mg daily (half a tablet in the morning) during the 1st week. In the 2nd week 10 mg per day (half a tablet twice a day) and in the 3rd week 15 mg per day is recommended (one tablet in the morning and half a tablet in the afternoon). From the 4th week on, treatment can be continued with the recommended maintenance dose of 20 mg per day (one tablet twice a day).

Special populations:
Elderly: The recommended dose for patients over the age of 65 years is 20 mg per day (10 mg twice a day) as described above.
Renal impairment: In patients with normal to mildly impaired renal function (serum creatinine levels of up to 130 µmol/liter) no dose reduction is needed. In patients with moderate renal impairment (creatinine clearance 40 - 60 ml/min/1.73 m^2) daily dose should be reduced to 10 mg per day. No data are available for patients with severely reduced kidney function (see Sections 4.4 & 5.2).
Hepatic impairment:
There are no data on the use of **NOALZH 10** in patients with severe hepatic impairment (see Section 5.2).
Paediatric population:
Safety and efficacy have not been established in children and adolescents under the age of 18 years (see section 4.3).

Method of administration
NOALZH 10 film-coated tablets are for oral use.
NOALZH 10 can be taken with or without food.

4.3 Contraindications
- Hypersensitivity to memantine hydrochloride or to any of the excipients of **NOALZH 10** listed in section 6.1.
- Children and adolescents under the age of 18 years, as safety and efficacy have not been established.

4.4 Special warnings and precautions for use
As no data on memantine are available for patients with severe renal impairment (creatinine clearance less than 9 ml/min/1.73 m^2), **NOALZH 10** therapy is not recommended (see Section 4.2).

Based on pharmacological considerations and single case reports, caution is recommended with patients suffering from epilepsy.

Concomitant use of N-methyl-D-aspartate (NMDA)-antagonists such as amantadine, ketamine or dextromethorphan should be avoided. These compounds act at the same receptor system as memantine as in **NOALZH 10** and therefore adverse reactions (mainly CNS-related) may be more frequent or more pronounced (see Section 4.5).
Some factors that may raise urine pH (see Section 5.2) may necessitate careful monitoring of the patient. These factors include drastic changes in diet, e.g. from a carnivore to a vegetarian diet, or a massive ingestion of alkalising gastric buffers. Also, urine pH may be elevated by states of renal tubulary acidosis (RTA) or severe infections of the urinary tract with *Proteus bacteria*.
In most clinical trials, patients with recent myocardial infarction, congestive heart failure (NYHA III-IV), and uncontrolled hypertension were excluded. As a consequence, only limited data are available and patients with these conditions should be closely supervised.
NOALZH 10 contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction
Due to the pharmacological effects and the mechanism of action of memantine as in **NOALZH 10** the following interactions may occur:

The mode of action suggests that the effects of L-dopa, dopaminergic agonists and anticholinergics may be enhanced by concomitant treatment with NMDA-antagonists such as memantine. The effects of barbiturates and neuroleptics may be reduced. Concomitant administration of memantine as in **NOALZH 10** with the antispasmodic medicines, dantrolene or baclofen, can modify their effects and a dosage adjustment may be necessary.

Concomitant use of memantine as in **NOALZH 10** and amantadine should be avoided, owing to the risk of pharmacotoxic psychosis. Both compounds are chemically related NMDA-antagonists. The same may be true for ketamine and dextromethorphan (see Section 4.4). There is a possible risk also for the combination of memantine as in **NOALZH 10** and phenytoin.
Other medicines such as cimetidine, ranitidine, procainamide, quinidine, quinine and nicotine that use the same renal cationic transport system as amantadine may also possibly interact with memantine as in **NOALZH 10** leading to a potential risk of increased plasma levels.
There may be a possibility of reduced serum level of hydrochlorothiazide (HCT) when memantine as in **NOALZH 10** is co-administered with HCT or any combination with HCT.
Cases of international normalized ratio (INR) increases have been reported in patients concomitantly treated with warfarin. Although no causal relationship has been established, close monitoring of prothrombin time or INR is advisable for patients concomitantly treated with oral anticoagulants.

Memantine as in **NOALZH 10** does not inhibit CYP 1A2, 2A6, 2C9, 2D6, 2E1, 3A, flavin containing monooxygenase, epoxide hydrolase or sulphation *in vitro*.

4.6 Fertility, pregnancy and lactation
Pregnancy:
Safety and efficacy of memantine as in **NOALZH 10** in pregnancy have not been established.
Breastfeeding:
Safety and efficacy of memantine as in **NOALZH 10** in breastfeeding have not been established.
Fertility:
No effects of memantine as in **NOALZH 10** on male and female fertility were observed.

4.7 Effects on ability to drive and use machines
Moderate to severe Alzheimer's disease usually causes impairment of driving performance and compromises the ability to use machinery. Furthermore, **NOALZH 10** may change reactivity such that patients should be warned to take special care when driving a vehicle or operating machinery.
NOALZH 10 may cause dizziness and somnolence (see section 4.8). Patients must be advised not to drive, operate machinery or engage in other potentially hazardous activities until it is known whether **NOALZH 10** affects their ability to perform these activities.

4.8 Undesirable effects
Summary of the reported safety profile
The most frequent adverse reactions include hallucinations, confusion, dizziness, headache and tiredness.

Tabulated summary of adverse events

System organ class	Frequency	Undesirable effect
Infections and infestations	Less frequent	Fungal infections
Immune system disorders	Frequent	Hypersensitivity reactions
Psychiatric disorders	Frequent	Agitation, inflicted injury insomnia, somnolence
	Less frequent	Anxiety, confusion, hallucinations, increased libido
	Frequency unknown	Psychotic reactions, depression, suicidal ideation, suicide
Nervous system disorders	Frequent	Dizziness, fall, balance disorder.
	Less frequent	Abnormal gait
	Frequency unknown	Seizures
Cardiac disorders	Less frequent	Cardiac failure
Vascular disorders	Frequent	Hypertension
	Less frequent	Venous thrombosis / thromboembolism
Respiratory, thoracic and mediastinal disorders	Frequent	Coughing, dyspnoea
Gastrointestinal disorders	Frequent	Diarrhoea, constipation
	Less frequent	Vomiting
	Frequency not known	Pancreatitis
Hepatobiliary disorders	Frequent	Elevated liver function test
	Frequency unknown	Hepatitis
Musculoskeletal and connective tissue disorders	Less frequent	Hypertonia
Renal and urinary disorders	Less frequent	Urinary incontinence, cystitis
General disorders and administration site conditions	Frequent	Headache
	Less frequent	Fatigue

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Treatment of overdosage should be symptomatic and supportive.

In one case of suicidal overdosage the patient survived the oral intake of up to 400 mg memantine with effects on the central nervous system (e.g. restlessness, psychosis, visual hallucinations, preconvulsiveness, somnolence, stupor and unconsciousness) which resolved without permanent sequelae.

5. PHARMACOLOGICAL PROPERTIES

Category and Class: A 34 Other
Pharmacotherapeutic group: Psychoanaleptics. Other Anti-dementia drugs, ATC code: N06DX01.

5.1 Pharmacodynamic properties
Mechanism of action
There is increasing evidence that malfunctioning of glutamatergic neurotransmission, in particular at NMDA-receptors, contributes to both expression of symptoms and disease progression in neurodegenerative dementia.

Memantine is a voltage-dependent, moderate-affinity uncompetitive NMDA-receptor antagonist. It modulates the effects of pathologically elevated tonic levels of glutamate that may lead to neuronal dysfunction.

5.2 Pharmacokinetic properties
Absorption
Memantine has an absolute bioavailability of approximately 100 %. t_{max} is between 3 and 8 hours. There is no indication that food influences the absorption of memantine.

Distribution
Daily doses of 20 mg lead to steady-state plasma concentrations of memantine ranging from 70 to 150 ng/ml (0,5 - 1 µmol) with large interindividual variations. When daily doses of 5 to 30 mg were administered, a mean CSF/serum ratio of 0,52 was calculated. The volume of distribution is about 10 litres/kg. About 45 % of memantine is bound to plasma-proteins.

Biotransformation
In man, about 80 % of the circulating memantine-related material is present as the parent compound. Main human metabolites are N-3,5-dimethyl-gludantan,the isomeric mixture of 4- and 6-hydroxy-memantine, and 1-nitroso-3,5-dimethyl-adamantane. None of these metabolites exhibit NMDA-antagonistic activity. No cytochrome P 450 catalyzed metabolism has been detected *in vitro*.
In a study using orally administered ^{14}C-memantine, a mean of 84 % of the dose was recovered within 20 days, more than 99 % being excreted renally.

Elimination
Memantine is eliminated in a monoexponential manner with a terminal $t_{½}$ of 60 to 100 hours. In volunteers with normal kidney function, total clearance (Cl_{tot}) amounts to 170 ml/min/1.73 m^2 and part of total renal clearance is achieved by tubular secretion.Renal handling also involves tubular reabsorption, probably mediated by cation transport proteins. The renal elimination rate of memantine under alkaline urine conditions may be reduced by a factor of 7 to 9 (see Section 4.4). Alkalization of urine may result from drastic changes in diet, e.g. from a carnivore to a vegetarian diet, or from the massive ingestion of alkalizing gastric buffers.

Linearity/non-linearity:
Studies in volunteers have demonstrated linear pharmacokinetics in the dose range of 10 – 40 mg.

Other special populations
Elderly patients (above 65 years):
In elderly volunteers with normal and reduced renal function (creatinine clearance of 50-100 ml/min/1.73 m^2), a significant correlation was observed between creatinine clearance and total renal clearance of memantine (see Section 4.2).

Patients with hepatic impairment:
The effect of liver disease on the pharmacokinetics of memantine has not been studied. As memantine is metabolised to a minor extent only, and into metabolites with no NMDA-antagonistic activity, clinically relevant changes in the pharmacokinetics are not expected in mild to moderate liver impairment.

Pharmacokinetic/pharmacodynamic relationship:
At a dose of memantine of 20 mg per day the cerebrospinal fluid (CSF) levels match the k_i-value (k_i, inhibition constant) of memantine which is 0,5 µmol in human frontal cortex.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Croscarmellose sodium, magnesium stearate, silicified microcrystalline cellulose (microcrystalline cellulose and colloidal silicon dioxide), talc. Coating containing hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide (CI No.: 77891).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months from the date of manufacture.

6.4 Special precautions for storage
Store at or below 25 °C. Protect from light and moisture.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container
Blister Pack:
Tablets are packed plain 25 µ aluminium foil coated with 6-8 gsm Heat Seal Lacquer and clear film 250 µ PVC coated with 40 gsm PVdC.

Pack size: 14's, 28's, 56's, 84's and 112's
Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

8. REGISTRATION NUMBER(S)

NOALZH 10: 47/34/0187

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 JULY 2022

10. DATE OF REVISION OF THE TEXT

--

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

NOALZH 10, film-coated tablet
Contains 10 mg of memantine hydrochloride
Sugar free

Read all of this leaflet carefully before you start taking NOALZH 10
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **NOALZH 10** has 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.

What is in this leaflet

1. What **NOALZH 10** is and what it is used for
2. What you need to know before you take **NOALZH 10**
3. How to take **NOALZH 10**
4. Possible side effects
5. How to store **NOALZH 10**
6. Contents of the pack and other information

1. What NOALZH 10 is and what it is used for

NOALZH 10 is used for the treatment of patients with moderate to severe Alzheimer's disease.
NOALZH 10 contains memantine hydrochloride. It belongs to a group of medicines called NMDA receptor antagonists which are anti-dementia medicines. Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory.

2. What you need to know before you take NOALZH 10

Do not take NOALZH 10:
- If you are allergic (hypersensitive) to memantine hydrochloride or any of the other ingredients of **NOALZH 10** as listed in section 6.
- If you are under the age of 18 years.

Warnings and precautions
Talk to your doctor or pharmacist before taking **NOALZH 10**.
Special care should be taken with **NOALZH 10**:
- If you have a history of epileptic seizures (fits)
- If you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).
- If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary and will adjust your **NOALZH 10** dose accordingly.
- The use of medicines called amantadine (for the treatment of Parkinson´s disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists (e.g. methadone used to treat substance addiction) at the same time should be avoided.
- If your urine pH is increased by sudden change in diet for example from eating meat to a vegetarian diet or taking too much anti-acids. The urine pH can also increase with a urinary tract infection or when your kidneys do not remove acids from the blood in the urine as they should.

In these situations the treatment should be carefully supervised, and the clinical benefit of **NOALZH 10** reassessed by your doctor on a regular basis.

Children and adolescents
NOALZH 10 is not recommended for children and patients under the age of 18 years.

Other medicines and NOALZH 10
Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicines.
The following are medicines that are not recommended with **NOALZH 10**:
- Amantadine (used for treatment of Parkinson's disease) should be avoided together with **NOALZH 10** as these can cause a pharmacotoxic psychosis (when your thoughts and emotions become severely impaired).
- Ketamine (used in anaesthesia), dextromethorphan (used for cough), dantrolene (used for muscle stiffness and tightness), baclofen (used for pain, muscle stiffness and tightness). **NOALZH 10** can alter the effects of these medicines.
- Cimetidine and ranitidine (used for reducing stomach acid and treatment of ulcers), procainamide and quinidine (used to treat irregular heartbeat), quinine (used to treat malaria) and nicotine (found in cigarettes). These medicines can be increased in the blood when given together with **NOALZH 10**.
- hydrochlorothiazide (or any combination with hydrochlorothiazide) is used to reduce excess water in the body. **NOALZH 10** can cause the hydrochlorothiazide levels in the blood to decrease.
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps such as dyclomine). **NOALZH 10** can increase the effects of anticholinergics.
- anticonvulsants (substances used to prevent and relieve seizures, such as phenytoin). **NOALZH 10** can increase the effects of medicines used to treat fits.
- barbiturates (substances generally used to induce sleep for example phenobarbitone). **NOALZH 10** can decrease the effects of barbiturates.
- dopaminergic agonists (substances such as L-dopa, bromocriptine). **NOALZH 10** can increase the effects of these medicines.
- neuroleptics (substances used in the treatment of mental disorders such as olanzapine). **NOALZH 10** can reduce the effects of neuroleptics.
- Oral anticoagulants (such as warfarin, used to thin the blood). When these medicines are used with **NOALZH 10**, your blood may clot slowly which may lead to bleeding. Your doctor will do blood tests to monitor your clotting time.

NOALZH 10 with food and drink:
You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet), as your doctor may need to adjust the dose of your medicine.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **NOALZH 10**.
You should not use **NOALZH 10** if you are pregnant.
You should not breastfeed your baby whilst you are on **NOALZH 10** treatment.

Driving and using machines
Alzheimer's disease usually causes impairment of driving and using machines. **NOALZH 10** may cause dizziness and sleepiness which may affect driving and using machines and also your reactivity/responsiveness. You should not drive or use machines until you know how treatment with **NOALZH 10** affects you.

NOALZH 10 contains Sodium
NOALZH 10 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

NOALZH 10
(Film-coated Tablets)
PM03985401

335 mm

Back Side

350 mm

3. How to take NOALZH 10

Do not share medicines prescribed for you with any other person.
Always take **NOALZH 10** exactly as your doctor has instructed you.
You should check with your doctor or pharmacist if you are not sure.
You will start treatment with **NOALZH 10** under the supervision of a doctor experienced in the diagnosis and treatment of Alzheimer's disease. You should have a caregiver to help you take the correct dose each day.

Take **NOALZH 10** by mouth.
Swallow the tablet whole with some water.
NOALZH 10 can be taken with or without food.
Adults:
The recommended adult starting dose of **NOALZH 10** is half a tablet twice daily. Your doctor will increase your dose every week until a maintenance dose of one tablet twice a day is achieved.

If you have kidney problems, your doctor will reduce the maintenance dose.
Your doctor will tell you how long your treatment with **NOALZH 10** will last. Do not stop treatment early.

If you have the impression that the effect of **NOALZH 10** is too strong or too weak, talk to your doctor or pharmacist.

If you take more NOALZH 10 than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Some symptoms may include hallucinations, restlessness, excess sleepiness and psychosis (impaired thoughts and emotions).

If you forget to take NOALZH 10
If you find you have forgotten to take your dose of **NOALZH 10**, wait and take your next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

NOALZH 10 can have side effects.
Not all side effects reported for **NOALZH 10** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NOALZH 10**, please consult your health care provider for advice.

If any of the following happens, stop taking NOALZH 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.

These are very serious side effects. If you have them, you may have had a serious reaction to **NOALZH 10**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects may include:
- Allergic reaction
- Sleepiness, dizziness
- High blood pressure
- Shortness of breath
- Constipation
- Diarrhoea
- Increased liver enzyme tests
- Headache
- Agitation
- Coughing

Less frequent side effects
- Fungal infections
- Confusion, hallucinations, anxiety
- abnormal gait
- seizures or fits
- heart failure
- venous blood clotting
- vomiting
- abnormal muscle tension
- loss of bladder control
- tiredness
- cystitis

Frequency unknown
Some additional side effects include:
- depression, thoughts of suicide, completed suicide, impaired thoughts and emotions (psychosis)
- inflammation of the pancreas
- inflammation of the liver

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **NOALZH 10**.

5. How to store NOALZH 10

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What NOALZH 10 contains
The active ingredient in **NOALZH 10** is memantine hydrochloride.
Other ingredients include:
Croscarmellose sodium, magnesium stearate, silicified microcrystalline cellulose (microcrystalline cellulose and colloidal silicon dioxide), talc. Coating containing hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide (CI No.: 77891).

What NOALZH 10 looks like and contents of the pack
NOALZH 10:
White to off white, capsule shape, film-coated tablet, debossed with "CL 29" on one side and break line on both the sides.

Blister Pack:
Tablets are packed plain 25 µ aluminium foil coated with 6-8 gsm Heat Seal Lacquer and clear film 250 µ PVC coated with 40 gsm PVdC.
Pack size: 14's, 28's, 56's, 84's and 112's
Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
12 JULY 2022.

Registration number
NOALZH 10: 47/34/0187

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

NOALZH 10, filmbedekte tablet
Bevat 10 mg van memantienhidrochloried
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy NOALZH 10 begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **NOALZH 10** 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.

Wat is in hierdie inligtingstuk

1. Wat **NOALZH 10** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **NOALZH 10** neem
3. Hoe om **NOALZH 10** te neem
4. Moontlike newe-effekte
5. Hoe om **NOALZH 10** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat NOALZH 10 is en waarvoor dit gebruik word

NOALZH 10 word gebruik vir die behandeling van pasiënte met matige tot ernstige Alzheimer se siekte.
NOALZH 10 bevat memantienhidrochloried. Dit behoort aan 'n groep van medisyne genaamd NMDA-reseptor antagoniste wat medisyne teen demensie is. Geheueverlies in Alzheimer se siekte is as gevolg van 'n versteuring van boodskapseine in die brein. Die brein bevat sogenaamde N-metiel-D-aspartaat (NMDA)-reseptore wat betrokke is in die oordrag van senuwee-seine wat belangrik is vir leer en geheue.

2. Wat jy behoort te weet voordat jy NOALZH 10 neem

Moet nie NOALZH 10 neem nie:
- Indien jy allergies (hipersensitief) is vir memantienhidrochloried of enige van die ander bestanddele van **NOALZH 10** soos gelys in afdeling 6.
- Indien jy jonger as 18 jarige ouderdom is.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **NOALZH 10** neem.
Spesiale sorg moet geneem word met **NOALZH 10:**
- Indien jy 'n geskiedenis van epileptiese aanvalle het (stuipe)
- Indien jy onlangs 'n miokardiale infarksie (hartaanval) ervaar het, of as jy aan kongestiewe hartversaking of aan 'n ongekontrolleerde hipertensie (hoë bloeddruk) ly.
- Indien jy aan renale inkorting (nierprobleme) ly, moet jou dokter jou nierfunksie noukeurig monitor en indien nodig sal jou **NOALZH 10** dosis dienooreenkomstig aangepas word.
- Die gebruik van medisyne op dieselfde tyd, naamlik amantadien (vir die behandeling van Parkinson se siekte), ketamien ('n middel wat gewoonlik as 'n narkose gebruik word), dekstrometorfaan (gewoonlik gebruik om hoes te behandel) en ander NMDA-antagoniste (bv. metadoon wat gebruik word om dwelmverslawing te behandel), moet vermy word.
- Indien jou uriene se pH verhoog word deur skielike verandering in dieet, byvoorbeeld van die eet van vleis na 'n vegetariese dieet of die neem van te veel teensure. Die uriene se pH kan ook verhoog met 'n urienweginfeksie of wanneer jou niere nie sure uit die bloed in die uriene verwyder soos wat hulle moet nie.

In hierdie situasies moet noukeurig toesig gehou word oor die behandeling, en die kliniese voordeel van **NOALZH 10** moet op 'n gereelde basis deur jou dokter heroorweeg word.

Kinders en adolessente
NOALZH 10 word nie aanbeveel vir kinders en pasiënte onder die ouderdom van 18 jaar nie.

Ander medisyne en NOALZH 10
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem, insluitend komplementêre of tradisionele medisyne.
Die volgende is medisyne wat nie saam met **NOALZH 10** aanbeveel word nie:
- Amantadien (wat gebruik word vir die behandeling van Parkinson se siekte) moet vermy word saam met **NOALZH 10** aangesien dit 'n farmakotoksiese psigose kan veroorsaak (wanneer jou gedagtes en emosies ernstig ingekort word).
- Ketamien (gebruik in narkose), dekstrometorfaan (gebruik vir hoes), dantroleen (gebruik vir spierstyfheid en strakheid), baklofen (gebruik vir pyn, spierstyfheid en strakheid). **NOALZH 10** kan die effekte van hierdie medisyne verander.
- Simetidien en ranitidien (gebruik vir die vermindering van maagsuur en behandeling van ulkusse), prokaïnamied en kinidien (gebruik om onreëlmatige hartklop te behandel), kinien (gebruik om malaria te behandel) en nikotien (gevind in sigarette). Hierdie medisyne kan in die bloed verhoog word, wanneer dit saam met **NOALZH 10** gegee word.
- hidrochloortiasied (of enige kombinasie met hidrochloortiasied) word gebruik om oortollige water in die liggaam te verminder. **NOALZH 10** kan die hidrochloortiasiedvlakke in die bloed laat afneem.
- anticholinergiese middels (middels wat gewoonlik gebruik word om bewegingsafwykings of dermkrampe te behandel, soos diklomien). **NOALZH 10** kan die effekte van anticholinergiese middels verhoog.
- antikonvulsiewe middels (stowwe wat gebruik word om aanvalle te voorkom en te verlig, soos fenitoïen). **NOALZH 10** kan die uitwerking van medisyne wat gebruik word om aanvalle te behandel, verhoog.
- barbiturate (stowwe wat gewoonlik gebruik word om slaap te induseer, byvoorbeeld fenobarbitoon). **NOALZH 10** kan die effekte van barbiturate verminder.
- dopaminergiese agoniste (stowwe soos L-dopa, bromokriptien). **NOALZH 10** kan die uitwerking van hierdie medisyne verhoog.
- neuroleptika (stowwe wat gebruik word in die behandeling van geestesversteurings soos olansapien). **NOALZH 10** kan die effekte van neuroleptika verminder.
- Orale antikoagulante (soos warfarien, wat gebruik word om die bloed te verdun). Wanneer hierdie medisyne saam met **NOALZH 10** gebruik word, kan jou bloed stadig stol wat tot bloeding kan lei. Jou dokter sal bloedtoetse doen om jou stollingstyd te monitor.

NOALZH 10 met voedsel en vloeistof:
Jy moet jou dokter inlig indien jy onlangs jou dieet aansienlik verander het of van plan is om jou dieet te verander (bv. van normale dieet na streng vegetariese dieet), aangesien jou dokter dalk die dosis van jou medisyne sal moet aanpas.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, dink dat jy moontlik swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **NOALZH 10** neem.
Jy moet nie **NOALZH 10** gebruik indien jy swanger is nie.
Jy moet nie jou baba borsvoed terwyl jy op **NOALZH 10** behandeling is nie.

Bestuur en gebruik van masjinerie
Alzheimer se siekte veroorsaak gewoonlik belemmering van bestuur en gebruik van masjiene. **NOALZH 10** kan duiseligheid en slaperigheid veroorsaak wat die bestuur en die gebruik van masjiene en ook jou reaktiwiteit/responsiwiteit kan beïnvloed. Jy moet nie bestuur of masjiene gebruik totdat jy weet hoe behandeling met **NOALZH 10** jou affekteer nie.

NOALZH 10 bevat natrium
NOALZH 10 bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om NOALZH 10 te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **NOALZH 10** presies soos jou dokter jou voorgeskryf het.
Raadpleeg jou dokter of apteker indien jy nie seker is nie.
Jy sal behandeling met **NOALZH 10** begin onder toesig van 'n dokter wat ondervinding het in die diagnose en behandeling van Alzheimer se siekte. Jy moet 'n versorger hê om jou te help om elke dag die korrekte dosis te neem.

Neem **NOALZH 10** per mond.
Sluk die tablet heel met 'n bietjie water.

NOALZH 10 kan met of sonder kos geneem word.
Volwassenes:
Die aanbevole aanvangsdosis vir volwassenes van **NOALZH 10** is 'n halwe tablet twee keer per dag. Jou dokter sal jou dosis elke week verhoog totdat 'n onderhoudsdosis van een tablet twee keer per dag bereik word.

Indien jy nierprobleme het, sal jou dokter die onderhoudsdosis verminder.
Jou dokter sal jou vertel hoe lank jou behandeling met **NOALZH 10** sal duur. Moet nie die behandeling vroegtydig stop nie.

Indien jy die indruk het dat die effek van **NOALZH 10** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer NOALZH 10 neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Sommige simptome kan hallusinasies, rusteloosheid, oormatige slaperigheid en psigose (ingekorte gedagtes en emosies) insluit.

Indien jy vergeet om NOALZH 10 te neem
Indien jy agterkom dat jy vergeet het om jou dosis van **NOALZH 10** te neem, wag en neem jou volgende dosis op die gewone tyd. Moet nie 'n dubbele dosis neem om op te maak vir 'n vergete tablet nie.

4. Moontlike newe-effekte

NOALZH 10 kan newe-effekte hê.
Nie al die newe-effkte wat vir **NOALZH 10** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy **NOALZH 10** gebruik, kontak asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om NOALZH 10 te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat probleme kan veroorsaak om te sluk of asem te haal.
- uitslag of jeuk.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **NOALZH 10** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- borskaspyn,
- angina,
- verandering in die manier waarop jou hart klop, byvoorbeeld, as jy agterkom dat dit vinniger klop
- moeilike asemhaling,
- tekens van herhalende infeksies soos koors of seer keel,
- minder uriene as wat normaal is vir jou,
- vergeling van die vel en oë, donker uriene, en moegheid wat simptome van lewerprobleme kan wees

Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte kan insluit:
- Allergiese reaksie
- Slaperigheid, duiseligheid
- Hoë bloeddruk
- Kort van asem
- Hardlywigheid
- Diaree
- Verhoogde lewerensiemtoetse
- Hoofpyn
- Opgewondenheid
- Hoes

Minder gereelde newe-effekte
- Swambesmetting
- Verwarring, hallusinasies, angs
- abnormale gang
- aanvalle of stuipe
- hartversaking
- veneuse bloedstolling
- braking
- abnormale spierspanning
- verlies aan blaasbeheer
- moegheid
- sistitis

Frekwensie onbekend
Sommige bykomende newe-effekte sluit in:
- depressie, gedagtes aan selfmoord, voltooide selfmoord, ingekorte gedagtes en emosies (psigose)
- ontsteking van die pankreas
- inflammasie van die lewer

Indien jy enige newe-effekte kry, praat met jou dokter of apteker. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies:https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **NOALZH 10**.

5. Hoe om NOALZH 10 te bewaar

Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Berg in die oorspronklike verpakking om sodoende teen lig en vog te beskerm.
HOU BUITE DIE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton /bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat NOALZH 10 bevat
Die aktiewe bestanddeel in **NOALZH 10** is memantienhidrochloried.
Ander bestanddele sluit in:
Natriumkruiskarmellose, magnesiumstearaat, versilikifiseerde mikrokristallyne sellulose (mikrokristallyne sellulose en kolloïdale silikondioksied), talk. Bedekking wat hidroksipropielmetielsellulose, poliëtileenglikol, titaandioksied bevat (CI No.: 77891).

Hoe NOALZH 10 lyk en inhoud van die pak
NOALZH 10:
Wit tot naaswit, kapsulevorm, filmbedekte tablet, gegraveer met "CL 29" aan die een kant en breeklyn aan albei kante.

Stulpstrook verpakking:
Tablette is verpak gewone 25 µ aluminiumfoelie bedek met 6-8 gsm hitteseëlak en deursigtige film 250 µ PVC bedek met 40 gsm PVdC.
Verpakkingsgrootte: 14's, 28's, 56's, 84's, en 112's
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
12 JULIE 2022

Registrasienommer
NOALZH 10: 47/34/0187

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: NOALZH 10 (Memantine hydrochloride Tablets 10 mg)	
2. Country: South Africa (Private Market)	**3. Packaging component: Patient Information**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 350 (L) x 335(W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03985401**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 32112 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name: Y:\Memantine Hydrochloride\SA Private Market\Memantine Hydrochloride Tablets 10 mg PI & PIL - PM03985401.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA Date: 2022.10.21 17:35:48 +02'00'				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03985401		