Front Side

300 mm

235 mm

Ensorin 5/10 mg
(film-coated tablet)
PM03909202

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

ENSORIN 5 mg (film-coated tablet)
Contains sugar (87,9 mg lactose monohydrate).

ENSORIN 10 mg (film-coated tablet)
Contains sugar (175,8 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking ENSORIN
- 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.
- **ENSORIN** 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 **ENSORIN** is and what it is used for
2. What you need to know before you take **ENSORIN**
3. How to take **ENSORIN**
4. Possible side effects
5. How to store **ENSORIN**
6. Contents of the pack and other information

1. What ENSORIN is and what it is used for

ENSORIN is used for the treatment of mild to moderate Alzheimer's dementia.

2. What you need to know before you take ENSORIN

Do not take ENSORIN:
- If you are hypersensitive (allergic) to donepezil hydrochloride, or to piperidine derivatives or to any of the other used in **ENSORIN** (listed in section 6).
- If you are a child or adolescent under the age of 18 years.

Warnings and precautions
Take special care with **ENSORIN** if**:**
- You have ever had stomach or duodenal ulcers
- You have ever had a seizure
- You have a heart condition
- You have asthma or other lung diseases
- You have ever had any liver problems or hepatitis (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine)
- You have difficulty passing urine
- If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking **ENSORIN**. This is because **ENSORIN** may affect the amount of anaesthetic needed.

Other medicines and ENSORIN
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
- Pain killers (e.g. aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs))
- Medicines for treatment for arthritis (e.g. ibuprofen and diclofenac sodium)
- Antibiotics (e.g. erythromycin, rifampicin) or anti-fungal medicine (e.g. ketoconazole)
- Muscle relaxants (e.g. diazepam, succinylcholine)
- Anti-depressants (e.g. fluoxetine)
- Anti-convulsants (e.g. phenytoin, carbamazepine)
- Medication for a heart condition (e.g. quinidine, beta blockers (propranolol and atenolol)

ENSORIN with food or drink
ENSORIN may be taken with or without food.
ENSORIN should not be taken with alcohol.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, 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 this medicine.
You should not take **ENSORIN** when you are pregnant or breast-feeding your baby.

Driving and using machines
ENSORIN can cause fatigue, dizziness and muscle cramps and, if affected, you must not drive or operate machinery.

ENSORIN contains lactose
Tell your doctor if you have galactosaemia (a condition in which the body is unable to use the sugar galactose) or glucose / galactose malabsorption syndrome (a condition in which lactose (milk sugar) and other carbohydrates which contain the sugars glucose and galactose cannot be digested by the body). **ENSORIN** contains lactose (milk sugar) and is unsuitable for patients with these disorders.

3. How to take ENSORIN

Do not share medicines prescribed for you with any other person.
Always take or give **ENSORIN** exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are unsure.
Take your **ENSORIN** tablet by mouth with a drink of water at night before you go to bed.
The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor will recommend. Usually, you will start by taking 5 mg (one white tablet) every night.
After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night. The maximum recommended dose is 10 mg each night.
If you have the impression that the effect of **ENSORIN** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ENSORIN than you should
DO NOT take more than one tablet each day.
In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.
Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.
The signs to be expected following acute overdosage with **ENSORIN** are severe nausea, vomiting, drooling, sweating, slow heart beat, low blood pressure, difficulty in breathing, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death, if respiratory muscles are involved.

If you forget to take ENSORIN
If you have missed a dose of **ENSORIN** take it as soon as you remember. However if it is almost time for the next dose, skip the missed dose and go back to your regular scheduling. Never double the dose.

4. Possible side effects

ENSORIN can have side effects.
Not all side effects reported for **ENSORIN** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **ENSORIN**, please consult your, health care provider for advice.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Loss of appetite, hallucinations, agitation, aggressive behaviour, fainting, seizures, shaking, stiffness or uncontrollable movement (especially of the face and tongue, but also of the limbs), slow heart beat, abdominal disturbances (including bleeding, stomach and duodenal ulcers), liver disorders (including hepatitis, a liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine), itching, rash and urinary incontinence.
These are all serious side-effects. You may need urgent medical attention. Serious side-effects occur less frequently.

The frequent side-effects of **ENSORIN** are:
Diarrhoea, nausea, vomiting, muscle cramps, fatigue and insomnia (difficulty in sleeping), dizziness, headaches, pain, accidents, the common cold, abnormal dreams, delusions, depression, loss of bowel control resulting in involuntary passage of faeces, sweating and decrease in weight .
These are all mild side-effects of **ENSORIN**. In most cases these go away without having to stop treatment. Tell your doctor if you have any of these effects. Other side effects that may occur less frequently include:
Urinary tract infections, dehydration, abnormal crying, increased libido (sexual drive), irritability, nervousness, restlessness, difficulty remembering words or losing the ability to speak, read, or write, poor muscle co-ordination which can result in difficulties in walking and speaking, pins and needles or tingling or numbness of the hands and feet, confusion, cataracts, eye irritation, blurred vision, vertigo (spinning sensation), disturbances in the normal rhythm of the heart, chest pain, hot flushes, low blood pressure, difficulty in breathing, sore throat, bloating, toothache, pain in the upper abdomen, excessive sweating, bruising, need to wake up and pass urine at night and bone fracture.
Laboratory tests may reveal and increase in muscle creatine kinase and increased liver enzymes.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com By reporting side effects, you can help provide more information on the safety of **ENSORIN**.

5. How to store ENSORIN

Store **ENSORIN** at room temperature (do not store above 25 °C). Keep the container closed tightly. The blister strips to be kept in the carton until required for use.
Store in the original package in order to protect from light and moisture.
Do not use **ENSORIN** after the expiry date on the label.
STORE ALL MEDICINE 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).

6. Contents of the pack and other information

What ENSORIN contains
The active ingredient in each **ENSORIN 5 mg** film-coated tablet is 5 mg donepezil hydrochloride.
The active ingredient in each **ENSORIN 10 mg** film-coated tablet is 10 mg donepezil hydrochloride.
The other ingredients are: Colloidal silicon dioxide, lactose monohydrate, microcrystalline cellulose, pregelatinised starch, magnesium stearate, hypromellose, titanium dioxide, talc, propylene glycol & yellow iron oxide (for 10mg only).

What ENSORIN looks like and contents of the pack
ENSORIN 5 mg: White to off white, round shaped biconvex, film coated tablets, debossed with "ML 89" on one side and plain on the other side.
ENSORIN 10 mg: Yellow colour, round shaped biconvex, film coated tablets, debossed with "ML 88" on one side and plain on the other side.

Blister packs of 30 and 100 tablets.
HDPE bottles with white child resistant cap containing 30 or 90 tablets.

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.

This leaflet was last revised in
03 September 2024

REGISTRATION NUMBER
ENSORIN 5 mg: 45/5.3/0682
ENSORIN 10 mg: 45/5.3/0683

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

Back Side

300 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S5

ENSORIN 5 mg (filmbedekte tablet)
Bevat suiker (87,9 mg laktosemonohidraat).

ENSORIN 10 mg (filmbedekte tablet)
Bevat suiker (175,8 mg laktosemonohidraat).

Lees hierdie hele inligtingstuk noukeurig deur voordat jy ENSORIN begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **ENSORIN** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat ENSORIN is en waarvoor dit gebruik word

ENSORIN word gebruik vir die behandeling van ligte tot matige Alzheimer se demensie.

2. Wat jy behoort te weet voordat jy ENSORIN neem

Moet nie ENSORIN neem nie:
- Indien jy hipersensitief (allergies) is vir donepesilhidrochloried, of vir piperidien derivates of vir enige van die ander bestanddele gebruik in **ENSORIN** (gelys in afdeling 6).
- Indien jy 'n kind of adolessent onder die ouderdom van 18 jaar is.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **ENSORIN** indien**:**
- Jy al ooit maag- of duodenale ulkusse gehad het
- Jy al ooit 'n aanval gehad het
- Jy 'n hartkwaal het
- Jy asma of ander longsiektes het
- Jy al ooit enige lewerprobleme of hepatitis gehad het (lewersiekte met naarheid, braking, verlies aan eetlus, algemene gevoel van ongesteldheid, koors, gejeuk, vergeling van die vel en oë, en donkerkleurige uriene)
- Jy sukkel om te urineer
- Indien jy 'n operasie gaan ondergaan wat vereis dat jy 'n algemene narkose moet kry, moet jy jou dokter en die narkotiseur vertel dat jy **ENSORIN** neem. Dit is omdat **ENSORIN** die hoeveelheid narkose wat benodig gaan word, kan beïnvloed.

Ander medisyne en ENSORIN
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
- Pynstillers (bv. aspirien, nie-steroïed anti-inflammatoriese middels (NSAIMs))
- Medisyne vir die behandeling van artritis (bv. ibuprofen en natriumdiklofenak)
- Antibiotika (bv. eritromisien, rifampisien) of swambestrydende medisyne (bv. ketokonasool)
- Spierverslappers (bv. diasepam, suksinielcholien)
- Anti-depressante (bv. fluoksetien)
- Anti-konvulsante (bv. fenitoïen, karbamasepien)
- Medikasie vir 'n harttoestand (bv. kinidien, beta-blokkers (propranolol en atenolol)

ENSORIN met kos of vloeistowwe
ENSORIN kan met of sonder kos geneem word.
ENSORIN moet nie saam met alkohol geneem word nie.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, dink dat jy dalk swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat hierdie medisyne geneem word.
Jy moet nie **ENSORIN** neem terwyl jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik van masjinerie
ENSORIN kan moegheid, duiseligheid en spierkrampe veroorsaak en, indien aangetas, moet jy nie bestuur of masjinerie gebruik nie.

ENSORIN bevat laktose
Vertel jou dokter as jy galaktosemie het ('n toestand waarin die liggaam nie die suiker galaktose kan gebruik nie) of glukose/galaktose-wanabsorpsie sindroom ('n toestand waarin laktose (melksuiker) en ander koolhidrate wat die suikers glukose en galaktose bevat, nie deur die liggaam verteer kan word nie). **ENSORIN** bevat laktose (melksuiker) en is nie geskik vir pasiënte met hierdie afwykings nie.

3. Hoe om ENSORIN te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem of gee altyd **ENSORIN** presies soos wat jou dokter of apteker jou aangesê het.
Raadpleeg jou dokter of apteker indien jy nie seker is.
Neem jou **ENSORIN** tablet saans per mond, met 'n glas water, voordat jy gaan slaap.
Die tabletsterkte wat jy sal neem, kan verander afhangende van hoe lank jy die medisyne al neem en wat jou dokter sal aanbeveel. Gewoonlik sal jy begin deur elke aand 5 mg (een wit tablet) te neem.
Na een maand kan jou dokter jou beveel om elke aand 10 mg (een geel tablet) te neem. Die maksimum aanbevole dosis is 10 mg elke aand.
Indien jy die indruk het dat die effek van **ENSORIN** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ENSORIN neem as wat jy behoort
MOET NIE meer as een tablet per dag neem nie.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Neem altyd die tablette en die karton saam met jou na die hospitaal toe sodat die dokter weet wat geneem is.
Die tekens wat verwag kan word na akute oordosering met **ENSORIN** is erge naarheid, braking, kwyl, sweet, stadige hartklop, lae bloeddruk, probleme met asemhaling, ineenstorting en stuiptrekkings. Toenemende spierswakheid is 'n moontlikheid en kan tot die dood lei indien die respiratoriese spiere betrokke is.

Indien jy vergeet om ENSORIN te neem
Indien jy 'n dosis van **ENSORIN** gemis het, neem dit sodra jy daarvan onthou. Indien dit egter amper tyd is vir die volgende dosis, slaan die gemiste dosis oor en gaan terug na jou gereelde skedule. Moet nooit die dosis verdubbel nie**.**

4. Moontlike newe-effekte

ENSORIN kan newe-effekte hê.
Nie alle newe-effekte wat vir **ENSORIN** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **ENSORIN** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.
Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
Verlies aan eetlus, hallusinasies, rusteloosheid, aggressiewe gedrag, floutes, aanvalle, bewerasie, styfheid of onbeheerbare beweging (veral van die gesig en tong, maar ook van die ledemate), stadige hartklop, abdominale steurnisse (insluitend bloeding, maag- en duodenale ulkusse), lewerafwykings (insluitend hepatitis, 'n lewersiekte met naarheid, braking, verlies aan eetlus, algemene gevoel van ongesteldheid, koors, gejeuk, vergeling van die vel en oë, en donkerkleurige uriene), gejeuk, uitslag en urinêre inkontinensie.
Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag. Ernstige newe-effekte kom minder gereeld voor.

Die gereelde newe-effekte van **ENSORIN** is**:**
Diarree, naarheid, braking, spierkrampe, moegheid en slapeloosheid (probleme om te slaap), duiseligheid, hoofpyn, pyn, ongelukke, die algemene verkoue, abnormale drome, waamvoorstellings, depressie, verlies aan dermbeheer wat lei tot onwillekeurige ontlasting, sweet en afname in gewig.
Dit is alles ligte newe-effekte van **ENSORIN**. In die meeste gevalle verdwyn dit sonder dat behandeling gestaak hoef te word. Vertel jou dokter as jy enige van hierdie effekte ervaar. Ander newe-effekte wat minder gereeld kan voorkom, sluit in:
Urienweginfeksies, dehidrasie, abnormale gehuil, verhoogde libido (seksdrang), prikkelbaarheid, senuweeagtigheid, rusteloosheid, probleme met die onthou van woorde of die verlies van die vermoë om te praat, lees, of skryf, swak spierkoördinasie wat kan lei tot probleme met loop en praat, spelde en naalde of tinteling of gevoelloosheid van die hande en voete, verwarring, katarakte, oogirritasie, dowwe sig, vertigo (draai sensasie), steurnisse in die normale ritme van die hart, borskaspyn, warm gloede, lae bloeddruk, probleme met asemhaling, seer keel, opgeblasenheid, tandpyn, pyn in die boonste buik, oormatige sweet, kneusing, behoefte om snags wakker te word en te urineer en beenfraktuur.
Laboratoriumtoetse kan 'n toename in spierkreatinien kinase en verhoogde lewerensieme toon.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word, of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting te verskaf aangaande die veiligheid van **ENSORIN**.

5. Hoe om ENSORIN te bêre

Bêre **ENSORIN** by kamertemperatuur (moet nie bo 25 °C bêre nie). Hou die houer styf toe.
Die stulpstroke moet in die karton gehou word totdat dit benodig word vir gebruik.
Bêre in die oorspronklike verpakking om teen lig en vog te beskerm.
Moet nie **ENSORIN** gebruik na die vervaldatum op die etiket nie.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
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 ENSORIN bevat
Die aktiewe bestanddeel in elke **ENSORIN 5 mg** filmbedekte tablet is 5 mg donepesilhidrochloried. Die aktiewe bestanddeel in elke **ENSORIN 10 mg** filmbedekte tablet is 10 mg donepesilhidrochloried.
Die ander bestanddele is: Kolloïdale silikondioksied, laktosemonohidraat, mikrokristallyne sellulose, voorafgelatineerde stysel, magnesiumstearaat, hipromellose, titaandioksied, talk, propileenglikol en geel ysteroksied (slegs vir 10 mg).

Hoe ENSORIN lyk en inhoud van die pak
ENSORIN 5 mg: Wit tot af-wit, ronde vorm, bikonvekse, filmbedekte tablette bedruk met 'ML 89' aan die een kant en glad aan die ander kant.
ENSORIN 10 mg: Geelkleurige, ronde vorm, bikonvekse, filmbedekte tablette bedruk met 'ML 88' aan die een kant en glad aan die ander kant.
Stulpstrookverpakkings van 30 en 100 tablette.
HDPE-bottels met wit kinderbestande doppie wat 30 of 90 tablette bevat.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
1 Cussonia-rylaan, Bassonia Rock, Uitbr. 12
Alberton, Suid-Afrika

Hierdie inligtingstuk was laas hersien op
03 September 2024

Registrasienommers
ENSORIN 5 mg: 45/5.3/0682
ENSORIN 10 mg: 45/5.3/0683

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

235 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Updation of leaflet as per latest SmPC format along with change in dimensions and removal of PI from leaflet

1. Product: Ensorin 5/10 mg (Donepezil hydrochloride 5/10 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: 300 (L) x 235 (W) mm**
9. Design / Style: Booklet Type	**10. Item code No.: PM03909202**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40179 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: PM03909201**
15. Revision No: 01	**16. A/W File name: Z:\South Africa\Donepezil\SA Private Market\01\ENSORIN 5-10 MG PIL - PM03909202.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD/MEDICAL	QC	PRODN	QA
	25/07/2025				

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.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	PM03909201	26/08/22	30/09/22
2) Updation of leaflet as per latest SmPC format along with change in dimensions and removal of PI from leaflet	PM03909202		