

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.

ENSORIN 10 mg: Yellow, round shaped, biconvex, film-coated tablets debossed with 'ML 88' on one side and plain on the other.

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.

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ENSORIN 5 mg: 45/5.3/0682

ENSORIN 10 mg: 45/5.3/0683