Patient package insert in accorance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a doctor's prescription only

Asenta 5 mg, 10 mg
Tablets

Each **Asenta 5 mg** tablet contains donepezil hydrochloride 5 mg
Each **Asenta 10 mg** tablet contains donepezil hydrochloride 10 mg

Inactive ingredients and allergens in the medicine - see in section 2 "**Important information about some of the ingredients of this medicine**" and in section 6 in the leaflet.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist. Keep this leaflet, you may wish to read it again.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

For the treatment of mild to moderate Alzheimer's dementia.

Therapeutic group: Acetylcholinesterase inhibitors.
Acetylcholine is involved in memory processes in the brain. Donepezil increases the amount of acetylcholine by slowing down its breakdown.

Donepezil is used to treat the symptoms of Alzheimer's disease such as increasing memory loss, confusion and behavioral changes, that impair the normal daily routine of the patients. The drug is intended for adults only.

2. Before using the medicine

Do not use Asenta if:

- You are hypersensitive (allergic) to the active ingredient donepezil hydrochloride, piperidine derivatives or to any of the other ingredients this medicine contains (see section 6 "**Additional information**" in this leaflet).

Special warnings regarding the use of the medicine

Before the treatment with **Asenta**, tell the doctor if you suffer or have ever suffered from:

- stomach or duodenal ulcers.
- seizures or convulsions.
- heart condition (irregular or very slow heart rate).
- asthma or other chronic lung disease.
- liver problems or hepatitis.
- difficulty passing urine or mild kidney disease.

Also, tell your doctor if you are pregnant or think you might be pregnant.

Patients with kidney disease can use **Asenta**, but the doctor should be consulted. Patients with mild to moderate liver disease can use **Asenta**, but the doctor should be consulted. The use of the medicine is not recommended in patients with severe liver disease.

Children and adolescents:

This medicine is not intended for children and adolescents under the age of 18 years.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, since these medicines may affect the efficacy of Asenta, especially if you are taking:

- other Alzheimer's disease medicines such as galantamine.
- pain relievers or arthritis medicines, such as aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen or diclofenac sodium).
- anticholinergic medicines, such as tolterodine.
- antibiotics such as erythromycin, rifampicin.
- antifungal medicines such as ketoconazole.
- anti-depressants such as fluoxetine.
- anticonvulsants such as phenytoin or carbamazepine.
- medicines to treat heart conditiom, such as quinidine or beta blockers (e.g., propanolol and atenolol).
- muscle relaxants such as diazepam, succinylcholine.
- general anesthetics.
- non-prescription medications including medicinal herbs.

If you are about to undergo surgery involving general anesthesia, inform the anesthesiologist and the attending physician that you are taking **Asenta**. **Asenta** may affect the amount of anesthetic required.

Inform your doctor or pharmacist who your caregiver is. Your caregiver can help you take the medicines as needed**.**

Use of Asenta and food

Food has no influence on the effect of the medicine.

Use of Asenta and alcohol consumption

Do not drink alcohol during trearment with **Asenta**. Alcohol may influence the effect of the medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using **Asenta**.
Pregnancy
There is not enough information about the use of **Asenta** in pregnant women.
Animal research has not shown a teratogenic effect (congenital malformations), but has shown that there is prenatal and postnatal toxicity. The risk during pregnancy in humans is unknown. Therefore, it is not recommended to use **Asenta** during pregnancy unless there is a clear need.
Breastfeeding
Asenta is excreted in rat's milk. It is unknown whether **Asenta** is also excreted in human breast milk and there is no research on breastfeeding women. Therefore, do not use **Asenta** while breastfeeding.

Driving and using machines

Do not drive or operate dangerous machines while using the medicine as Alzheimer's disease may impair your ability to drive or operate dangerous machinery or devices. For your safety, you must not perform these operations unless your doctor has allowed you to do so. Also, **Asenta** can cause tiredeness, dizziness and muscle cramp. If these effects appear, do not drive or operate dangerous machinery or devices.

Important information about some of the ingredients of this medicine

The medicine contains lactose. If you have been told by your doctor that you are hypersensitive to certain sugars, consult the doctor before starting treatment with **Asenta**.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.
The usual dosage is**:**
The recommended starting dose is **Asenta 5 mg** (white tablet) every night before bed. After a month, your doctor may recommend that you take **Asenta 10 mg** (yellow tablet) every night before bed. The strength of the medicine may change depending on the length of time you are taking the medicine and your doctor's recommendations. The maximum recommended dose is **Asenta 10 mg** each night. Always follow the doctor's or pharmacist's recommendations on how and when to take the medicine. Do not change the dose unless instructed to do so by a doctor.
Do not exceed the recommended dose.

Duration of treatment with Asenta:

You should see your doctor from time to time to review your treatment and assess your symptoms.

Method of administration:

Take a whole **Asenta** tablet with water before bed. The tablet is coated and therefore, it should not be crushed, chewed or halved.

If you have accidentally taken a higher dosage of Asenta or if a child or anyone else has accidently swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine, the leaflet and the remaining tablets with you. Signs of **Asenta** overdose may include nausea and vomiting, drooling, sweating, slow heart rate, low blood pressure (dizziness while standing), difficulty in breathing, loss of consciousness, seizures or convulsions.

If you forgot to take the medicine:

If you forgot to take **Asenta** at the designated time, do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time and consult the doctor. If you forget to take **Asenta** for longer than a week, consult the doctor before taking **Asenta** again. Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

If you stop taking Asenta:

Do not stop taking this medicine unless your doctor instructed you to do so. If you stop taking **Asenta**, the benefits of the treatment will gradually disappear. Before stopping, discuss the consequences with the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding the use of Asenta, consult the doctor or pharmacist.

4. Side effects

Like all medicines, the use of **Asenta** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects

You should refer to your doctor immediately if any of the following serious effects occur, you may need urgent medical treatment:

- liver damage such as hepatitis. The symptoms of hepatitis are: nausea and vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark colored urine (appear at a frequency of up to one user out of 1,000).
- stomach or duodenal ulcers. The symptoms are: stomach pain and discomfort (indigestion) in the abdominal area between the navel and the breast bone (appear at a frequency of up to one user in 100).
- bleeding in the stomach or intestines, manifested by coal-black stools or visible blood from the rectum (appear at a frequency of up to one user in 100).
- seizures or convulsions (appear at a frequency of up to one user in 100).
- high fever with muscle stiffness, sweating, or a lowered level of consciousness [a disorder called Neuroleptic Malignant Syndrome (NMS)] (appear at a frequency of up to one user in 10,000).
- muscle weakness, tenderness or pain, and especially if you feel sick at the same time, have a fever or dark urine. These signs may be caused by abnormal muscle tissue breakdown, which can be life threatening and cause kidney problems (a condition called rhabdomyolysis) (appear at a frequency of up to one user in 10,000).

Other side effects

Very common side effects appear in more than one user in 10:
Diarrhea, nausea, headaches.

Common side effects appear at a frequency of up to one user in 10:
Muscle cramps, tiredness, insomnia, the common cold, hallucinations (seeing and hearing things that are not really there), unusual dreams including nightmares, agitation, aggressive behavior, fainting, dizziness, stomach feeling uncomfortable, vomiting, anorexia, rash, passing urine uncontrollably, pain, accidents (patients are more likely to fall and be injured).

Uncommon side effects appear at a frequency of up to one user in 100:
Slow heart rate, salivary hypersecretion.

Rare side effects appear at a frequency of up to one user in 1,000:
Stiffness, shaking or uncontrollable movements especially of the face and tongue but also of the limbs, heart rate disorders.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting Side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: https://sideeffects.health.gov.il
Additionally, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and blister. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not discard medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that are not longer needed. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient this medicine also contains:
  Lactose monohydrate, microcrystalline cellulose, maize starch, hydroxypropyl cellulose, hydroxypropylmethylcellulose, titanium dioxide, magnesium stearate, polyethylene glycol 400.
  Additional ingredient in **Asenta 10** tablets only - yellow iron oxide.
- What the medicine looks like and what the package contains:
  Blisters (trays) containing 10, 28 or 30 tablets.
  Asenta 5: Round, white tablet with the number 5 embossed on one side.
  Asenta 10: Round, yellow tablet with the number 10 embossed on one side.
- Registration Holder, Manufacturer and address: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in December 2020.
- Drug registration number in the National Drug Registry of the Ministry of Health:
- **Asenta 5:** 11717.29882, **Asenta 10:** 11718.29883

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