

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **EDRAK® ODT** is and what it is used for.
2. Before you take **EDRAK® ODT**
3. How to take **EDRAK® ODT**
4. Possible side effects.
5. How to store **EDRAK® ODT**
6. Further information.

1. What EDRAK® ODT is and what it is used for:

Pharmacotherapeutic group:
EDRAK® ODT (Memantine Hydrochloride) belongs to a group of medicines known as anti-dementia medicines.

Memory loss in Alzheimer's disease is due to a 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. **EDRAK® ODT** belongs to a group of medicines called NMDA-receptor antagonists. **EDRAK® ODT** acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

Therapeutic indications:

EDRAK® ODT is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. Before you take EDRAK® ODT:

a. Do not Take EDRAK® ODT:
If you are allergic (hypersensitive) to memantine hydrochloride or any of the other ingredients of **EDRAK® ODT** tablets.

b. Take special care with EDRAK® ODT:

- If you have a history of epileptic seizures.
- 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). In these situations the treatment should be carefully supervised, and the clinical benefit of **EDRAK® ODT** reassessed by your doctor on a regular basis.
- If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the memantine doses accordingly.
- The use of medicinal products called amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.
- **EDRAK® ODT** is not recommended for children and adolescents under the age of 18 years.

C. Taking other medicines,

herbal, or dietary supplements:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular **EDRAK® ODT** may change the effects of the following medicines and their dose may need to be adjusted by your doctor:
Amantadine, ketamine, dextromethorphan, dantrolene, baclofen, cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine, hydrochlorothiazide (or any combination with hydrochlorothiazide), anticholinergics (substances generally used to treat movement disorders or intestinal cramps), anticonvulsants (substances used to prevent and relieve seizures), barbiturates (substances generally used to induce sleep), dopaminergic agonists (substances such as L-dopa, bromocriptine), neuroleptics (substances used in the treatment of mental disorders), oral anticoagulants.

If you go into hospital, let your doctor know that you are taking **EDRAK® ODT**

d. Taking 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) or if you are suffering from states of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

The tablets can be taken with or without food.

e. Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.
Tell your doctor if you are pregnant or planning to become pregnant. The use of memantine in pregnant women is not recommended.
Women taking **EDRAK® ODT** should not breast-feed.

f. Driving and using machines:

Your doctor will tell you whether your illness allows you to drive and to use machines safely.

Also, **EDRAK® ODT** may change your reactivity, making driving or operating machinery inappropriate.

3. How to take EDRAK® ODT:

Always take **EDRAK® ODT** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage:

The recommended dose of **EDRAK® ODT** for adults and elderly patients is 20 mg once a day. In order to reduce the risk of side effects, this dose is achieved gradually by the following daily treatment scheme.

For up-titration other tablet strengths are available.

At the beginning of treatment you will start by using **EDRAK® ODT** 5 mg once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20mg once a day, which is

reached at the beginning of the 4th week.

Dosage in patients with impaired kidney function:

If you have impaired kidney function, your doctor will decide upon a dose that suits your condition. In this case, monitoring of your kidney function should be performed by your doctor at specified intervals.

Administration:

EDRAK® ODT should be administered orally once a day. To benefit from your medicine you should take it regularly every day at the same time of the day. The tablets can be taken with or without food.

Posology and method of administration:

EDRAK® ODT should be taken as the following:

1. Place the tablet in your mouth on your tongue. Since **EDRAK® ODT** is fragile, it should be taken immediately on opening the blister.
2. Allow it to dissolve, slowly for five minutes (it must never be chewed or swallowed undissolved).
3. Swallow with 240 mL of water.
4. If you have a dry mouth, use water to moisten it first.
5. Never take more than the recommended dose.

Duration of treatment:

Continue to take **EDRAK® ODT** as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

If you take more EDRAK® ODT than you should:

In general, taking too much **EDRAK® ODT** should not result in any harm to you. You may experience increased symptoms.

- If you take a large overdose of **EDRAK® ODT**, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take EDRAK® ODT

• If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.

• Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **EDRAK® ODT** can cause side effects, although not everybody gets them.

In general, the observed side effects are mild to moderate.

Common (affects 1 to 10 users in 100):

- Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity.

Uncommon (affects 1 to 10 users in 1,000):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/ thromboembolism).

Very Rare (affects less than 1 user in 10,000):

- Seizures.

Not known (frequency cannot be estimated from the available data):

- Inflammation of the pancreas, inflammation of the liver (hepatitis) and psychotic reactions.

Alzheimer's disease has been associated with depression, suicidal

ideation and suicide. These events have been reported in patients treated with memantine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store EDRAK® ODT

- Keep out of the reach and sight of children.

- Do not use **EDRAK® ODT** after the expiry date, which is stated on the carton and the blister after Exp. . The expiry date refers to the last day of that month.

- Do not store above 30°C.

- Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What EDRAK® ODT contains:

The active substance is: Memantine hydrochloride

b. what EDRAK® ODT look like and contents of the pack:

EDRAK® ODT 5mg: Each orodispersible tablet contains Memantine Hydrochloride 5 mg in packs of 30 tablets.

EDRAK® ODT 10mg: Each orodispersible tablet contains Memantine Hydrochloride 10 mg in packs of 30 tablets.

EDRAK® ODT 15mg: Each orodispersible tablet contains Memantine Hydrochloride 15 mg in packs of 30 tablets.

EDRAK® ODT 20mg: Each orodispersible tablet contains Memantine Hydrochloride 20 mg in packs of 30 tablets.

Hospital packs are also available (500, 1000).

Not all pack sizes are available in all countries.

The other ingredient: Polacrillin, Sodium Hydroxide, water, lactose monohydrate, Microcrystalline Cellulose, Mannitol, Croscarmellose Sodium, Aspartame, Colloidal silicon anhydrous, Red Iron oxide and peppermint flavor and Magnesium Stearate (for 10, 15 & 20mg).

- Physical Description:

EDRAK® ODT (5, 10, 15 & 20): Light pink, round, flat tablets with beveled edges

- Pharmaceutical form:

Orodispersible Tablets for oral use
EDRAK® ODT are packed in: Alu, Peelable Alu Blister in carton box with a folded leaflet

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d. This leaflet was last approved in 11/ 2017; I-Edrak-EDK-LMO-R0/AE

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor
- Keep medicament out of the reach of children.

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