

**PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Alimemazin Evolan 20 mg capsule, hard**

alimemazine

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What <Invented name> is what it is used for**

<Invented name> contains alimemazine which has calming properties and makes you sleep better.

<Invented name> is used

- in short-term treatment of sleep disorders in adults.
- as a tranquilizer before anesthesia in adults and children over 12 years.

#### **2. What you need to know before you take <Invented name>**

##### **Do not take <Invented name>**

- If you are allergic to alimemazine or any of the other ingredients of this medicine (listed in section 6).
- 
- If you have leucopenia or have previously suffered from agranulocytosis (blood changes),
- If you suffer from myasthenia gravis (a disease causing muscle weakness)
- <Invented name> capsules should not be given to children, see section 2.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking <Invented name> if you have

- Liver or kidney damage.
- Diseases with seizures (e.g. epilepsy)
- Parkinson's disease.
- Pronounced slow heart rhythm (bradycardia), cardiovascular diseases or a hereditary form of ECG changes (prolonged QT time).
- had narrow-angle glaucoma.
- risk factors for stroke.
- or previously have had problems with the abuse of alcohol, drugs or medicines.

Contact your doctor immediately if you get a state called neuroleptic malignant syndrome, which causes a combination of among others fever, stiffness in the muscles, consciousness disorder and variations in the blood pressure. You may need immediate medical treatment.

You should not be exposed to sunlight when you are being treated with medicines such as <Invented name>.

If you get treatment for other diseases than those prescribed for <Invented name>, talk to your doctor.

### **Elderly**

<Invented name> should be used with caution in the elderly, as they may be more sensitive to the effects of alimemazine, such as muscular effects, anxiety, restlessness, dizziness, tiredness, fall in blood pressure, inability to empty the urine bladder and constipation.

Because alimemazine may lead to an inability to empty the bladder, Alimemazine Evolan should be used with caution in elderly patients with suspected prostate enlargement.

### **Children**

Alimemazine should not be used in children under the age of 3 years.

<Invented name> capsules should not be given to children aged 3-12 years, Other pharmaceutical forms such as alimemazine in the form of oral drops, solution are available for children 3-12 years..

### **Other medicines and <Invented name>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription. If certain other medicines are taken at the same time, the treatment effect may be affected and the dose of <Invented name> or of the other medicine may need to be changed, or other measures of caution may be necessary.

It is very important that you tell your doctor if you are using any of the following medicines:

- certain neuroleptics (medicines for treatment of mental diseases)
- certain medicines for irregular heart rhythm (e.g. quinidine)
- erythromycin, moxifloxacin (antibiotics)
- methadone (medicine for treatment of addiction)
- mefloquine (medicine for treatment of malaria)
- certain antidepressants (tricyclic)
- medicines that alleviate or reduce anxiety
- medicines for sleep problems
- opioids (in case of pain)
- barbiturates (sedatives and antispasmodics)
- levodopa (medicine for treatment of Parkinson's disease)
- lithium (medicine for treatment of states of mania and depressions)
- cisapride (medicine for treatment of disturbances of the movements in the gastrointestinal tract)
- some types of diuretics
- medicines used to treat urinary incontinence

Concomitant use of sedatives, medicines for sleep problems or strong painkillers (opioids) can lead to extreme tiredness and unconsciousness, which can be life-threatening.

### **<Invented name> with alcohol**

Do not drink alcohol while being treated with <Invented name>.

Concomitant use with alcohol can lead to extreme tiredness and unconsciousness, which can be life-threatening.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

The foetus may be affected when using Alimemazine Evolan during pregnancy.

#### Breast-feeding

Alimemazine passes into breast milk.

### **Driving and using machines**

In treatment with <Invented name>, your possibility to react may be reduced. Side effects such as tiredness, dizziness and temporary reduction of visual acuity may occur.

#### **<Invented name> contains lactose**

If you have an intolerance to some sugars, contact your doctor before taking <Invented name>.

## **3. How to take <Invented name>**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose should be determined by a doctor who will adjust it individually for you. Never exceed the dose prescribed by your doctor. Your doctor should prescribe the lowest effective dose for the shortest possible treatment time.

The recommended dose is

*Short-term treatment of sleep disorders in adults:* 10-30 mg 1-2 hours before bedtime. At doses other than 20 mg, other alimemazine-containing medicinal products should be selected.

### **Use in children and adolescents**

Alimemazine capsules should not be given to children.

### **If you take more <Invented name> than you should**

If you have taken a too much of the medicine or if e.g. a child has taken your medicine by mistake, contact your doctor or hospital immediately for assessment of the risk and advice. If possible, show them the pack of <Invented name>. Symptoms of overdose are tiredness, drowsiness, unconsciousness and heart effects such as rapid heartbeat. Overdose can be life-threatening, especially with concomitant use of alcohol, drugs and/or certain medicines (see “<Invented name> with alcohol”).

### **If you forget to take <Invented name>**

Do not take a double dose to make up for a forgotten dose.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking <Invented name> and contact your doctor immediately if you get any of the following symptoms:**

- Fever, sweating, stiff muscles, rapid heartbeat, confusion and anxiety. This may be due to a rare life-threatening condition called "malignant neuroleptic syndrome" (may affect up to 1 in 1,000 people).
- Very fast, uneven or forceful heartbeat (palpitations), difficulty breathing, chest pain and dizziness. These can be symptoms of serious heart side effects (may affect up to 1 in 1,000 people).
- In rare cases <Invented name> may affect the white blood cells to the detriment of the immune system. If you develop an infection with symptoms such as fever coupled with a severely deteriorated general state of health or a fever with local infection symptoms such as sore throat/mouth or difficulty urinating, you are to contact a doctor immediately so blood samples can be used to rule out a lack of white blood cells (agranulocytosis). It is important that you in connection with this inform medical personnel about your medication.

The side effects vary depending on the dose, treatment duration and the disease treated. Many of the possible side effects generally occur only at the start of treatment and will then disappear after some time.

*Common (may affect up to 1 in 10 people):*

- Tiredness.
- Headache, light dizziness.
- Nasal congestion.
- Dry mouth. Longterm treatment may lead to dry mouth and an increased risk of damage to the teeth and oral mucous membranes. You should therefore brush your teeth and take extra care of your oral hygiene during the treatment with Alimemazin Evolan.

*Uncommon (may affect up to 1 in 100 people):*

- Constipation.
- Difficulty urinating.
- A temporary reduction of the visual acuity.

*Rare (may affect up to 1 in 1000 people):*

- Effect on the blood.
- Drop in blood pressure with dizziness, especially in elderly and patients that are dehydrated or have a low blood volume.
- Jaundice without liver damage.
- Clouding of the lens and cornea of the eye (at high dose and long-term treatment).
- Light tremor, stiffness, shaking in e.g. hands and fingers, twitches in the face, grimacing and strange movements of the tongue. Sometimes, a special form of nervousness may occur, e.g. difficulty sitting still.

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

- Seizures
- High prolactin levels, milky secretion from the breasts, enlarged breasts in men, absence of a menstrual period (in woman of reproductive age) and impotence have been reported for drugs in the phenothiazine group, to which alimemazine belongs.

### **Reporting of suspected side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[to be nationally completed]

## **5. How to store <Invented name>**

Keep this medicine out of the sight and reach of children and adolescents.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What <Invented name> contains**

- The active substance is alimemazine (as alimemazine hemitartrate).
- The other ingredients are lactose monohydrate, cornstarch, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate, titanium dioxide (E171), gelatin.

### **What <Invented name> looks like and contents of the pack**

White, cylindrical gelatin capsule, length  $14.3 \pm 0.3$  mm

A white plastic bottle with 100, 120 or 200 capsules.

### **Marketing Authorisation Holder**

Evolan Pharma AB

P.O. Box 120

SE-182 12 Danderyd, Sweden

### **Manufacturer**

Balkanpharma-Razgrad AD

68 "Aprilsko vastanie" Blvd.

BGR-7200 Razgrad, Bulgaria

### **This leaflet was last revised**

2024-10-02