

# Katena<sup>®</sup> instructions (Gabapentinum)

translated from original Russian instructions by Extrapharmacy Online Store

<http://extrapharmacy.ru>

**Name in Cyrillic :** КАТЭНА

**Active substance :** Gabapentinum

**Pharmacologic effect :** antiepileptic

## **Indications :**

The treatment of neuropathic pain in adults (18 years and older). Efficacy and safety in patients below the age of 18 years have not been established;

Monotherapy of partial seizures in epilepsy (with secondary generalization and without) in adults and children over the age of 12 years.

The efficacy and safety of monotherapy in children under the age of 12 years have not been established;

As an adjunct in the treatment of partial seizures in epilepsy (with secondary generalization and without) in adults and children aged 3 years and older.

Safety and efficacy of gabapentin adjunctive therapy in children aged less than 3 years have not been established.

## **Contraindications**

- Children under 3 years of age;
- Hypersensitivity to gabapentin or auxiliary ingredients.

Katena should be prescribed with precautions in renal failure.

## **Side effects**

Cardio-vascular system: vasodilation symptoms of hypertension.

Digestive system: dyspepsia, flatulence, nausea, vomiting, abdominal pain, constipation, diarrhea, dry mouth or throat, anorexia, gingivitis, dental disease, increase in appetite, increase in liver transaminases.

Musculoskeletal system: myalgia, arthralgia, back pain, increased fragility of bones.

Nervous system: drowsiness, dizziness, ataxia, amnesia, confusion, loss of coordination, fatigue, abnormal thinking, tremor, hypoesthesia, depression, dysarthria, insomnia, nervousness, nystagmus, strengthening, weakening or absence of reflexes, fatigue, anxiety, hostility, hyperkinesia, emotional lability.

Respiratory system: pharyngitis, rhinitis, dyspnea, cough, pneumonia, bronchitis, respiratory infection.

Genitourinary system: urinary tract infection, impotence.

Senses: blurred vision, amblyopia, diplopia.

Hematopoiesis: leukopenia, purpura (often it is described as bruising, occurred when a physical injury).

Allergic reactions: skin rash, itching, acne.

Other: fever, viral infection, weight gain, pain of various localization, peripheral edema, facial edema, headache.

## **Interaction**

With simultaneous use of gabapentin and morphine when morphine was taken 2 hours prior to gabapentin, it was observed the increasing of average AUC of gabapentinum by 44% compared to a monotherapy of gabapentinum, that was associated with an increase in pain threshold. The clinical significance of this change is not established, the pharmacokinetic characteristics of morphine is not changed. Side effects of morphine during coadministration with gabapentinum did not differ from that of morphine when taking in conjunction with the placebo.

The interaction between gabapentinum and phenobarbital, phenytoin, carbamazepine and valproic acid were not observed. The pharmacokinetics of Katena in the equilibrium state is the same in healthy subjects and patients receiving other anticonvulsants.

Concomitant use of Katena with oral contraceptives containing norethisterone and / or ethinyl estradiol, was not accompanied by changes in the pharmacokinetics of the two components.

The simultaneous use of Katena with antacids that contain aluminum and magnesium, caused reduction of gabapentin

bioavailability by approximately 20%. Katena is recommended to take approximately 2 hours after taking an antacid. Probenecid does not affect the renal excretion of gabapentinum.

## Dosing and Administration

Katena (Gabapentinum) capsules are taken regardless of the meal

If you need to reduce the dose, stop the drug or replace it with an alternative means, it should be done gradually over a minimum of 1 week.

### Neuropathic pain in adults :

The initial dose of Gabapentinum is 900 mg per day in 3 divided doses;

if necessary, depending on the effect - the dose should be gradually increased until a maximum - 3600 mg / day. Treatment can be started immediately with a dose of 900 mg / day (300 mg 3 times daily) or within the first 3 days, the dose can be increased gradually to 900 mg / day as follows:

1st day - 300 mg x 1 time per day;

2nd day - 300 mg x 2 times a day;

3rd day - 300 mg x 3 times a day.

### Partial seizures :

Adults and children over the age of 12 years: the effective dose of Katena varies from 900 to 3600 mg per day.

The therapy can be started with a dose of 300 mg three times a day for 1 day or increased gradually to 900 mg according to the scheme described above (see Neuropathic pain in adults). Subsequently the dose may be increased to the maximum - 3600 mg / day in 3 divided equal doses. The maximum interval between doses at 3-fold taking the drug should not exceed 12 hours in order to prevent the resumption of seizures. It was well tolerated in doses up to 4800 mg / day.

Children aged 3-12 years: initial dose varies from 10 to 15 mg / kg / day, which is administered in equal doses three times a day and increased to effective dose for about 3 days.

The effective dose of gabapentin in children aged 5 years and older is 25-35 mg / kg / day in 3 equal doses reception.

The effective dose of gabapentin in children aged 3 to 5 years is 40 mg / kg / day in 3 equal doses reception.

Katena (Gabapentinum) is well tolerated in doses up to 50 mg / kg / day for prolonged use. The maximum interval between doses of the drug dose should not exceed 12 hours in order to avoid the resumption of seizures.

### Selection of doses in renal failure

Patients with renal impairment is recommended to decrease the dose of gabapentin according to the table:

<b>creatinine Cl , ml/min</b>	<b>Daily dose , mg/day*</b>
>80	900-3600
50-79	600-1800
30-49	300-900
15-29	150**-600
<15	150**-300

\* The daily dose should be administered in 3 doses.

\*\* Prescribed by 300 mg every other day.

### The recommendations for patients on hemodialysis

Patients on hemodialysis who had not previously received gabapentin, a drug is recommended to be administered in a saturating dose of 300-400 mg, and then apply it to 200-300 mg every 4 hours of hemodialysis.

**Overdose:**

Symptoms: dizziness, double vision, impaired speech, drowsiness, lethargy and diarrhea.

Treatment: gastric lavage, activated charcoal, symptomatic therapy. For patients with severe renal insufficiency - hemodialysis may be indicated.

**Pregnancy and breast-feeding**

There is no data on the safety and efficacy of gabapentinum in pregnancy, so the use of Katena during pregnancy is possible only if the expected benefit to the mother justifies the potential risk to the fetus.

Gabapentinum is excreted in breast milk, so during treatment should abandon breastfeeding.

**Special instructions**

There is no need to control the concentration of gabapentin in plasma.

Katena may be used in combination with other anticonvulsants excluding changes in its concentration in plasma or other anticonvulsants concentration in serum.

**Manufacturer**

Belupo, Croatia

**Reliable supplier with fast Worldwide shipping**

Extrapharmacy Online Store

<http://extrapharmacy.ru>

**Storage**

The temperature is not above 25 ° C.

Keep out of the reach of children.

Shelf-life of the drug is 3 years.