

Package leaflet: Information for the user

Zouma 100 mg, 300 mg, and 400 mg CAPSULES, hard Gabapentin

Read all of this leaflet carefully before you start taking 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 Zouma is and what it is used for
2. What you need to know before you take Zouma
3. How to take Zouma
4. Possible side effects
5. How to store Zouma
6. Contents of the pack and other information

1. What Zouma is and what it is used for

Zouma belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

The active substance in Zouma capsules hard is gabapentin.

Zouma is used to treat

- Various forms of **epilepsy** (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). Your doctor will prescribe Zouma for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Zouma in addition to your current treatment unless told otherwise. Zouma can also be used on its own to treat adults and children over 12 years of age.
- **Peripheral neuropathic pain** (long lasting pain caused by damage to the nerves): A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes or shingles. These pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles.

2. What you need to know before you take Zouma

Do not take Zouma:

- if you are allergic to gabapentin or any of the other ingredients of this medicine (listed in section 6)..

Warnings and precautions

Talk to your doctor or pharmacist before taking Zouma

- If you suffer from kidney problems your doctor may prescribe a different dosing schedule
- If you are receiving haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness
- if you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas)

- if you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen

Cases of abuse and dependence have been reported for gabapentin from the post-marketing experience. Talk to your doctor if you have a history of abuse or dependence.

A small number of people being treated with anti-epileptics such as gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Important information about potentially serious reactions

A small number of people taking Gabapentin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking Gabapentin.

Read the description of these symptoms in section 4 of this leaflet under ‘Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious’

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems. You may also experience discoloration of your urine, and a change in blood test results (notably blood creatine phosphokinase increased). If you experience any of these signs or symptoms, please contact your doctor immediately.

Other medicines and Zouma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

Medicines containing opioids such as morphine

If you are taking any medicines containing opioids (such as morphine) please tell your doctor or pharmacist as opioids may increase the effect of Zouma.

In addition, combination of Zouma

with opioids may cause symptoms like sleepiness and/or decrease in breathing.

Antacids for indigestion

If Zouma and antacids containing aluminium and magnesium are taken at the same time, absorption of Zouma from the stomach may be reduced. **It is therefore recommended that Zouma is taken at the earliest two hours after taking an antacid.**

Zouma

- is not expected to interact with other antiepileptic drugs or the oral contraceptive pill.
- may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking.

Pregnancy, breast-feeding and fertility

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

Zouma should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There have been no studies specifically looking at the use of gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Zouma. Do not suddenly discontinue taking this medicine as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding

Gabapentin, the active substance of Zouma Capsules, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Zouma.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Zouma may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

Zouma 300 mg contains sunset yellow (E110)

The capsules contain **sunset yellow (E110)** which may cause rarely allergic reactions.

3. How to take Zouma

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

Your doctor will determine what dose is appropriate for you.

Epilepsy - the recommended dose is

Adults and adolescents

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually.

- The starting dose will generally be between 300 mg and 900 mg each day.
- Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children aged 6 years and above

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days.

- The usual dose to control epilepsy is 25-35 mg per kg of body weight per day. It is usually given in 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Zouma is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain – the recommended dose is

Adults

Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually.

- The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

If you have kidney problems or are receiving haemodialysis

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

If you are an elderly patient (over 65 years of age)

You should take the normal dose of Zouma unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you have the impression that the effect of Zouma too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Zouma is for oral use. Always swallow the capsules whole with plenty of water. Zouma can be taken with or without food.

Continue taking Zouma until your doctor tells you to stop.

If you take more Zouma than you should

Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more Zouma than your doctor prescribed. Take along any capsules that you have not yet taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Zouma

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Zouma

DO NOT stop taking Zouma unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking Zouma suddenly or before your doctor tells you, there is an increased risk of seizures.

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

4. Possible side effects

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

Contact your doctor immediately if you experience **any of the following symptoms after taking this medicine as they can be serious:**

- Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- Severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness, and/or hair loss (these may be symptoms of a serious allergic reaction)
- Persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- Zouma may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop Zouma. Call your doctor right away if you have any of the following symptoms:
 - skin rash
 - hives
 - fever
 - swollen glands that do not go away
 - swelling of your lip and tongue
 - yellowing of your skin or of the whites of the eyes
 - unusual bruising or bleeding
 - severe fatigue or weakness
 - unexpected muscle pain
 - frequent infections
 - breathing problems, which if severe you may need emergency and intensive care to continue breathing normally

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Zouma.

If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Other side effects include:

Very common: (may affect more than 1 in 10 people)

- viral infection
- feeling drowsy, dizziness, lack of coordination
- feeling tired, fever.

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

- pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections
- low white blood cell counts
- anorexia, increased appetite
- anger towards others, confusion, in mood changes, depression, anxiety, nervousness, difficulty with thinking
- convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
- blurred vision, double vision
- vertigo
- high blood pressure, flushing or dilation of blood vessels
- difficulty breathing, bronchitis, sore throat, cough, dry nose

- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- facial swelling, bruises, rash, itch, acne
- joint pain, muscle pain, back pain, twitching
- difficulties with erection (impotence)
- swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- decrease in white blood cells, increase in weight
- accidental injury, fracture, abrasion

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

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

- Agitation (a state of chronic restlessness and unintentional and purposeless motions)
- Allergic reaction such as hives
- Decreased movement
- Racing heartbeat
- Swelling that may involve the face, trunk and limbs
- Abnormal blood test results suggesting problems with the liver.
- Mental impairment
- Fall
- Increase in blood glucose levels (most often observed in patients with diabetes)
- Difficulty swallowing

Rare: (may affect up to 1 in 1,000 people)

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- Loss of consciousness
- Decrease in blood glucose levels (most often observed in patients with diabetes)
- Trouble breathing, shallow breaths (respiratory depression)

After marketing gabapentin the following side-effects have also been reported:

- Decreased platelets (blood clotting cells)
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- A group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of liver occurring together
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- Yellowing of the skin and eyes (jaundice), inflammation of the liver
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- Acute kidney failure, incontinence
- Increased breast tissue, breast enlargement
- Adverse events following the abrupt discontinuation of Gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
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- Breakdown of muscle fibers (rhabdomyolysis)
- Change in blood test results (creatinine phosphokinase increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Low blood sodium level

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme [at Website: www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zouma

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

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

Do not store above 25°C. Store in the original container. Keep blister in the outer carton.

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 to protect the environment.

6. Contents of the pack and other information

What Zouma capsules contain:

- The active substance is gabapentin. Each hard capsule contains either 100 mg, 300 mg or 400 mg gabapentin.
- The other ingredients are:

Capsule contents: talc, pregelatinised (maize) starch.

Capsule cap/body: gelatin, black iron oxide (E172) [100 mg & 400 mg], titanium dioxide (E171), erythrosin (E127) [300 mg], sunset yellow (E110) [300 mg], red iron oxide (E172) [400 mg], yellow iron oxide (E172) [400 mg].

Printing ink: shellac, black iron oxide (E172), propylene glycol.

What Zouma Capsules look like and contents of the pack:

Zouma 100 mg capsules, hard

Hard gelatin capsules with a grey cap and body, filled with a white to off-white powder with small agglomerates. The capsule cap and body are each imprinted with the numbers '93' and '38'. The capsules are available in packs of 10, 20, 28, 50, 90, 100, 200 (4 x 50), 500 (10 x 50) or 1000 (20 x 50).

Zouma 300 mg capsules, hard

Hard gelatin capsules with an orange cap and body, filled with a white to off-white powder with small agglomerates. The capsule cap and body are each imprinted with the numbers '93' and '39'. The capsules are available in packs of 10, 20, 28, 50, 90, 100, 200 (2 x 100), 500 (10 x 50) or 1000 (20 x 50).

Zouma 400 mg capsules, hard

Hard gelatin capsules with a brown cap and body, filled with a white to off-white powder with small agglomerates. The capsule cap and body are each imprinted with the numbers '93' and '40'. The capsules are available in packs of 10, 20, 28, 30, 50, 90, 100, 200 (2 x 100), 500 (10 x 50) or 1000 (20 x 50).

Not all pack sizes may be marketed.

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APPROVALS

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Tina Dedman	Regulatory Affairs Approval	29-Apr-2019 10:29:01 AM