

Package leaflet: Information for the user

Shaktatin 50 mg/ml oral solution

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

1. What Shaktatin is and what it is used for

Shaktatin contains the active substance gabapentin which belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long-lasting pain caused by damage to the nerves).

Shaktatin 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 Shaktatin for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Shaktatin in addition to your current treatment unless told otherwise. Shaktatin 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. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

2. What you need to know before you take Shaktatin

Do not take Shaktatin:

- ◆ 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 Shaktatin:

- ◆ If you have kidney problems your doctor may prescribe a different dosing schedule
- ◆ If you are on 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.

- ◆ Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs; it may mean you have a greater risk of becoming dependent on Shaktatin.
- ◆ If you have myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse.

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

Dependence

Some people may become dependent on Shaktatin (a need to keep taking the medicine). They may have withdrawal effects when they stop using Shaktatin or reduce the dose (see section 3, “How to take Shaktatin” and “If you stop taking Shaktatin”). If you have concerns that you may become dependent on Shaktatin, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Shaktatin, it could be a sign that you have become dependent.

- You feel you need to take the medicine for longer than advised by your prescriber
- You feel you need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

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.

Important information about potentially serious reactions

Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin. Stop using Shaktatin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 Shaktatin

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine including medicines obtained without a prescription (including herbal medicines). This is because Shaktatin can affect the way some other medicines work. Also some other medicines can affect the way Shaktatin

works. 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 Shaktatin. In addition, combination of Shaktatin with opioids may cause sleepiness, sedation, decrease in breathing, or death.

Antacids for indigestion

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

Shaktatin

- Is not expected to interact with other antiepileptic 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.

Shaktatin with food

Shaktatin can be taken with or without food.

Pregnancy and breast-feeding

- If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.
- You should not stop your treatment without discussing this with your doctor.
- If you are planning to become pregnant you should discuss your treatment with your doctor <or pharmacist> as early as possible before you become pregnant.
- If you are breastfeeding or planning to breastfeed, ask your doctor <or pharmacist> for advice before taking this medicine.

Pregnancy

Shaktatin can be used during the first 3 months of pregnancy if needed.

If you plan to become pregnant or if you are pregnant or think you may be pregnant, talk to your doctor straight away.

If you have become pregnant and you have epilepsy, it is important that you do not stop taking your medicine without first consulting your doctor, as this may worsen your illness. Worsening of your epilepsy may put you and your unborn child at risk.

In a study reviewing data from women in Nordic countries who took gabapentin in the first 3 months of pregnancy, there was no increased risk of birth defects or problems with the development of brain function (neurodevelopment disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth.

If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (medicines for treatment of severe pain). Newborns should be monitored carefully by the healthcare professionals.

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Neurontin. 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 Shaktatin, is passed on through human milk. Because the effect on the baby is unknown, this medicine should only be used in breast-feeding mothers only if the benefits clearly outweigh the risks.

Driving and using machines

Shaktatin 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.

Shaktatin contains:

- Methyl parahydroxybenzoate (E218) and Ethyl parahydroxybenzoate (E214), which may cause allergic reactions (possibly delayed).
- Propylene glycol (E1520): If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- This medicine contains less than 1 mmol sodium (23 mg) per dose (300 mg gabapentin), that is to say essentially „sodium-free“.

3. How to take Shaktatin

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

Your doctor will determine what dose is appropriate for you. Always use the amount of medicine the doctor has told you. For doses not practicable with this medicinal product, other pharmaceutical forms and products are available.

Epilepsy, the recommended dose is:

Adults and adolescents from 12 years:

Your doctor will usually build up your dose gradually. The dose build up will generally be from 6 ml (300 mg) once a day to 18 ml (900 mg) divided in 3 doses per day. Thereafter, the dose may be further increased as instructed by your doctor, to reach a dose suitable for you, but up to a maximum of 72 ml (3600 mg) each day. Your doctor will tell you to take the daily dose divided in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children from 6 years and up to 12 years:

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 0.5 ml to 0.7 ml (25 to 35 mg) per kg of body weight per day. It is usually given in 3 separate doses each day, usually once in the morning, once in the afternoon and once in the evening.

Children under 6 years

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

Peripheral neuropathic pain, the recommended dose is:

Adults:

Your doctor will usually build up your dose gradually. The dose build up will generally be from 6 ml (300 mg) once a day to 18 ml (900 mg) divided in 3 doses per day. Thereafter, the dose may be further increased as instructed by your doctor, to reach a dose suitable for you, but up to a maximum of 72 ml

(3600 mg) each day. Your doctor will tell you to take the daily dose divided 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 Shaktatin 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 Shaktatin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

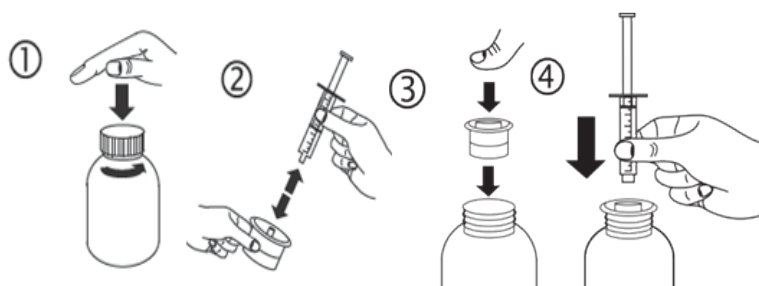
Method of administration:

This medicinal product must be taken orally.

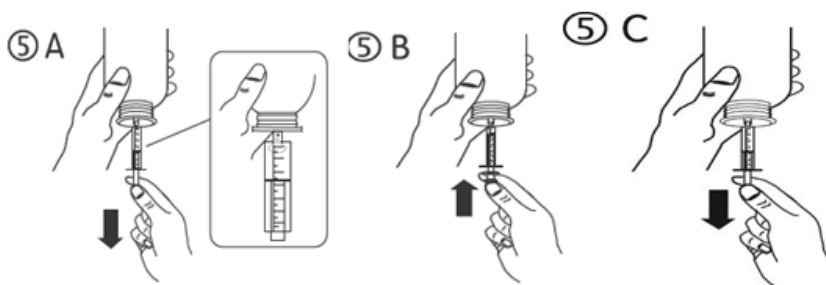
A 10 ml oral syringe, with 0.5 ml graduation, is included in the carton together with a bottle adaptor for the syringe. Use these to measure the required dose.

How to use the syringe:

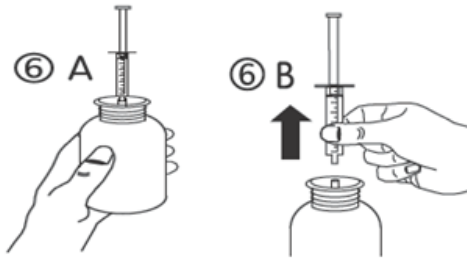
1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3)
3. Ensure that the adaptor is properly fixed by pressing down hard with your thumb, so the adaptor is in line with the bottle opening. Put the syringe in the adaptor opening (figure 4).



4. Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A). Push the piston upwards to remove any possible bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



5. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



6. Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe.
7. For higher doses, repeat step 3 to 6.
8. Close the bottle with the plastic screw cap, leaving the adaptor within the bottle. Wash the syringe on the out- and inside with water.

Alternative method of administration (with feeding tubes)

This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. Ask your doctor, pharmacist, or nurse about this if the medicine cannot be swallowed.

Taking this medicine via NG or PEG tubes

Use silicone, PVC or polyurethane NG or PEG tubes.

1. Ensure the tube is clear before taking the medicine.
2. Flush the tube with 15 mL water.
3. Administer the medicine into the tube with a suitable measuring device. A doctor, nurse or pharmacist will guide you how to do this
4. Immediately flush the tube again with 15 mL of water.

If you take more Shaktatin 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 Shaktatin than your doctor prescribed. Always take any leftover medicine with you, as well as the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Shaktatin

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 Shaktatin

Do not suddenly stop taking Shaktatin or reduce your dose, unless you receive any of the skin reactions described in section 4.

If you want to stop taking Shaktatin or reduce your dose, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped or your dose is reduced it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with Shaktatin or after reducing your dose, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping Shaktatin or reducing your dose. If you experience withdrawal effects, you should contact your doctor.

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.

Stop using Shaktatin and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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

- Severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness (these may be symptoms of a serious allergic reaction called angioedema).
- Persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- Breathing problems, which if severe you may need emergency and intensive care to continue breathing normally.
- Muscle pain, dark urine and feeling weak or tired as these may be symptoms of rhabdomyolysis (breakdown of muscle fibers).
- Shaktatin may cause anaphylaxis, 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 a rash when you get this type of reaction. It may cause you to be hospitalised or to stop Shaktatin. 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

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

- 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, 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, flulike 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):

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

Not known: frequency cannot be estimated from the available data

- Becoming dependent on Shaktatin (drug dependence)
- Hair loss (alopecia)

After marketing of Shaktatin the following side effects have been reported:

- Decreased platelets (blood clotting cells)
- Suicidal thoughts, hallucinations

- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Ringing in the ears
- Yellowing of the skin and eyes (jaundice), inflammation of the liver
- 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
- Change in blood test results (creatine phosphokinase increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Worsening of myasthenia gravis (a disease causing muscle weakness) (frequency not known)

After stopping a short or long-term treatment with Shaktatin or after reducing your dose, you need to know that you may experience certain side effects, so-called withdrawal effects (see “If you stop taking Shaktatin”).

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

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 national reporting system listed in Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Shaktatin

- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date which is stated on the carton or bottle after “EXP”. The expiry date refers to the last day of that month.
- Do not store above 25 °C. Do not refrigerate or freeze.
- Discard 30 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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 Shaktatin contains

The active substance is gabapentin.

Each ml of oral solution contains 50 mg gabapentin.

The other ingredients are acesulfame potassium (E950), saccharin sodium (E954), propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), carmellose sodium (E466) and purified water.

What Shaktatin looks like and contents of the pack

Shaktatin is a clear, colourless oral solution supplied in an amber glass bottle closed with a tamper-evident and child-resistant plastic cap. A 10 ml plastic oral syringe with 0.5 ml graduation and a plastic bottle adaptor for syringe is also included.

Shaktatin is supplied in bottles containing 1 x 150 ml of solution.

Marketing Authorisation Holder:

To be completed nationally

This leaflet was last revised in 2026-01-17