

Package leaflet: Information for the user

Gabapentin Strides 600 mg film-coated tablets Gabapentin Strides 800 mg film-coated tablets

Gabapentin

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.

Read all of this leaflet carefully before you start taking this medicine because it

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.

1. What Gabapentin is and what it is used for

What you need to know before you take Gabapentin 3. How to take Gabapentin

4. Possible side effects

5. How to store Gabapentin

6. Contents of the pack and other information

1. What Gabapentin is and what it is used for

Gabapentin 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 Gabapentin tablet is gabapentin.

Gabapentin 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). The doctor treating you or your child 6 years of age and older will prescribe Gabapentin to help treat epilepsy when the current treatment is not fully controlling the condition You or your child 6 years of age and older should take Gabapentin in addition to the current treatment unless told otherwise. Gabapentin 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 Gabapentin

Do not take Gabapentin

if you are allergic (hypersensitive) 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 Gabapentin:

if you suffer from 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 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 gabapentin.

Dependence

Some people may become dependent on gabapentin (a need to keep taking the

They may have withdrawal effects when they stop using gabapentin (see section 3, "How to take Gabapentin" and "If you stop taking gabapentin"). If you have concerns that you may become dependent on gabapentin, it is important that you consult your doctor. If you notice any of the following signs whilst taking gabapentin, 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 postmarketing 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

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 gabapentin 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 leanet 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 Gabapentin

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 Gabapentin. In addition, combination of Gabapentin with opioids may cause symptoms like sleepiness and/or

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

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. Gabapentin with food

Gabapentin can be taken with or without food. Pregnancy, breast-feeding and fertility

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

- If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant. You should not stop your treatment without discussing this with your doctor.

Gabapentin 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 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 (drugs fortreatment of severe pain).

There have been very few studies specifically looking at the use of gabapentin in pregnant women. More research is needed to better understand the safety of use of gabapentin during pregnancy and whether it is associated with an increased risk of harm to the unborn child. Some medicines used to treat epilepsy have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. This means that where possible, your doctor should consider using one epilepsy medicine to control your epilepsy. Contact your doctor immediately if you become pregnant, think you might be pregnant or

are planning to become pregnant while taking Gabapentin. 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 Gabapentin tablet, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabapentin.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Gabapentin 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.

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. **Epilepsy, the recommended dose is** Adults and adolescents

Take the number of tablets 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 per day. It is usually given in 3 separate doses, by taking the tablet(s) each day, usually once in the morning, once in the afternoon and once in the

Gabapentin is not recommended for use in children below 6 years of age. Peripheral Neuropathic Pain, the recommended dose is

Take the number of tablets as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 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 Gabapentin 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 Gabapentin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Gabapentin is for oral use. Always swallow the tablets with plenty of water. The tablet can be divided into equal halves.

Method of administration

Continue taking Gabapentin until your doctor tells you to stop.

If you take more Gabapentin 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

Product Buyer/Country

Dimension

New Item Code

Colour Shades

Design/Style

Substrate

Change Control No.

Special Instructions

Autocartonator

your doctor or go to the nearest hospital emergency unit immediately if you take more Gabapentin than your doctor prescribed. Take along any tablets that you have not taken, together with the container and the label so that the hospital can easily tell what medicine vou have taken.

If you forget to take Gabapentin

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 Gabapentin Do not suddenly stop taking gabapentin. If you want to stop taking gabapentin, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped

it should be done gradually over a minimum of 1 week. After stopping a short or longterm treatment with gabapentin, 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 gabapentin. If you experience withdrawal effects, you should contact

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

4. Possible side effects

Stop using gabapentin 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-Johnsonsyndrome, toxic epidermal necrolysis).

 Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). Like all medicines, this medicine can cause side effects, although not everybody gets

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, and/or hair loss (these may be symptoms of a serious allergic

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

Gabapentin 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 Gabapentin. 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

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

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

Other side effects include:

frequent infections

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

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),

reflexes

low white blood cell counts

difficulty breathing, bronchitis, sore throat, cough, dry nose

blurred vision, double vision high blood pressure, flushing or dilation of blood vessels

difficulty with coordination, unusual eye movement, increased, decreased or absent

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

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 gabapentin ('drug dependence') After stopping a short or long-term treatment with gabapentin, you need to know that you

may experience certain side effects, so-called withdrawal effects (see "If you stop taking gabapentin ").

After marketing Gabapentin 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 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 breakdown of muscle fibres (rhabdomyolysis) change in blood test results (creatine phosphokinase increased) problems with sexual functioning including inability to achieve a sexual climax,

delayed ejaculation low blood sodium level anaphylaxis (serious, potentially life threatening allergic reaction including

requiring emergency treatment) **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: www.mhra.gov.uk/yellowcard or search for MHŘA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide

difficulty breathing, swelling of the lips, throat, and tongue, and hypotension

more information on the safety of this medicine.

5. How to store Gabapentin Keep this medicine out of the sight and reach of children.

The expiry date refers to the last day of that month. Store below 30°C. Protect from light. Do not throw away any medicines via wastewater or household waste. Ask your

Do not use this medicine after the expiry date which is stated on the carton and the bottle.

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 Gabapentin contains

side. Tablet size is 17.30 x 9.00 mm.

The active substance is gabapentin. Each film-coated tablet contains either 600 mg

The other ingredients in Gabapentin film-coated tablet are: maize starch, mannitol (E421), crospovidone, copovidone, talc (E553b), magnesium stearate (E572), silica, colloidal anhydrous. Film coating: Opadry white YS-1-18111 (consists of; talc (E553b), hydroxypropylcellulose (E463)). What Gabapentin looks like and contents of the pack The 600 mg tablets are white to off white coloured, film coated, elliptical shaped, lip break line on both sides, debossed with "S" and "l" separated by lip break line on one

The 800 mg tablets are white to off white coloured, film coated, elliptical shaped, lip break line on both sides, debossed with "S" and "2" separated by lip break line on one side. Tablet size is 19.00 x 9.90 mm.

Packed in a white opaque, round cylindrical high-density polyethylene (HDPE) bottle, capped either with one of the below polypropylene (PP) closure cap along with Silica gel - white polypropylene (PP), child resistant (CR) closure (for up to 100's pack sizes);

- white polypropylene (PP), continuous thread (CT) screw cap (for 200's and 500's

pack sizes). Bottles are supplied in packs of 20, 30, 45, 50, 60, 84, 90, 100, 200, 500 tablets. Packed in blisters of PVC/PVDC in 10, 20, 30, 50, 60, 90, 100, 200 and 500's pack sizes.

Marketing Authorisation Holder and Manufacturer Strides Pharma UK Ltd.

Unit 4, The Metro Centre, Dwight Road, Watford, WD18 9SS, United Kingdom

PL 13606/0235

Not all pack sizes may be marketed.

PL 13606/0236 This leaflet was last revised in 10/2023.

Back Side

Font: Times New Roman

ARTWORK DETAIL LABEL

Gabapentin Strides 600 mg & 800 mg film-coated tablets

Printing clarity to be clear & sharp.

Front Side 130 x 680 mm

Minimum Fonts size: 9 points

130 x 680 mm

Maximum Fonts size: 13 points

Non printing colour

Pharma code Position shall be changed depending upon the folding dimension or as per machine requirements.

SPUK Component Pack Insert 130 x 680 mm Pack 1049002 1049531 Old Item Code No. of Colours BLACK PC-PYF/2023/422 - Record No.: 402599 Artwork Version 6.0 Front & Back Printing. To be supplied in the folded size of 130 x 38 mm 60 GSM Maplitho paper

Requirements Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC. RD/PD/003/F-08/R0