

SCHEDULING STATUS S3

GRALISE 300 mg and 600 mg, prolonged-release tablets

Gabapentin

Sugar free.

Read all of this leaflet carefully before you start taking GRALISE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- GRALISE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What GRALISE is and what it is used for

GRALISE contains the active substance gabapentin. GRALISE is used to treat post-herpetic neuralgia in adults. Post-herpetic neuralgia is long lasting pain syndrome caused by damage to the nerves associated with the reactivation of virus causing shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing and sharp.

2. What you need to know before you take GRALISE

Do not take GRALISE

- If you are hypersensitive (allergic) to gabapentin or any of the other ingredients of GRALISE (listed in section 6).
- If you are on haemodialysis (a machine filters waste products from your blood when your kidneys are no longer healthy enough to do this work).
- If you have kidney problems.
- GRALISE 300 contains lecithin (soya). If you are allergic to peanuts or soya, do not use GRALISE 300.

Warnings and precautions

Take special care with GRALISE, if you:

- Have a history of medicine abuse or dependence.
- Have nervous system problems.
- Suffer with different types of seizures including absence seizures.
- Are over 65 years of age.
- Suffer from mild or moderate kidney impairment.
- DRESS (drug reaction with eosinophilia and systemic systems) also known as multiorgan hypersensitivity can be experienced when taking GRALISE. Symptoms typically include fever, rash, swelling of lymph nodes, inflammation of the liver and/or kidneys. Immediately contact your doctor if you experience any of these symptoms.
- When taking GRALISE you can get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if not treated. Symptoms to look out for while you are taking GRALISE are swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing (refer to section 4).
- When taking GRALISE you may have suicidal thoughts. If at any time you have these thoughts, immediately contact your doctor.
- If you develop signs such as persistent stomach pain, feeling sick and being sick. These may

be symptoms of acute pancreatitis (an inflamed pancreas) and you should contact your doctor immediately.

- GRALISE can cause breathing problems. If you develop breathing problems while taking GRALISE tell your doctor immediately. Your doctor may adjust your dose.
- GRALISE may interfere with some laboratory tests, if you require a urine test tell your doctor or nurse that you are taking GRALISE.

Children and adolescents

Do not give GRALISE to paediatric patients because there is no data available for use in the paediatric population.

Other medicines and GRALISE

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Morphine or any other medicines containing opioids (used to treat pain).
- Any medicines for central nervous system disorders such as convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.
- Antacids containing aluminium and magnesium for indigestion (medicines neutralising the acid in your stomach to relieve heartburn).

GRALISE with alcohol

Do not drink alcohol when you take GRALISE, since it may worsen your symptoms such as drowsiness, dizziness or lack of coordination.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking GRALISE.

Driving and using machines

GRALISE may cause dizziness, drowsiness and tiredness (see section 4).

It is not always possible to predict to what extent GRALISE may interfere with your daily activities.

You should not drive a vehicle, operate complex machinery or take part in other potentially hazardous activities until you are aware of the measure to which GRALISE affects you. This is especially important at the beginning of the treatment and after your dose has been increased

3. How to take GRALISE

Do not share medicines prescribed for you with any other person.

Always take GRALISE exactly as your doctor has told you. Check with your doctor if you are not sure.

GRALISE is taken orally, once a day with your evening meal.

Swallow GRALISE whole with water. Do not break, crush or chew the tablets.

The usual starting dose is 300 mg.

Your doctor may increase your dose over a period of time.

Your doctor will tell you how long your treatment with GRALISE will last.

If you have the impression that the effect of GRALISE is too strong or too weak, tell your doctor or pharmacist.

If you take more GRALISE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Symptoms of overdosage are dizziness, double vision, slurred speech, drowsiness and mild diarrhoea. Always take the labelled medicine package with you, whether there are any GRALISE tablets left or not.

If you forget to take GRALISE

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take GRALISE at the next regularly scheduled time.

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

If you stop taking GRALISE:

Do not stop taking GRALISE unless your doctor tells you to. If your treatment is to be discontinued it should be done gradually as per your doctor's recommendation.

4. Possible side effects

GRALISE can have side effects.

Not all side effects reported for GRALISE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GRALISE, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking GRALISE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to

GRALISE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Drug reaction with eosinophilia and systemic symptoms (DRESS) is a rare, potentially life-threatening, drug-induced hypersensitivity reaction that includes skin eruption, hematologic abnormalities (eosinophilia), lymphadenopathy, and internal organ involvement (liver, kidney, lung).
- Painful, blistering or peeling skin rash (Stevens-Johnson syndrome).
- Erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea).
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Racing heartbeat.
- Trouble breathing, shallow breaths (respiratory depression).
- Difficulty swallowing.
- Loss of consciousness, mental problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Viral infection, respiratory/chest infection, urinary tract/bladder infection, inflammation of the ear or other infections.
- Eating problems (anorexia), increased appetite.
- Anger towards others (hostility), confusion and mood changes, depression, anxiety, nervousness, difficulty with thinking.
- Feeling drowsy, sleepy, dizziness, problems falling and staying asleep, headache, burning/

prickling sensations in the hands/arms/legs or feet, sensitive skin, abnormal coordination, rapid and repetitive uncontrolled movements of the eyes, increased, decreased, or absent reflexes.

- Lack of coordination (ataxia), involuntary shaking/tremor, restlessness, slow and slurred speech, loss of memory.
- Blurred vision, double vision.
- Vertigo.
- High blood pressure, flushing or dilation of blood vessels.
- Sore throat, cough, runny nose, sneezing, nasal congestion, bronchitis or difficulty breathing.
- Vomiting (being sick), nausea (feeling sick), problems with teeth, swollen gums, diarrhoea, stomach pain, indigestion or heartburn, constipation, dry mouth or throat, flatulence or passing wind.
- Swelling of the face, bruises resulting from physical trauma, rash, itchiness, acne.
- Joint pain, muscle pain, back pain, twitching.
- Difficulties with erection (impotence).
- Loss of bladder control (incontinence).
- Feeling tired, fever, swelling of legs/feet and arms, difficulty with walking, weakness/lack of energy, pain, feeling unwell, flu-like symptoms.
- Increase in weight.
- Accidental injury, fracture, abrasion, falling.

Less frequent side effects:

- Persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- Increase or decrease in the sugar levels in your blood.
- Agitation (feeling restless).
- Abnormal blood test results suggesting problems with the liver.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GRALISE.

5. How to store GRALISE

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 30 °C.
- Do not use after the expiry date printed on the carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GRALISE contains:

The active substance is gabapentin. Each prolonged-release tablet contains either 300 mg or 600 mg gabapentin.

The other ingredients are macrogol, hypromellose, copovidone, magnesium stearate, cellulose microcrystalline (GRALISE 300 only).

GRALISE 300 also contains Opadry II 85g18490 white (consisting of polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), macrogol 4000 (polyethylene glycol) (E1521) and lecithin (soya) (E322)).

GRALISE 600 also contains Opadry II 85F91355 beige (consisting of polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 4000 (polyethylene glycol) (E1521), talc (E553b), iron oxide

yellow (E172), iron oxide red (E173)).

What GRALISE looks like and contents of the pack:

GRALISE 300: White to off-white, oval shaped tablets, debossed with 'SLV' on one side and '300' on the other side.

GRALISE 600: Beige, oval shaped tablets, debossed with 'SLV' on one side and '600' on the other side.

GRALISE is packed in:

Starting (titration) pack

Carton tri-fold card containing 33 tablets (with both strengths) for 15 days of treatment, arranged in a single PVC/PCTFE aluminium blister strip. Each day of treatment is marked from day 1 to day 15 and each daily dose is on its own row. The starting pack contains:

- 9 tablets of GRALISE 300 and
- 24 tablets of GRALISE 600.

Maintenance packs

Carton boxes containing 30 or 90 tablets in PVC/PCTFE aluminium blister strips (standard blister strips or unit dose perforated blister strips) of 10 tablets each.

Not all pack sizes may be marketed.

Holder of certificate of registration:

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