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MEDICATION GUIDE
GRALISE® (gra leez')
(gabapentin) Tablets

Read this Medication Guide before you start taking GRALISE and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about GRALISE, ask your healthcare provider or pharmacist.

What is the most important information I should know about GRALISE?

Do not stop taking GRALISE without first talking with your healthcare provider. Stopping GRALISE suddenly can cause serious problems.

Like other antiepileptic drugs, gabapentin, the active ingredient in GRALISE, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. However, it is not known if GRALISE is safe and effective in people with seizure problems (epilepsy). Therefore, GRALISE should not be used in place of other gabapentin products.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

- 570 • Call your healthcare provider between visits as needed, especially if you are worried
571 about symptoms.

572 **Do not stop taking GRALISE without first talking with your healthcare provider.**

- 573 • Stopping GRALISE suddenly can cause serious problems.

574 **What is GRALISE?**

575 GRALISE is a prescription medicine used in adults, 18 years and older, to treat:

- 576 • pain from damaged nerves (neuropathic pain) that follows healing of shingles (a painful
577 rash that comes after a herpes zoster infection).

578 It is not known if GRALISE is safe and effective in people with seizure problems (epilepsy).

579 It is not known if GRALISE is safe and effective in children under 18 years of age with
580 postherpetic pain.

581 GRALISE is not interchangeable with other gabapentin products.

582 **Who should not take GRALISE?**

583 Do not take GRALISE if you are allergic to gabapentin or any of the ingredients in GRALISE.
584 See the end of this Medication Guide for a complete list of ingredients in GRALISE.

585 **What should I tell my healthcare provider before taking GRALISE?**

586 Before taking GRALISE, tell your healthcare provider if you:

- 587 • have or have had depression, mood problems or suicidal thoughts or behavior
588 • have seizures
589 • have kidney problems or get kidney dialysis
590 • are pregnant or plan to become pregnant. It is not known if GRALISE can harm your
591 unborn baby. Tell your healthcare provider right away if you become pregnant while
592 taking GRALISE. You and your healthcare provider will decide if you should take
593 GRALISE while you are pregnant.
- 594 ○ If you become pregnant while taking GRALISE, talk to your healthcare provider
595 about registering with the North American Antiepileptic Drug (NAAED)
596 Pregnancy Registry. The purpose of this registry is to collect information about
597 the safety of antiepileptic drugs, including gabapentin, the active ingredient in
598 GRALISE, during pregnancy. You can enroll in this registry by calling 1-888-
599 233-2334.
- 600 • are breastfeeding or plan to breastfeed. GRALISE can pass into your breast milk. You
601 and your healthcare provider should decide how you will feed your baby while you take
602 GRALISE.

603 Tell your healthcare provider about all the medicines you take including prescription and non-
604 prescription medicines, vitamins or herbal supplements.

605 Taking GRALISE with certain other medicines can cause side effects or affect how well they
606 work. Do not start or stop other medicines without talking to your healthcare provider.

607 Know the medicines you take. Keep a list of them and show it to your healthcare provider and
608 pharmacist when you get a new medicine.

609 **How should I take GRALISE?**

610 • Take GRALISE exactly as prescribed. Your healthcare provider will tell you how much
611 GRALISE to take and when to take it. Take GRALISE at the same time each day.

612 • **Do not change your dose or stop taking GRALISE without talking with your**
613 **healthcare provider.** If you stop taking GRALISE suddenly, you may experience side
614 effects. Talk with your healthcare provider about how to stop GRALISE slowly.

615 • Take GRALISE with food one time each day with your evening meal.

616 • Take GRALISE tablets whole. Do not split, crush, or chew GRALISE tablets before
617 swallowing.

618 • Your healthcare provider may change your dose of GRALISE. Do not change your dose
619 of GRALISE without talking to your healthcare provider.

620 • If you miss a dose, take it as soon as you remember with food. If it is almost time for
621 your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not**
622 **take two doses at the same time.**

623 • If you take too much GRALISE, call your healthcare provider or poison control center,
624 or go to the nearest emergency room right away.

625 • If you are taking an antacid containing aluminum hydroxide and magnesium hydroxide,
626 it is recommended that GRALISE be taken at least 2 hours following administration of
627 the antacid.

628 **What should I avoid while taking GRALISE?**

629 • Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking
630 GRALISE without first talking to your healthcare provider. Taking GRALISE with
631 alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or
632 dizziness worse.

633 • Do not operate heavy machines or do other dangerous activities until you know how
634 GRALISE affects you. GRALISE can slow your thinking and motor skills.

635 **What are the possible side effects of GRALISE?**

636 The most common side effect of GRALISE is:

- 637
 - dizziness

638 Tell your healthcare provider about any side effect that bothers you or that does not go away.

639 These are not all the possible side effects of GRALISE. For more information, ask your
640 healthcare provider or pharmacist.

641 Call your doctor for medical advice about side effects. You may report side effects to FDA at
642 1-800-FDA-1088.

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644 **How should I store GRALISE?**

645 Store GRALISE at 59°F to 86°F (15°C to 30°C)

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 - **Keep GRALISE and all medicines out of the reach of children.**

647 **General information about the safe and effective use of GRALISE**

648 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
649 Do not use GRALISE for a condition for which it was not prescribed. Do not give GRALISE to
650 other people, even if they have the same symptoms you have. It may harm them.

651 This Medication Guide summarizes the most important information about GRALISE. If you
652 would like more information, talk with your healthcare provider. You can ask your healthcare
653 provider or pharmacist for information about GRALISE that is written for health professionals.

654 For more information about GRALISE, call 1-866-458-6389.

655 **What are the ingredients in GRALISE?**

656 Active ingredient: gabapentin

657 Inactive ingredients:

658 300 mg tablet: copovidone, hypromellose, magnesium stearate, microcrystalline cellulose,
659 polyethylene oxide, and Opadry® II white. Opadry® II white contains polyvinyl alcohol,
660 titanium dioxide, talc, polyethylene glycol 3350, and lecithin (soya).

661 600 mg tablet: copovidone, hypromellose, magnesium stearate, polyethylene oxide, and
662 Opadry® II beige. Opadry® II beige contains polyvinyl alcohol, titanium dioxide, talc,
663 polyethylene glycol 3350, iron oxide yellow, and iron oxide red.

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665 **Marketed by:**

666 Depomed, Inc.

667 Menlo Park, CA 94025

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672 GRA-004-C.5 SEP 2012

673 Issued SEP 2012

674 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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