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MEDICATION GUIDE

533

GRALISE™ (gra leez')

534

(gabapentin) Tablets

535

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

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

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

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

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

- 549
- 550 • thoughts about suicide or dying
 - 551 • attempts to commit suicide
 - 552 • new or worse depression
 - 553 • new or worse anxiety
 - 554 • feeling agitated or restless
 - 555 • panic attacks
 - 556 • trouble sleeping (insomnia)
 - 557 • new or worse irritability
 - 558 • acting aggressive, being angry, or violent
 - 559 • acting on dangerous impulses
 - 560 • an extreme increase in activity and talking (mania)
 - 561 • other unusual changes in behavior or mood

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

- 562
- 563 • Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts,
564 or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled.

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

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

- 568 • Stopping GRALISE suddenly can cause serious problems.

569 **What is GRALISE?**

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

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

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

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

576 GRALISE is not interchangeable with other gabapentin products.

577 **Who should not take GRALISE?**

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

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

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

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

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

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

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

604 **How should I take GRALISE?**

- 605 • Take GRALISE exactly as prescribed. Your healthcare provider will tell you how much
606 GRALISE to take and when to take it. Take GRALISE at the same time each day.
- 607 • **Do not change your dose or stop taking GRALISE without talking with your**
608 **healthcare provider.** If you stop taking GRALISE suddenly, you may experience side
609 effects. Talk with your healthcare provider about how to stop GRALISE slowly.
- 610 • Take GRALISE with food one time each day with your evening meal.
- 611 • Take GRALISE tablets whole. Do not split, crush, or chew GRALISE tablets before
612 swallowing.
- 613 • Your healthcare provider may change your dose of GRALISE. Do not change your dose
614 of GRALISE without talking to your healthcare provider.
- 615 • If you miss a dose, take it as soon as you remember with food. If it is almost time for
616 your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not**
617 **take two doses at the same time.**
- 618 • If you take too much GRALISE, call your healthcare provider or poison control center,
619 or go to the nearest emergency room right away.
- 620 • If you are taking an antacid containing aluminum hydroxide and magnesium hydroxide,
621 it is recommended that GRALISE be taken at least 2 hours following administration of
622 the antacid.

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

- 624 • Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking
625 GRALISE without first talking to your healthcare provider. Taking GRALISE with
626 alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or
627 dizziness worse.
- 628 • Do not operate heavy machines or do other dangerous activities until you know how
629 GRALISE affects you. GRALISE can slow your thinking and motor skills.

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

631 The most common side effect of GRALISE is:

- 632
 - dizziness

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

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

636 Call your doctor for medical advice about side effects. You may report side effects to FDA at
637 1-800-FDA-1088.

638

639 **How should I store GRALISE?**

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

- 641
 - **Keep GRALISE and all medicines out of the reach of children.**

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

643 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

644 Do not use GRALISE for a condition for which it was not prescribed. Do not give GRALISE to
645 other people, even if they have the same symptoms you have. It may harm them.

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

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

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

651 Active ingredient: gabapentin

652 Inactive ingredients:

653 300 mg tablet: copovidone, hypromellose, magnesium stearate, microcrystalline cellulose,
654 polyethylene oxide, and Opadry® II white. Opadry® II white contains polyvinyl alcohol,
655 titanium dioxide, talc, polyethylene glycol 3350, and lecithin (soya).

656 600 mg tablet: copovidone, hypromellose, magnesium stearate, polyethylene oxide, and
657 Opadry® II beige. Opadry® II beige contains polyvinyl alcohol, titanium dioxide, talc,
658 polyethylene glycol 3350, iron oxide yellow, and iron oxide red.

659

660 **Marketed by:**

661 Depomed, Inc.

662 Menlo Park, CA 94025

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