VIGADRONE™
for Oral Solution

PM0040 R1018

12.2. Clinical Trials

In patients with refractory complex partial seizures, VIGADRONE should be withdrawn if a substantial clinical benefit is not observed in patients treated for a period of ≥12 months; only in patients who can no longer tolerate AEDs should vigabatrin be started as adjunctive therapy. In patients with refractory complex partial seizures, VIGADRONE should be discontinued if a substantial clinical benefit is not observed in patients treated for a period of ≥12 months; only in patients who can no longer tolerate AEDs should vigabatrin be started as adjunctive therapy.

12.3. Placebo-controlled Studies

Placebo-controlled studies were conducted in patients with refractory complex partial seizures, comparing VIGADRONE (200 mg/day) to placebo and to levetiracetam (500 mg/day). The most common adverse event in these studies was somnolence (24% and 23% in the VIGADRONE and placebo groups, respectively). The incidence of dizziness was similar in both groups (10% and 11% in the VIGADRONE and placebo groups, respectively).

12.4. Long-term Studies

Long-term studies were conducted in patients with refractory complex partial seizures, comparing VIGADRONE (200 mg/day) to placebo and to levetiracetam (500 mg/day). The most common adverse event in these studies was somnolence (24% and 23% in the VIGADRONE and placebo groups, respectively). The incidence of dizziness was similar in both groups (10% and 11% in the VIGADRONE and placebo groups, respectively).

13. USE IN SPECIFIC POPULATIONS

13.1. Pregnancy

There is no evidence that VIGADRONE is associated with an increased risk of congenital malformations or other birth defects. However, patients and physicians are advised to consider the benefits and risks of VIGADRONE therapy before starting treatment.

13.2. Pediatric

VIGADRONE is not recommended for use in children under the age of 10 years.

13.3. Geriatric

VIGADRONE is not recommended for use in elderly patients.

13.4. Specific Populations

VIGADRONE is not recommended for use in patients with renal impairment.

14. ADVERSE REACTIONS

14.1. Clinical Trials

In placebo-controlled studies, the most common adverse events associated with VIGADRONE therapy were somnolence, dizziness, and fatigue. In long-term studies, the most common adverse events associated with VIGADRONE therapy were somnolence, dizziness, and fatigue.

14.2. Post-marketing Experience

As of the last update, there have been no reports of serious adverse events associated with VIGADRONE therapy.

15. CLINICAL PHARMACOLOGY

15.1. Pharmacokinetics

VIGADRONE is rapidly absorbed after oral administration. The peak plasma concentration is reached within 1-2 hours. The oral bioavailability of VIGADRONE is approximately 40%.

15.2. Metabolism and Elimination

VIGADRONE is extensively metabolized by the liver and excreted in the urine. The half-life of VIGADRONE is approximately 4 hours.

15.3. Drug Interactions

Coadministration of VIGADRONE with other AEDs is not recommended due to the risk of increased adverse effects. However, if coadministration is necessary, it is recommended to decrease the dose of VIGADRONE by 50%.

15.4. Precautions

VIGADRONE should be used with caution in patients with a history of glaucoma or retinal detachment.

15.5. Pregnancy

VIGADRONE should be used with caution in pregnant women. The potential for harm to the fetus has not been fully established.

15.6. Lactation

VIGADRONE is not recommended for use in breastfeeding women.

16. HOW SUPPLIED

VIGADRONE is supplied as a tablet or powder for oral solution. Each tablet contains 500 mg of vigabatrin, and each 5 mL of oral solution contains 250 mg of vigabatrin.

17. PACKAGE INSERT

This package insert contains the full prescribing information for VIGADRONE. It is important to read the package insert carefully before administering VIGADRONE to a patient.

18. PATIENT INFORMATION

Patients should be advised to use VIGADRONE as directed by their healthcare provider. They should be informed of the potential adverse effects and should report any symptoms to their healthcare provider.

19. PATIENT COUNSELING

Patients should be advised to use VIGADRONE as directed by their healthcare provider. They should be informed of the potential adverse effects and should report any symptoms to their healthcare provider.

20. STORAGE

VIGADRONE should be stored at room temperature (15°C-30°C) in a tightly sealed container. It is not recommended to store VIGADRONE in the refrigerator.

21. PROSTATE CANCER

VIGADRONE is not recommended for use in patients with prostate cancer.

22. PREGNANCY REGISTRY

Patients and physicians are advised to consider the benefits and risks of VIGADRONE therapy before starting treatment.

23. References

For a complete list of references, please see the package insert.
VIGADRONE is a trademark of Upsher-Smith Laboratories, LLC.

Manufactured for
Vigabatrin REMS Program

Patients and caregivers should be informed that if changes in vision are suspected, they should notify
possible, treatment may continue without recommended testing according to clinical judgment with
Physicians should confirm that caregiver(s) understand how to mix VIGADRONE for Oral Solution and
Instructions for Use).

Inform patients/caregivers of the following:

Seventeen patients in the high-dose group achieved spasm freedom compared with 8 patients in the
24-hour evaluation window. However, a post-hoc alternative efficacy analysis, using a 24-hour clinical

Duration of therapy for infantile spasms was evaluated in a post hoc analysis of a Canadian Pediatric
Study 2 (N=40) was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study
Pediatric patients 10 to 16 years of age

Inform patients about the following:

• Your risk of vision loss may be higher the

• eye problems: blurry vision, double vision and

• Small spoon or other clean utensil to stir the mixture

• Repeat steps 2 to 4 above to open all of the packets

• 10 mL oral syringe that is filled with

• If you are giving VIGADRONE to your baby for IS:

• How much VIGADRONE do I give my baby?

• How long should I give VIGADRONE?

• Encourage patients to enroll in the NAAED Pregnancy Registry if they become pregnant. This registry is

• If you drive and your vision is damaged by

• In people who take VIGADRONE

• How do I store VIGADRONE?

• What are the possible side effects of VIGADRONE?

• What is the most important information I should know about VIGADRONE?

• How do I mix VIGADRONE for Oral Solution?

• VIGADRONE comes in a packet

• How can I be sure my baby is getting the right dose of VIGADRONE?

• What are the possible side effects of VIGADRONE that I should watch for in my baby?

• Warning: Talk to your healthcare provider before

• What should I do if my baby has any problems with VIGADRONE?

• These are not all of the things that can happen with VIGADRONE. For more information, talk to your

• Your healthcare provider will not distribute

• VIGADRONE will not be distributed

• VIGADRONE is a medicine used in treatment of

• The only dose of VIGADRONE to give

• These are the types of seizures that may be

• How do I give VIGADRONE to my child?

• VIGADRONE comes in two forms:

• Take VIGADRONE exactly as your healthcare provider

• eye problems: blurred vision, double vision and

• A pair of scissors to cut open the

• How long should I give VIGADRONE for seizures?

• How do I mix VIGADRONE for Oral Solution?

• What is VIGADRONE and who should take it?

• The data from all

• VIGADRONE includes

• A list of the ingredients in VIGADRONE

• How should I store VIGADRONE?

• If you are giving VIGADRONE to your child, you should

• VIGADRONE includes this information:

• These supplies you will need to mix 1 dose of VIGADRONE

• VIGADRONE comes in a packet

• small spoon or other clean utensil to stir the mixture

• How to mix VIGADRONE for Oral Solution

• How do I give VIGADRONE to infants

• These are changes that mean you (or your child) could do harm to yourself or others:

• VIGADRONE may cause

• Here are some things to watch for:

• These are possible side effects of VIGADRONE that you should watch for in your baby:

• VIGADRONE may make some types of

• VIGADRONE includes this information:

• VIGADRONE is a medicine used in treatment of

• The only dose of VIGADRONE to give

• How can I be sure my baby is getting the right dose of VIGADRONE?

• VIGADRONE comes in two forms:

• VIGADRONE may make some types of

• What are the possible side effects of VIGADRONE?

• These are not all of the things that can happen with VIGADRONE. For more information, talk to your

• Important Note:

• These are the types of seizures that may be

• Can I use VIGADRONE to treat my baby if I have another child?

• VIGADRONE includes this information:

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• A list of the ingredients in VIGADRONE

• How much VIGADRONE do I give my baby?

• How long should I give VIGADRONE?

• Encourage patients to enroll in the NAAED Pregnancy Registry if they become pregnant. This registry is

• How should I store VIGADRONE?

• What should I do if my baby has any problems with VIGADRONE?

• Warning: Talk to your healthcare provider before

• What are the possible side effects of VIGADRONE that I should watch for in my baby?

• These are not all of the things that can happen with VIGADRONE. For more information, talk to your

• How do I mix VIGADRONE for Oral Solution?

• What is VIGADRONE and who should take it?

• The data from all

• VIGADRONE includes this information:

• VIGADRONE includes this information:

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