VIGADRONE™ (vi-ga-dro¯ne)

MEDICATION GUIDE

VIGADRONE can cause serious side effects, including:

- Magnetic resonance imaging (MRI) changes in babies with infantile spasms
- Risk of suicidal thoughts or actions

1. Permanent vision loss:

- People who take VIGADRONE do not lose all of their vision, but severe vision loss may happen.
- You may not be able to see straight in front of you (sometimes called “tunnel vision”).
- You may have difficulty seeing things that are not right in front of you.
- Your baby may be acting differently than normal.

Vision loss and use of VIGADRONE in adults and children 10 years and older:

- Because VIGADRONE might cause permanent vision loss, it is only available to healthcare providers and patients only under a Mitigation Strategy (REMS) Program. VIGADRONE can only be used by a Healthcare provider who can activate the North American Pregnancy Registry:
  - Pregnancy Registry: 1-866-244-8175.

Tell your healthcare provider right away if you (or your child):

- Tell your healthcare provider about the best way to feed your baby if you take VIGADRONE while you are pregnant or breastfeeding.
- Tell your healthcare provider right away if you (or your child) have any of these symptoms, especially if they are new, have changed, are more important than the possible risk of vision loss.

What is risk of suicidal thoughts or actions?

- People who take VIGADRONE do not lose all of their vision, but severe vision loss may happen.
- You may not be able to see straight in front of you (sometimes called “tunnel vision”).
- Your baby may be acting differently than normal.

Risk of suicidal thoughts or actions:

- VIGADRONE is a prescription medicine used along with other treatment medicines in babies 1 month to 2 years of age with complex partial seizures (CPS) and in adults 10 years and older:
  - VIGADRONE is used to treat complex partial seizures (CPS) only in people who do not respond well enough to several other medicines.

Tell your healthcare provider right away if you (or your child):

- Do not stop taking VIGADRONE suddenly.
- Do not take prescribed medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures.

Tell your healthcare provider right away if you (or your child) have any of these symptoms, especially if they are new, have changed, are more important than the possible risk of vision loss:

- Vision loss and use of VIGADRONE in adults and children 10 years and older:
  - Because VIGADRONE might cause permanent vision loss, it is only available to healthcare providers and patients only under a Mitigation Strategy (REMS) Program. VIGADRONE can only be used by a Healthcare provider who can activate the North American Pregnancy Registry:
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- Tell your healthcare provider right away if you (or your child) have any of these symptoms, especially if they are new, have changed, are more important than the possible risk of vision loss:

What is VIGADRONE?

- VIGADRONE is a prescription medicine used along with other treatment medicines in babies 1 month to 2 years of age with complex partial seizures (CPS) and in adults 10 years and older:
  - VIGADRONE is used to treat complex partial seizures (CPS) only in people who do not respond well enough to several other medicines.

Tell your healthcare provider right away if you (or your child) have any of these symptoms, especially if they are new, have changed, are more important than the possible risk of vision loss:

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- Vision loss and use of VIGADRONE in adults and children 10 years and older:
  - Because VIGADRONE might cause permanent vision loss, it is only available to healthcare providers and patients only under a Mitigation Strategy (REMS) Program. VIGADRONE can only be used by a Healthcare provider who can activate the North American Pregnancy Registry:
    - Pregnancy Registry: 1-866-244-8175.
Do not stop taking VIGADRONE without talking to your healthcare provider. If VIGADRONE improves your (or your child’s) seizures and you and your healthcare provider decide that the benefit of taking VIGADRONE is more important than the risk of vision loss, and decide if you (or your child) will continue to take VIGADRONE.

If you are giving VIGADRONE powder for oral solution to your child, it can be given at the same time as their meal. VIGADRONE for oral solution powder should be mixed with water only.

See “Instructions for Use” for detailed information about how to mix and give VIGADRONE powder for oral solution to your baby the right way.

What should I avoid while taking VIGADRONE?
VIGADRONE causes sleepiness and tiredness. Adults taking VIGADRONE should not drive, operate machinery, or perform any hazardous task, unless you and your healthcare provider have decided that you can do these things safely.

What are the possible side effects of VIGADRONE?
VIGADRONE can cause serious side effects, including:

• See “What is the most important information I should know about VIGADRONE?”
• sleepiness and tiredness.
• What should I avoid while taking VIGADRONE?
• VIGADRONE may cause your baby to be sleepy. Sleepy babies may have a harder time sucking and feeding, or may be irritable.
• weight gain that happens without swelling

The following serious side effects happen in adults. It is not known if these side effects also happen in babies who take VIGADRONE.

• low red blood cell counts (anemia)
• nerve problems. Symptoms of a nerve problem can include numbness and tingling in your toes or feet. It is not known if nerve problems will go away after you stop taking VIGADRONE.

The most common side effects of VIGADRONE include:

• waking up with feeling uncoordinated
• feeling dizziness
• shaking (tremor)
• joint pain
• memory problems and not thinking clearly
• eye problems: blurry vision, double vision and eye movements that you cannot control

• swelling

If you or your child has CPS, VIGADRONE may make certain types of seizures worse. Tell your healthcare provider right away if your (or your child’s) seizures get worse.

The most common side effects of VIGADRONE in adults include:

• weight gain
• upper respiratory tract infection
• tiredness
• aggression
• Also expect side effects like those seen in adults

If you are giving VIGADRONE to your baby for IS:

VIGADRONE may make certain types of seizures worse. You should tell your baby’s healthcare provider right away if your baby’s seizures get worse. Tell your baby’s healthcare provider if you see any changes in your baby’s behavior.

The most common side effects of VIGADRONE in babies include:

• sleeping – VIGADRONE may cause your baby to be sleepy. Sleepy babies may have a harder time sucking and feeding, or may be irritable.
• swelling in the bronchial tubes (bronchitis)
• ear infection
• irritability

Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away. These are not all the possible side effects of VIGADRONE.

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

How should I store VIGADRONE?
• Store VIGADRONE packets at room temperature, between 20° to 25°C (68° to 77°F).
• Keep VIGADRONE powder in the container they come in.

General information about the safe and effective use of VIGADRONE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about VIGADRONE that is written for health professionals. Do not use VIGADRONE for a condition for which it was not prescribed. Do not give VIGADRONE to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in VIGADRONE?
Active Ingredient: vigabatrin
For Medication Guides, please visit www.upsher-smith.com or call 1-888-650-3789.

Manufactured for UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369

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Made in Germany

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

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