

Vilazover

Vilazodone hydrochloride 40 mg

Film coated tablet

INDICATIONS AND USAGE

VELAZOVER is indicated for the treatment of major depressive disorder (MDD) .

DOSAGE AND ADMINISTRATION

Dosage for Treatment of Major Depressive Disorder

The recommended target dosage for VELAZOVER is 20 mg to 40 mg orally once daily with food [see Clinical Pharmacology]. To achieve the target dosage, titrate VELAZOVER as follows:

- Start with an initial dosage of 10 mg once daily with food for 7 days,
- Then increase to 20 mg once daily with food.
- The dose may be increased up to 40 mg once daily with food after a minimum of 7 days between dosage increases.

If a dose is missed, it should be taken as soon as the patient remembers. If it is almost time for the next dose, the patient should skip the missed dose and take the next dose at the regular time. Two doses should not be taken at the same time.

Screen for Bipolar Disorder Prior to Starting VELAZOVER

Prior to initiating treatment with VELAZOVER or another antidepressant, screen patients for a personal or family history of bipolar disorder, mania, or hypomania [see Warnings and Precautions].

Switching to or from a Monoamine Oxidase Inhibitor Antidepressant

At least 14 days must elapse between discontinuation of a monoamine oxidase inhibitor (MAOI) antidepressant and initiation of VELAZOVER. In addition, at least 14 days must elapse after stopping VELAZOVER before starting an MAOI antidepressant [see Contraindications,, Warnings and Precautions].

Dosage Adjustments with CYP3A4 Inhibitors or Inducers

Patients receiving concomitant CYP3A4 inhibitors:

During concomitant use of a strong CYP3A4 inhibitor (e.g., itraconazole, clarithromycin, voriconazole), the VELAZOVER dose should not exceed 20 mg once daily. The original VELAZOVER dose level, can be resumed when the CYP3A4 inhibitor is discontinued [see Drug Interactions].

Patients receiving concomitant CYP3A4 inducers:

Based on clinical response, consider increasing the dosage of VELAZOVER by 2-fold, up to a maximum 80 mg once daily, over 1 to 2 weeks in patients taking strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin) for greater than 14 days. If CYP3A4 inducers are discontinued, gradually reduce the VELAZOVER dosage to its original level over 1 to 2 weeks [see Drug Interactions].

Discontinuing Treatment with VELAZOVER

Adverse reactions may occur upon discontinuation of VELAZOVER [see Warnings and Precautions]. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible. VELAZOVER should be down tapered from the 40 mg once daily dose to 20 mg once daily for 4 days, followed by 10 mg once daily for 3 days. Patients taking VELAZOVER 20 mg once daily should be tapered to 10 mg once daily for 7 days.

CONTRAINDICATIONS

VELAZOVER is contraindicated in:

- Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome [*see Warnings and Precautions , Drug Interactions*].

WARNINGS AND PRECAUTIONS

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase enzyme deficiency or glucose-galactose malabsorption should not take this medicine.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behaviors in patients aged 24 years and younger in short-term studies. Monitor closely for clinical worsening and for emergence of suicidal thoughts and behaviors. The safety and efficacy of Vilazodone have not been established in pediatric patients.

Antidepressant drugs (such as paroxetine) increase risk compared to placebo of suicidal thinking and behavior (suicidality) in children adolescents and young adults in short term studies of major depressive disorders (MDD) and other psychiatric disorders .

1) infant born to mother who took selective serotonin reuptake inhibitors (SSRI) after 20th week of pregnancy were 6 times more likely to have persistent pulmonary hypertension (PPHN) than infant born to mothers who did not take antidepressant during pregnancy .

2) The risk of major congenital malformation particularly cardiac malformation in infants born to women who take paroxetine during the first trimester may be approximately twice as high for women taking other antidepressant .

3) A life-threatening condition called serotonin syndrome can happen when medicines called selective serotonin reuptake inhibitors (SSRIs), such as Paroxetine, and medicines used to treat migraine headaches known as 5-hydroxytryptamine receptor agonists (triptans), are used together

Serotonin syndrome is characterised by the development of at least three of the following clinical features after a recent change in a treatment regimen involving: agitation ,ataxia ,diaphoresis ,diarrhoea ,fever ,hyperreflexia, myoclonus ,shivering, changes in mental status.

Suicidal Thoughts and Behavior in Children, Adolescents and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients, and over 4,400 pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater in antidepressant-treated patients than in placebo-treated patients. The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 1.

No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but the number was not sufficient to reach any conclusion about antidepressant drug effect on suicide.

Table 1: Risk Differences of the Number of Patients with Suicidal Thoughts or Behaviors in the Pooled Placebo-Controlled Trials of Antidepressants in Pediatric and Adult Patients

Age Range (years)	Drug-Placebo Difference in Number of Patients with Suicidal Thoughts or Behaviors per 1000 Patients Treated
	Increases Compared to Placebo
<18	14 additional patients
18-24	5 additional patients
	Decreases Compared to Placebo

25-64	1 fewer patient
≥65	6 fewer patients

It is unknown whether the risk of suicidal thoughts and behaviors in children, adolescents, and young adults extends to longer-term use, i.e., beyond four months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with MDD that antidepressants delay the recurrence of depression.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing VELAZOVER, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Serotonin Syndrome

SNRIs and SSRIs, including VELAZOVER, can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is increased with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., MAOIs [*see Contraindications and Drug Interactions*]. Serotonin syndrome can also occur when these drugs are used alone. Symptoms of serotonin syndrome were noted in 0.1% of MDD patients treated with vilazodone in premarketing clinical trials.

Serotonin syndrome signs and symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

The concomitant use of VELAZOVER with MAOIs is contraindicated. In addition, do not initiate VELAZOVER in a patient being treated with MAOIs such as linezolid or intravenous methylene blue. No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection). If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking VELAZOVER, discontinue VELAZOVER before initiating treatment with the MAOI [*see Contraindications , Drug Interactions*].

Monitor all patients taking VELAZOVER for the emergence of serotonin syndrome. Discontinue treatment with VELAZOVER and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of VELAZOVER with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome and monitor for symptoms.

Increased Risk of Bleeding

Drugs that interfere with serotonin reuptake inhibition, including VELAZOVER, increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to drugs that interfere with serotonin reuptake have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages.

Inform patients about the risk of bleeding associated with the concomitant use of VELAZOVER and antiplatelet agents or anticoagulants. For patients taking warfarin, carefully monitor coagulation indices when initiating, titrating, or discontinuing VELAZOVER.

Activation of Mania or Hypomania

In patients with bipolar disorder, treating a depressive episode with vilazodone or another antidepressant may precipitate a mixed/manic episode. In controlled clinical trials, patients with bipolar disorder were excluded; however, symptoms of mania or hypomania were reported in 0.1% of undiagnosed patients treated with vilazodone. Prior to initiating treatment with vilazodone, screen patients for any personal or family history of bipolar disorder, mania, or hypomania [*see Dosage and Administration*].

Discontinuation Syndrome

Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt discontinuation, include: nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible [*see Dosage and Administration*].

Seizures

vilazodone has not been systematically evaluated in patients with a seizure disorder. Patients with a history of seizures were excluded from clinical studies. vilazodone should be prescribed with caution in patients with a seizure disorder.

Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs including VELAZOVER may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including VELAZOVER, in patients with untreated anatomically narrow angles.

Hyponatremia

Hyponatremia may occur as a result of treatment with SNRIs and SSRIs, including vilazodone. Cases of serum sodium lower than 110 mmol/L have been reported. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

In patients with symptomatic hyponatremia, discontinue VELAZOVER and institute appropriate medical intervention. Elderly patients, patients taking diuretics, and those who are volume-depleted may be at greater risk of developing hyponatremia with SSRIs and SNRIs *[see Use in Specific Populations]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Suicidal Thoughts and Behaviors in Children, Adolescents, and Young Adults [see Warnings and Precautions].
- Serotonin Syndrome [see Warnings and Precautions].
- Increased Risk of Bleeding [see Warnings and Precautions].
- Activation of Mania or Hypomania [see Warnings and Precautions].
- Discontinuation Syndrome [see Warnings and Precautions].
- Seizures [see Warnings and Precautions]
- Angle-Closure Glaucoma [see Warnings and Precautions].
- Hyponatremia [see Warnings and Precautions].

Table 2: Common Adverse Reactions Occurring in $\geq 2\%$ of VELAZOVER-treated Patients

System Organ Class Preferred Term
Gastrointestinal disorders
Diarrhea
Nausea
Dry mouth
Vomiting
Abdominal pain ¹
Dyspepsia
Flatulence
Gastroenteritis
Abdominal distension
Nervous system disorders
Headache ²
Dizziness
Somnolence
Paresthesia
Psychiatric disorders

System Organ Class Preferred Term
Insomnia
Abnormal dreams
Restlessness ³
General disorders
Fatigue
Cardiac disorders
Palpitations
Metabolism and nutrition disorders
Increased appetite
Musculoskeletal and connective tissue disorders
Arthralgia
Investigations
Increased weight

¹ Includes abdominal discomfort, abdominal pain upper, and abdominal pain.

² Includes headache and tension headache

³ Includes restlessness, akathisia, and restless legs syndrome
Sexual adverse reactions are presented in Table 3

Sexual adverse reactions

Table 3 displays the most common sexual adverse reactions in the placebo-controlled MDD studies.

Table 3: Common Sexual Adverse Reactions Occurring in $\geq 2\%$ of VELAZOVER-treated Patients

Preferred Term	Males	Females
	VELAZOVER 40 mg/day	VELAZOVER 40 mg/day
Abnormal Orgasm*	2%	1%
Erectile dysfunction	3%	-
Libido decreased	4%	2%
Ejaculation disorder	2%	-

- Not applicable*Includes abnormal orgasm and anorgasmia

Other adverse reactions observed in clinical studies

The following list does not include reactions: 1) already listed in previous tables or elsewhere in labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have significant clinical implications, or 5) which occurred at a rate equal to or less than placebo.

Cardiac disorders: *infrequent*: ventricular extrasystoles

Eye disorders: *infrequent*: dry eye, vision blurred, *rare*: cataracts

Nervous System: *frequent*: sedation, tremor; *infrequent*: migraine

Psychiatric disorders: *infrequent*: panic attack

Skin and subcutaneous tissue disorders: infrequent: hyperhidrosis, night sweats

Other adverse reactions:

The following adverse reactions have been identified during post-approval use of vilazodone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to drug exposure. Reports of adverse reactions temporally associated with vilazodone that have been received since market introduction and that are not listed above include the following:

General Disorders and Administration Site Conditions: irritability

Psychiatric Disorders: hallucinations, suicide attempt, suicidal ideation

Skin and subcutaneous tissue disorders: rash, generalized rash, urticaria, drug eruption

DRUG INTERACTIONS

Concomitant Drug Name or Drug Class	Clinical Rationale	Clinical Recommendation
Monoamine Oxidase Inhibitors (MAOIs)	The concomitant use of MAOIs and serotonergic drugs including VELAZOVER increases the risk of serotonin syndrome.	VELAZOVER is contraindicated in patients taking MAOIs, including MAOIs such as linezolid or intravenous methylene blue [see <i>Contraindications, Dosage and Administration, and Warnings and Precautions</i>].
Other Serotonergic Drugs	The concomitant use of serotonergic drugs including VELAZOVER and other serotonergic drugs increases the risk of serotonin syndrome.	Monitor patients for signs and symptoms of serotonin syndrome, particularly during VELAZOVER initiation. If serotonin syndrome occurs, consider discontinuation of VELAZOVER and/or concomitant serotonergic drugs [see <i>Warnings and Precautions</i>].
Antiplatelet Agents and Anticoagulants	Serotonin release by platelets plays an important role in hemostasis. The concurrent use of an antiplatelet agent or anticoagulant with VELAZOVER may potentiate the risk of bleeding.	Inform patients of the increased risk of bleeding with the concomitant use of VELAZOVER and antiplatelet agents and anticoagulants. For patients taking warfarin, carefully monitor the international normalized ratio (INR) when initiating or discontinuing VELAZOVER [see <i>Warnings and Precautions</i>].
Strong CYP3A4 Inhibitors (e.g., itraconazole, clarithromycin, voriconazole)	The concomitant use of VELAZOVER and strong CYP3A4 inhibitors increased the exposure of vilazodone compared to the use of VELAZOVER alone [see <i>Clinical Pharmacology</i>].	The VELAZOVER dose should not exceed 20 mg once daily with the concomitant use of a strong CYP3A4 inhibitor [see <i>Dosage and Administration, Clinical Pharmacology</i>].
Strong CYP3A4 Inducers (e.g., carbamazepine, phenytoin, rifampin)	The concomitant use of VELAZOVER and strong CYP3A4 inducers decreased the exposure of vilazodone compared to the use of VELAZOVER alone [see <i>Clinical Pharmacology</i>].	Based on clinical response, consider increasing the dosage of VELAZOVER, over 1 to 2 weeks in patients taking strong CYP3A4 inducers for greater than 14 days [see <i>Dosage and Administration, Clinical Pharmacology</i>].
Digoxin	Digoxin is a narrow therapeutic index drug. Concomitant use of VELAZOVER increased digoxin concentrations [see <i>Clinical Pharmacology</i>].	Measure serum digoxin concentrations before initiating concomitant use of VELAZOVER. Continue monitoring and reduce digoxin dose as necessary.

Table 4:

Interactions with VELAZOVER

Drugs Having No Clinically Important Interactions With VELAZOVER

Based on pharmacokinetic studies, no dosage adjustment is required for drugs that are substrates of CYP1A2, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP3A4, and/or P-glycoprotein (except narrow therapeutic index drugs, e.g., digoxin), when VELAZOVER is administered concomitantly [*see Drug Interactions*, *Clinical Pharmacology*].

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no adequate and well-controlled studies of VELAZOVER in pregnant women. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Lactation

There are no data on the presence of vilazodone in human milk, the effects of vilazodone on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VELAZOVER and any potential adverse effects on the breastfed child from VELAZOVER or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of VELAZOVER in pediatric patients have not been established. Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients [*see Boxed Warning and Warnings and Precautions*].

Geriatric Use

Based on a pharmacokinetic study, no dosage adjustment of VELAZOVER is recommended on the basis of age .

Serotonergic antidepressants have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse reaction [*see Warnings and Precautions*]. No other differences in adverse reactions were observed between geriatric and younger patients.

Use in Other Patient Populations

No dosage adjustment of VELAZOVER is necessary on the basis of gender, renal function (mild to severe renal impairment, glomerular filtration rate: 15-90 mL/minute), or hepatic function (mild to severe hepatic impairment, Child-Pugh score: 5-15 [*see Clinical Pharmacology*]).

DRUG ABUSE AND DEPENDENCE

Controlled Substance

VELAZOVER is not a controlled substance.

Abuse and Dependence

VELAZOVER has been systematically studied in animals and did not demonstrate abuse or dependence potential. While VELAZOVER has not been systematically studied in humans for its potential for abuse, there was no suggested evidence of drug-seeking behavior in the clinical studies.

OVERDOSAGE

There is limited clinical trial experience regarding human overdose with vilazodone. The adverse reactions associated with overdose of vilazodone at doses of 200-280 mg (5 to 7 times the recommended dosage) as observed in clinical trials included serotonin syndrome, lethargy, restlessness, hallucinations, and disorientation.

No specific antidotes for vilazodone are known. Removal of vilazodone by dialysis has not been studied; however, the high volume of distribution of vilazodone suggests that dialysis will not be effective in reducing vilazodone plasma concentrations.

CLINICAL PHARMACOLOGY

Mechanism of action

The mechanism of the antidepressant effect of vilazodone is not fully understood but is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone is also a partial agonist at serotonergic 5-HT_{1A} receptors; however, the net result of this action on serotonergic transmission and its role in vilazodone's antidepressant effect are unknown.

Pharmacodynamics

Vilazodone binds with high affinity to the serotonin reuptake site ($K_i = 0.1$ nM), but not to the norepinephrine ($K_i = 56$ nM) or dopamine ($K_i = 37$ nM) reuptake sites. Vilazodone potently and selectively inhibits reuptake of serotonin ($IC_{50} = 1.6$ nM). Vilazodone also binds selectively with high affinity to 5-HT_{1A} receptors ($IC_{50} = 2.1$ nM) and is a 5-HT_{1A} receptor partial agonist.

Cardiac Electrophysiology

Treatment with VELAZOVER did not prolong the QTc interval. The effect of VELAZOVER [40 and 80 mg (2 times the recommended dosage)] on the QTc interval was evaluated in a randomized, placebo-, and active-controlled (moxifloxacin 400 mg),. Pharmacokinetics

Vilazodone activity is due primarily to the parent drug. The pharmacokinetics of vilazodone (5 mg – 80 mg) are dose-proportional. Accumulation of vilazodone after administration of single VELAZOVER doses did not vary with dose, and steady-state was achieved in about 3 days. Elimination of vilazodone is primarily by hepatic metabolism with a terminal half-life of approximately 25 hours. At steady-state, after daily dosing of VELAZOVER 40 mg under fed conditions, the mean C_{max} value was 156 ng/mL, and the mean AUC (0-24 hours) value was 1645 ng·h/mL.

Absorption

Vilazodone concentrations peaked at a median of 4-5 hours (T_{max}) after VELAZOVER administration and declined with a terminal half-life of approximately 25 hours. The absolute bioavailability of vilazodone was 72% with food. Vilazodone AUC and C_{max} in the fasted state can be decreased by approximately 50% and 60%, respectively, compared to the fed state. Administration without food can result in inadequate drug concentrations and may reduce effectiveness.

Coadministration of VELAZOVER with ethanol or with a proton pump inhibitor (pantoprazole) did not affect the rate or extent of vilazodone absorption. In addition, neither the T_{max} nor terminal elimination rate of vilazodone was altered by coadministration with either pantoprazole or ethanol.

Absorption is decreased by approximately 25% if vomiting occurs within 7 hours of ingestion; no replacement dose is needed. Distribution

Vilazodone is widely distributed and approximately 96-99% protein-bound. Administration of VELAZOVER to a patient taking another drug that is highly protein bound may cause increased free concentrations of the other drug, because vilazodone is highly bound to plasma protein. The interaction between vilazodone and other highly protein-bound drugs has not been evaluated.

Metabolism and Elimination

VELAZOVER is extensively metabolized through CYP and non-CYP pathways (possibly by carboxylesterase), with only 1% of the dose recovered in the urine and 2% of the dose recovered in the feces as unchanged vilazodone. CYP3A4 is primarily responsible for its metabolism among CYP pathways, with minor contributions from CYP2C19 and CYP2D6.

PATIENT COUNSELING INFORMATION

Suicidal Thoughts and Behaviors

Advise patients and caregivers to look for the emergence of suicidality, especially early during treatment and when the dosage is adjusted up or down and instruct them to report such symptoms to the healthcare provider [*see Box Warning and Warnings and Precautions*].

Dosage and Administration

Instruct patients to take VELAZOVER with food and to follow prescribed dosage instructions [*see Dosage and Administration*].

Serotonin Syndrome

Caution patients about the risk of serotonin syndrome, particularly with the concomitant use of VELAZOVER with other serotonergic drugs including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort, and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid). Patients should contact their health care provider or report to the emergency room if they experience signs or symptoms of serotonin syndrome [*see Warnings and Precautions and Drug Interactions*].

Increased Risk of Bleeding

Inform patients about the concomitant use of VELAZOVER with aspirin, NSAIDs, other antiplatelet drugs, warfarin, or other anticoagulants because the combined use of drugs that interfere with serotonin reuptake (e.g., VELAZOVER) and these medications has been associated with an increased risk of bleeding. Advise them to inform their health care providers if they are taking or planning to take any prescription or over-the-counter medications that increase the risk of bleeding [*see Warnings and Precautions*].

Activation of Mania/Hypomania

Advise patients and their caregivers to observe for signs of activation of mania/hypomania and instruct them to report such symptoms to the healthcare provider [*see Warnings and Precautions*].

Discontinuation Syndrome

Advise patients not to abruptly discontinue VELAZOVER and to discuss any tapering regimen with their healthcare provider. Adverse reactions can occur when VELAZOVER is discontinued [*see Warnings and Precautions*].

Seizures

Caution patients about using VELAZOVER if they have a history of a seizure disorder [*see Warnings and Precautions*].

Allergic Reactions

Advise patients to notify their healthcare provider if they develop an allergic reaction such as rash, hives, swelling, or difficulty breathing [*see Adverse Reactions*].

Concomitant Medications

Advise patients to inform their health care providers if they are taking, or plan to take any prescription or over-the-counter medications since there is a potential for interactions [*see Drug Interactions*].

Ingredients

In addition to the active ingredient 40 mg vilazodone , VELAZOVER tablets contain the following inactive ingredients: Lactose spray dried (Flowlac 100), Microcrystalline cellulose (Prosolv HD 90), Colloidal anhydrous silica, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide, Talc, Polyethylene glycol 3350, Methacrylic acid copolymer, Sodium bicarbonate, Triacetin, Sunset yellow.

Pack:

Carton box contains 1 or 2 or 3 Alu\PVDC strips each contains 10 film coated tablets + inner leaflet

Storage:

Store at temperature not exceeding 30° C in dry place.

**Manufactured by: Averroes Pharma for pharmaceutical industries
Block No. (6048) 6th industrial zone - Sadat city - Egypt.**