

# DESVENLAFAXINE

## EXTENDED-RELEASE TABLETS



*To most, "generics" means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.*

See reverse side for important safety information.

— MAKING —  
**GENERICS**  
REMARKABLE

### PRODUCT DETAILS

- Strength: Available in 25 mg, 50 mg and 100 mg oral solid tablets
- Therapeutic Class: Serotonin-Norepinephrine Reuptake Inhibitor

#### Saleable Unit:

25 mg | Bottle of 30 - Case of 70  
50 mg | Bottle of 30 - Case of 70  
50 mg | Bottle of 90 - Case of 70  
100 mg | Bottle of 30 - Case of 70  
100 mg | Bottle of 90 - Case of 70

#### NDC Numbers:

25 mg | Bottle of 30: **70436-036-04**  
50 mg | Bottle of 30: **70436-012-04**  
50 mg | Bottle of 90: **70436-012-06**  
100 mg | Bottle of 30: **70436-013-04**  
100 mg | Bottle of 90: **70436-013-06**

To place an order or learn more, call **844-529-8988 (Toll Free)** or email

[sales@slaterunpharma.com](mailto:sales@slaterunpharma.com)  
6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

#### NDC: 70436-036-04

Cardinal Health: 5695440  
McKesson: 1594035  
Amerisource: 10253048

#### NDC: 70436-012-04

Cardinal Health: 5663265  
McKesson: 1561521  
Amerisource: 10238230

#### NDC: 70436-012-06

Cardinal Health: 5663273  
McKesson: 1561539  
Amerisource: 10238144

#### NDC: 70436-013-04

Cardinal Health: 5663281  
McKesson: 1561554  
Amerisource: 10238146

#### NDC: 70436-013-06

Cardinal Health: 5663299  
McKesson: 1561513  
Amerisource: 10238209

# IMPORTANT SAFETY INFORMATION FOR: DESVENLAFAXINE EXTENDED-RELEASE TABLETS

**WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Desvenlafaxine is not approved for use in pediatric patients.

**Contraindications to Desvenlafaxine Extended-Release Tablets include:**

- Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the desvenlafaxine formulation. Angioedema has been reported in patients treated with desvenlafaxine.
- The use of Monoamine Oxidase Inhibitors (MAOIs) intended to treat psychiatric disorders with desvenlafaxine or within 7 days of stopping treatment with desvenlafaxine is contraindicated because of an increased risk of serotonin syndrome. The use of desvenlafaxine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.
- Starting desvenlafaxine in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.

Serotonin-norepinephrine reuptake inhibitors and selective-serotonin reuptake inhibitors, including desvenlafaxine, can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is increased with concomitant use of other serotonergic drugs but can also occur if taken alone. Patients receiving desvenlafaxine should have regular monitoring of blood pressure since increases in blood pressure were observed in clinical studies. Pre-existing hypertension should be controlled before initiating treatment with desvenlafaxine.

Drugs that interfere with serotonin reuptake inhibition, including desvenlafaxine, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to this risk.

The use of antidepressants including desvenlafaxine should be avoided in patients with untreated anatomically narrow angles (angle closure glaucoma).

Adverse reactions after discontinuation of desvenlafaxine, particularly abrupt discontinuation may occur. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible.

The most common adverse reactions (incidence  $\geq$  5% and twice the rate of placebo in the 50 mg and 100 mg dose groups) were: nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorder.

Please see the package insert for Desvenlafaxine Extended Release Tablets for full prescribing information.