FOR YOUR PATIENTS WITH TYPE 2 DIABETES NOT AT GOAL (HbA1c ≥7.5%), ALONG WITH DIET AND EXERCISE

YOUR KEY TO PRESCRIBING

CYCLOSET®
bromocriptine mesylate tablets

INDICATION

CYCLOSET® (bromocriptine mesylate) 0.8 mg tablets is a dopamine receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

LIMITATIONS OF USE

- CYCLOSET should not be used to treat type 1 diabetes or diabetic ketoacidosis.
- Limited efficacy data in combination with thiazolidinediones.
- Efficacy has not been confirmed in combination with insulin.

IMPORTANT SAFETY INFORMATION

Contraindications

CYCLOSET is contraindicated in:

- Patients with hypersensitivity to ergot-related drugs, bromocriptine or to any of the excipients in CYCLOSET.
- Patients with syncopal migraines. May precipitate hypotension.
- Postpartum patients. Serious and life-threatening adverse reactions have been reported.
- Lactating patients. CYCLOSET contains bromocriptine which inhibits lactation.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND ACCOMPANYING FULL PRESCRIBING INFORMATION.

HOW TO TITRATE
CYCLOSET IN PATIENTS WITH ADEQUATE INSULIN

Start patients at 1 tablet (0.8 mg) once daily within 2 hours of waking, with food. Increase weekly to a dose between 1.6 mg and 4.8 mg or as appropriate.[1]

WEEK	# OF TABLETS
WEEK 1	1
WEEK 2	2
WEEK 3	3
WEEK 4	4
PATIENTS SAW RESULTS WITH BETWEEN 2 AND 6 TABLETS PER DAY WITH A MEAN OF APPROXIMATELY 4 TABLETS[1,2]	
WEEK 5	5 (as needed)
WEEK 6	6 (as needed)

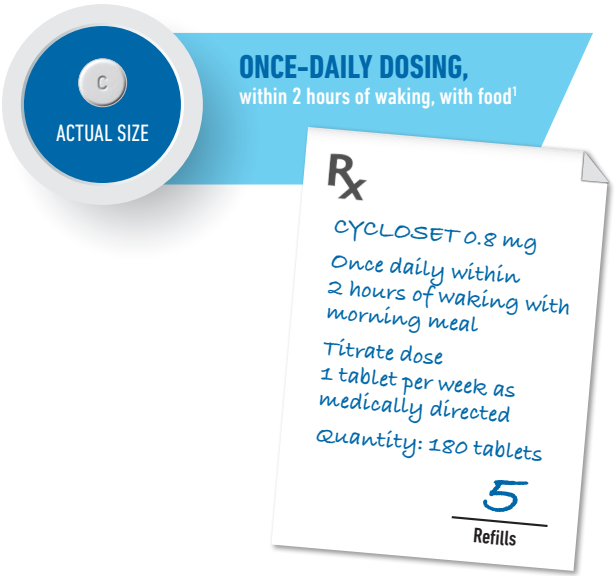
IMPORTANT SAFETY INFORMATION (cont'd)

Orthostatic Hypotension/Syncope

- CYCLOSET can cause orthostatic hypotension and syncope, particularly upon initiation or dose escalation. Use caution in patients taking antihypertensive medications. Orthostatic vital signs should be assessed prior to initiation of CYCLOSET and periodically thereafter.
- Advise patients during early treatment to avoid situations that could lead to injury if syncope were to occur, and to make slow postural changes.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND ACCOMPANYING FULL PRESCRIBING INFORMATION.

PRESCRIBING CYCLOSET



IMPORTANT SAFETY INFORMATION (cont'd)

Psychotic Disorders

- The use of CYCLOSET in patients with severe psychotic disorders is not recommended.

Impulse Control/Compulsive Behaviors

- Consider dose reduction or discontinuation of CYCLOSET if a patient develops intense urges to gamble, increased sexual urges, intense urges to spend money uncontrollably and/or other intense urges.

Somnolence

- CYCLOSET may cause somnolence, particularly when initiating therapy. Advise patients not to drive or operate heavy machinery if symptoms of somnolence occur.

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IMPORTANT SAFETY INFORMATION (cont'd)

Concomitant Use of Dopamine Antagonists or Agonists

- Concomitant use with dopamine antagonists, such as neuroleptic agents, may diminish the effectiveness of both drugs and is not recommended.
- Effectiveness and safety are unknown in patients already taking dopamine receptor agonists for other indications and concomitant use is not recommended.

Risks in Postpartum Patients

- CYCLOSET is contraindicated in postpartum patients. Serious and life-threatening adverse reactions have been reported in postpartum women who were administered bromocriptine for inhibition of lactation. These risks may be higher in postpartum patients with cardiovascular disease. The indication for use of bromocriptine for inhibition of postpartum lactation was withdrawn from bromocriptine-containing products and is not approved for CYCLOSET.

Safety and Effectiveness in Pediatrics

- The safety and effectiveness of CYCLOSET in pediatric patients have not been established.

Adverse Reactions

- In clinical trials, the most common adverse reactions reported in ≥5% of patients treated with CYCLOSET, and reported more commonly than in patients treated with placebo, included nausea, fatigue, dizziness, vomiting, and headache. Postmarketing reports with higher doses of bromocriptine used for other indications include psychotic disorders, hallucinations, and fibrotic complications.

Drug Interactions

- May increase the unbound fraction of highly protein-bound therapies, altering their effectiveness and safety profiles.
- May increase ergot-related side effects or reduce ergot effectiveness for migraines if co-administered within 6 hours of ergot-related drugs.
- Extensively metabolized by CYP3A4. Limit CYCLOSET dose to 1.6 mg/day during concomitant use of moderate CYP3A4 inhibitors. Avoid concomitant use of CYCLOSET with strong CYP3A4 inhibitors.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION THROUGHOUT AND ACCOMPANYING FULL PRESCRIBING INFORMATION.

References: 1. CYCLOSET [prescribing information]. Tiverton, RI: VeroScience, LLC.
2. Data on file, Salix Pharmaceuticals.

Salix Pharmaceuticals

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