

Patient Information
CYCLOSET® (Sikloset)
(bromocriptine mesylate tablets)
for oral use

Read this Patient Information that comes with CYCLOSET before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is CYCLOSET?

- CYCLOSET is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- CYCLOSET is not for people with type 1 diabetes.
- CYCLOSET is not for people with diabetic ketoacidosis.
- It is not known if CYCLOSET is safe and effective in children.

Who should not take CYCLOSET?

Do not take CYCLOSET if you:

- are allergic to bromocriptine or any of the ingredients in CYCLOSET. See the end of this Patient Information leaflet for a complete list of ingredients in CYCLOSET.
- are allergic to ergot medicines. Ask your healthcare provider for a list of these medicines, if you are not sure.
- have fainting (syncopal) migraine headaches.
- are a woman who has recently given birth to a child (postpartum). CYCLOSET can cause serious and life-threatening problems including high blood pressure (hypertension), heart attack, seizures, stroke and psychosis (losing touch with reality).
- are breastfeeding.

Talk to your healthcare provider before taking CYCLOSET if you have any of these conditions.

What should I tell my healthcare provider before taking CYCLOSET?

Before taking CYCLOSET, tell your healthcare provider about all of your medical conditions, including if you:

- have ever passed out (fainted).
- have migraine headaches.
- have or have had low blood pressure (hypotension).
- take medicines for high blood pressure (hypertension).
- have or have had a mental health problem, especially a psychotic disorder.
- are pregnant or plan to become pregnant. It is not known if CYCLOSET will harm your unborn baby. If you are pregnant, talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take:

- medicines for mental health problems, especially anti-psychotic medicines called dopamine receptor antagonists
- medicines for migraine or other types of headaches
- other medicines that work like CYCLOSET (dopamine receptor agonists) to treat conditions such as Parkinson's disease, high levels of a hormone called prolactin in your blood (hyperprolactinemia), restless leg syndrome and too much growth hormone (acromegaly)
- medicines for type 2 diabetes

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

CYCLOSET may affect the way other medicines work, and other medicines may affect how CYCLOSET works.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take CYCLOSET?

- Take CYCLOSET exactly as your healthcare provider tells you to take it.
- Take CYCLOSET by mouth each morning with food.
- Take CYCLOSET within 2 hours after waking in the morning.
- If you miss your morning dose, wait until the next morning to take your medication. Do not take a double dose of CYCLOSET.
- During periods of stress on the body, such as fever, trauma, infection, or surgery, your medication needs may change. Contact your healthcare provider right away as your medication needs change.
- If you take too much CYCLOSET, call your healthcare provider or go to the nearest emergency department right away.
- While taking CYCLOSET:
 - check your blood sugar as your healthcare provider tells you to
 - stay on your prescribed diet and exercise program

- talk to your doctor about how to prevent, recognize, and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and complications of diabetes
- see your healthcare provider for regular blood tests, including your blood sugar levels and hemoglobin A1C

What are the possible side effects of CYCLOSET?

CYCLOSET may cause serious side effects, including:

- **Low blood pressure (hypotension) including low blood pressure when you suddenly change positions (orthostatic hypotension).** This can happen more often when first starting CYCLOSET or if your dose is increased. Symptoms of low blood pressure when you suddenly change positions can include dizziness, nausea, sweating, fainting or light-headedness. Stand up slowly when moving from a sitting or lying position. You should avoid activities that could cause injury if you feel light-headed or faint.
- **Feeling tired and sleepy (somnolence).** Tiredness and sleepiness can happen with CYCLOSET, especially when first starting CYCLOSET. Tiredness and sleepiness are common but can also be serious. If you feel tired and sleepy while taking CYCLOSET, you should not drive or operate heavy machinery.
- **Uncontrollable (compulsive) behaviors.** CYCLOSET is in a class of medicines that may cause some people to get urges to behave in a way that may be unusual for them. Examples of these behaviors include strong urges to gamble, increased sexual urges, strong urges to spend money, binge eating or eating that you cannot control. If you or your family members notice that you are developing any unusual behaviors, talk to your healthcare provider. These behaviors may go away if your dose of CYCLOSET is lowered or stopped.
- **Serious and life-threatening problems in women who have recently given birth to a child (postpartum).** See “Who should not take CYCLOSET?”

The most common side effects of CYCLOSET include:

- nausea
- headache
- dizziness
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of CYCLOSET. For more information, ask your healthcare provider or pharmacist.

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 CYCLOSET?

- Store CYCLOSET at room temperature between 68°F and 77°F (20°C and 25°C).
- Store CYCLOSET in a tight, light resistant container.

Keep CYCLOSET and all medicines out of the reach of children.

General information about the safe and effective use of CYCLOSET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CYCLOSET for a condition for which it was not prescribed. Do not give CYCLOSET to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about CYCLOSET. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about CYCLOSET that is written for health professionals.

What are the ingredients in CYCLOSET?

Active ingredient: bromocriptine mesylate

Inactive ingredients: lactose, corn starch, magnesium stearate, colloidal silicon dioxide, and citric acid

Manufactured for:

VeroScience, LLC
Tiverton, RI 02878

Distributed by:

Salix Pharmaceuticals, a division of
Bausch Health US, LLC
Bridgewater, NJ 08807 USA

For information for healthcare professionals, call 1-800-321-4576.

CYCLOSET is a registered trademark of:

VeroScience, LLC
Tiverton, RI 02878

For more information, go to www.CYCLOSET.com or call 1-800-321-4576.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 08/2020