

PATIENT INFORMATION

What is BELVIQ?

BELVIQ is a prescription medicine that may help some obese adults or overweight adults who also have weight related medical problems lose weight and keep the weight off.

BELVIQ should be used with a reduced calorie diet and increased physical activity.

It is not known if BELVIQ is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products.

It is not known if BELVIQ changes your risk of heart problems or stroke or of death due to heart problems or stroke.

It is not known if BELVIQ is safe when taken with some other medicines that treat depression, migraines, mental problems, or the common cold (serotonergic or antidopaminergic agents).

It is not known if BELVIQ is safe and effective in children under 18 years old.

Do not take BELVIQ if you:

- are pregnant or planning to become pregnant. BELVIQ may harm your unborn baby.

What should I tell my healthcare provider before taking BELVIQ?

Have or have had heart problems including: congestive heart failure, heart valve problems, or a slow heart beat or heart block.

Caution should be used if you: have diabetes, sickle cell anemia, multiple myeloma, or leukemia, have a deformed penis, Peyronie's disease, or ever had an erection that lasted more than 4 hours, have kidney or liver problems, are pregnant or plan to become pregnant, or are breast feeding or plan to breastfeed (we recommend not breastfeeding while on Belviq)

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. BELVIQ may affect the way other medicines work, and other medicines may affect how BELVIQ works.

Especially tell your doctor if you take medicines for depression, migraines or other medical conditions such as: triptans, used to treat migraine headache, medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, selective serotonin uptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), or antipsychotics, cabergoline, linezolid, an antibiotic, tramadol, dextromethorphan, an over-the-counter medicine used to treat the common cold or cough, over-the-counter supplements such as typtophan or St. John's Wort, or medicines to treat erectile dysfunction

How should I take BELVIQ?

Take 1 tablet 2 times each day with or without food. **Do not** increase your dose of BELVIQ. Your doctor should start you on a diet and exercise program when you start taking BELVIQ. Stay on this program while you are taking BELVIQ. We recommend to stop taking BELVIQ if you do not lose 5% of your body weight within the first 12 weeks of treatment. If you take too much BELVIQ or overdose, go to the nearest emergency room right away.

What should I avoid while taking BELVIQ?

Do not drive a car or operate heavy machinery until you know how BELVIQ affects you as BELVIQ can slow your thinking.

BELVIQ may cause serious side effects, including:

- **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions.**

BELVIQ and certain medicines for depression, migraine, the common cold, or other medical problems may affect each other causing serious or life-threatening side effects. Call your doctor right away if you start to have any of the following symptoms while taking BELVIQ: mental changes such as agitation, hallucinations, confusion, or other changes in mental status, coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive

reflexes), restlessness, racing or fast heart beat, high or low blood pressure, sweating or fever, nausea, vomiting, or diarrhea, or muscle rigidity (stiff muscles)

- **Valvular heart disease.** Some people taking medicines like BELVIQ have had problems with the valves in their heart. Call your doctor right away if you have any of the following symptoms while taking BELVIQ: trouble breathing, swelling of the arms, legs, ankles, or feet, dizziness, fatigue, or weakness that will not go away, fast or irregular heartbeat
- **Changes in your attention or memory.**
- **Mental problems.** Taking BELVIQ in high doses may cause psychiatric problems such as: hallucinations, feeling high or in a very good mood (euphoria), or feelings of standing next to yourself or out of your body (disassociation)
- **Depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.
- **Low blood sugar (hypoglycemia) in people with type 2 diabetes mellitus who also take medicines used to treat type 2 diabetes mellitus.** Weight loss can cause low blood sugar in people with type 2 diabetes mellitus who also take medicines used to treat type 2 diabetes mellitus (such as insulin or sulfonylureas). You should check your blood sugar before you start taking BELVIQ and while you take BELVIQ.
- **Painful erections (priapism).** The medicine in BELVIQ can cause painful erections that last more than 6 hours. If you have an erection lasting more than 4 hours whether it is painful or not, stop using BELVIQ and call your doctor or go to the nearest emergency room right away.
- **Slow heart beat.** BELVIQ may cause your heart to beat slower. Tell your doctor if you have a history of your heart beating slow or heart block.
- **Decreases in your blood cell count.** BELVIQ may cause your red and white blood cell count to decrease. Your doctor may do tests to check your blood cell count while you are taking BELVIQ.
- **Increase in prolactin.** The medicine in BELVIQ may increase the amount of a certain hormone your body makes called prolactin. Tell your doctor if your breasts begin to make milk or a milky discharge or if you are a male and your breasts begin to increase in size.

The most common side effects of BELVIQ include: headache, dizziness, fatigue, nausea, dry mouth, constipation, cough, low blood sugar (hypoglycemia) in patients with diabetes and back pain. Tell to your doctor if you have any side effects (these or any others) that bothers you or that does not go away.