

BELVIQ® (BEL-VEEK) (lorcaserin hydrochloride) tablets, CIV	PATIENT INFORMATION	BELVIQ XR® (BEL-VEEK Eks-Are) (lorcaserin hydrochloride) extended release tablets, CIV
<p>What is BELVIQ?</p> <p>BELVIQ is a prescription medicine that may help adults with obesity, or some adults who are overweight and have weight-related medical problems, lose weight and keep the weight off.</p> <p>BELVIQ should be used with a reduced calorie diet and increased physical activity.</p> <p>It is not known if BELVIQ is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products.</p> <p>It is not known if BELVIQ changes your risk of heart problems or stroke or of death due to heart problems or stroke.</p> <p>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).</p> <p>It is not known if BELVIQ is safe and effective in children under 18 years old.</p>		
<p>BELVIQ is a federally controlled substance (CIV) because it contains lorcaserin hydrochloride and may be abused or lead to drug dependence. Keep your BELVIQ in a safe place, to protect it from theft. Never give your BELVIQ to anyone else, because it may cause harm to them. Selling or giving away this medicine is against the law.</p>		
<p>Do not take BELVIQ if you:</p> <ul style="list-style-type: none"> • are pregnant or planning to become pregnant. BELVIQ may harm your unborn baby. • are allergic to lorcaserin or any of the ingredients in BELVIQ or BELVIQ XR. See the end of this leaflet for a complete list of ingredients in BELVIQ and BELVIQ XR. 		
<p>Before you take BELVIQ, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have or have had heart problems including: <ul style="list-style-type: none"> o congestive heart failure o heart valve problems o slow heart beat or heart block • have diabetes • have a condition such as 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 problems • have liver problems • are pregnant or plan to become pregnant • are breastfeeding or plan to breastfeed. It is not known if BELVIQ passes into your breast milk. You and your healthcare provider should decide if you will take BELVIQ or breastfeed. You should not do both. <p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p> <p>BELVIQ may affect the way other medicines work, and other medicines may affect how BELVIQ works.</p> <p>Especially tell your healthcare provider if you take medicines for depression, migraines or other medical conditions such as:</p> <ul style="list-style-type: none"> • 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 tryptophan or St. John’s Wort • medicines to treat erectile dysfunction <p>Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.</p>		

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

How should I take BELVIQ?

- Take BELVIQ exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much BELVIQ to take and when to take it.
- BELVIQ comes in 2 different dose forms. Your doctor will prescribe the form of BELVIQ that is right for you.
 - **BELVIQ:** Take one tablet 2 times each day.
 - **BELVIQ XR:** Take one tablet 1 time each day.
- **Do not** increase your dose of BELVIQ.
 - BELVIQ can be taken with or without food.
 - Take the whole **BELVIQ XR extended release** tablet. **Do not** chew, crush, or divide the tablet.
- Your healthcare provider should start you on a diet and exercise program when you start taking BELVIQ. Stay on this program while you are taking BELVIQ.
- Your healthcare provider should tell you to stop taking BELVIQ if you do not lose a certain amount of weight within the first 12 weeks of treatment.
- If you take too much BELVIQ or overdose, call your healthcare provider or 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. BELVIQ can slow your thinking.

What are the possible side effects of BELVIQ?

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 healthcare provider 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
 - muscle rigidity (stiff muscles)
- **Valvular heart disease.** Some people taking medicines like BELVIQ have had problems with the valves in their heart. Call your healthcare provider 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)
 - 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 healthcare provider or go to the nearest emergency room right away.

- **Slow heart beat.** BELVIQ may cause your heart to beat slower. Tell your healthcare provider 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 healthcare provider 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 healthcare provider 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
- back pain

These are not all the possible side effects of BELVIQ.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BELVIQ?

Store BELVIQ at room temperature between 59°F to 86°F (15°C to 30°C).

Safely throw away medicine that is out of date or no longer needed.

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

General information about the safe and effective use of BELVIQ.

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

You can ask your healthcare provider or pharmacist for information about BELVIQ that is written for health professionals.

What are the ingredients in BELVIQ and BELVIQ XR?

BELVIQ tablets

Active ingredient: lorcaserin hydrochloride hemihydrate

Inactive ingredients: silicified microcrystalline cellulose NF; hydroxypropyl cellulose NF; croscarmellose sodium NF; polyvinyl alcohol USP; polyethylene glycol NF; titanium dioxide USP; talc USP; FD&C blue #2/indigo carmine aluminum lake; and magnesium stearate NF

BELVIQ XR extended-release tablets

Active ingredient: lorcaserin hydrochloride hemihydrate

Inactive ingredients: microcrystalline cellulose NF; mannitol USP; hypromellose USP; ethylcellulose dispersion Type B NF; colloidal silicon dioxide NF; polyvinyl alcohol USP; polyethylene glycol NF; titanium dioxide USP; talc USP; FD&C yellow #6/sunset yellow FCF aluminum lake; iron oxide yellow NF; iron oxide red NF; and magnesium stearate NF

Manufactured by Arena Pharmaceuticals GmbH, Untere Brühlstrasse 4, CH-4800, Zofingen, Switzerland. Distributed by Eisai Inc., Woodcliff Lake, NJ 07677 For more information, go to www.BELVIQ.com or call 1-888-274-2378.

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

Revised: 5/2017