

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

WELIREG®

belzutifan tablets

Read this carefully before you start taking **WELIREG®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **WELIREG®**.

Serious Warnings and Precautions

- **WELIREG®** can harm your unborn baby.
- Your healthcare professional will do a pregnancy test before you start taking **WELIREG®**.
- Use birth control that does not contain hormones while you take this medicine. This is because **WELIREG®** may cause hormonal birth control to not work. Keep using the birth control for at least 1 week after your last dose.

See the “*Other warnings you should know about: Pregnancy information for Females and Males*” section for more information.

What is **WELIREG® used for?**

WELIREG® is used to treat adults with von Hippel-Lindau (VHL) disease who need treatment for, and do not require surgery right away for:

- kidney cancer that has not spread to other parts of the body;
- tumors in the brain and spinal cord called central nervous system hemangioblastomas; or
- a type of pancreatic cancer called pancreatic neuroendocrine tumors, that has not spread to other parts of the body.

How does **WELIREG® work?**

WELIREG® blocks the action of a protein that causes your cancer to grow.

What are the ingredients in **WELIREG®?**

Medicinal ingredient: Belzutifan.

Non-medicinal ingredients: croscarmellose sodium, colloidal silicon dioxide, FD&C Blue #2 aluminum lake, hypromellose acetate succinate, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

****WELIREG®** comes in the following dosage forms:**

- Tablets, 40 mg

Do not use **WELIREG® if:**

- you are allergic to **WELIREG®** or any of the other ingredients of this medicine or container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take **WELIREG®. Talk about any health conditions or problems you may have, including if you:**

- have breathing or lung problems

- have low levels of oxygen in your blood
- have heart problems / heart disease
- have low levels of red blood cells (anemia)

Other warnings you should know about:

Check-ups and testing: You will have regular visits with your healthcare professional, before, during and at the end of your treatment. They will:

- Check for **hypoxia (low body oxygen levels)** using a pulse oximeter. WELIREG® may cause low oxygen levels in your body. Your healthcare professional may ask you to monitor your oxygen levels at home as well.
- Do blood tests to check for:
 - **Anemia (low red blood cell levels):** WELIREG® may cause low red blood cell levels in your blood.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Pregnancy information for Females and Males

Female Patients

- If you are pregnant, able to get pregnant, or plan to become pregnant, talk to your healthcare professional.
- WELIREG® can harm your unborn baby and cause a miscarriage.
- If you are able to become pregnant:
 - Your healthcare professional will do a pregnancy test before you start taking WELIREG®.
 - Avoid becoming pregnant while taking WELIREG®.
 - Use birth control while you take this medicine. Keep using birth control for at least 1 week after your last dose. The birth control methods you use must not contain hormones because WELIREG® may cause these types of birth control to not work. Ask your healthcare professional about birth control methods that may be right for you during this time.
 - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with WELIREG®.
- If you are breastfeeding or plan to breastfeed, talk to your healthcare professional.
 - It is not known if WELIREG® passes into your breast milk. It may harm your baby.
 - Do not breastfeed while you are taking WELIREG® and for at least 1 week after your last dose.

Male Patients

- Avoid fathering a child while you are taking WELIREG®.
- During your treatment with WELIREG®, use a condom each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using condoms for at least 1 week after your last dose.
- If during treatment with WELIREG®, your partner becomes pregnant or thinks she maybe pregnant, tell your healthcare professional right away.

Fertility

- WELIREG® may cause fertility problems in females and males. It is unknown if these problems would be permanent. If you want to have children, talk to your healthcare professional before taking WELIREG®.

Driving and using machines: Before you drive or do tasks that require special attention, wait until you know how you respond to WELIREG®. You may feel dizzy or tired after taking WELIREG®. If this happens, do not drive or use tools or machines until you no longer feel dizzy or tired.

Children and Adolescents (less than 18 years of age): It is not known if WELIREG® is safe and effective for use in people under 18 years old. Do not give this medicine to children and adolescents under 18 years old.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with WELIREG®:

- Some medicines may increase the risk of side effects with WELIREG®, like:
 - imatinib (used to treat cancer)
 - fluconazole (used to treat fungal infections)
 - fluoxetine, fluvoxamine (used to treat depressive disorders)
 - ticlopidine (used to prevent stroke)
- WELIREG® may affect the way other medicines work, like:
 - hormonal birth control such as desogestrel, ethinylestradiol and levonorgestrel
 - medicines used for sedation and to help sleep such as midazolam

How to take WELIREG®:

- Take WELIREG® exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take WELIREG® with or without food.
- Swallow each tablet whole. Do not break it up.

Usual dose:

- **Adults:** 120 mg (three 40 mg tablets) once per day.
- Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if:
 - you experience serious side effects, or
 - your disease gets worse

Overdose:

If you think you, or a person you are caring for, have taken too much WELIREG®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of WELIREG[®], take the missed dose as soon as possible on the same day. Take your regular dose of WELIREG[®] the next day.
- If you vomit after taking WELIREG[®], do not take another WELIREG[®] tablet. Take your regular dose of WELIREG[®] the next day.
- Do not take 2 doses at the same time.

What are possible side effects from using WELIREG[®]?

These are not all the possible side effects you may have when taking WELIREG[®]. If you experience any side effects not listed here, tell your healthcare professional.

- feeling like you're going to throw up (nausea)
- dizziness
- shortness of breath
- feeling tired
- headaches
- muscle pain
- back pain
- stiff joints
- constipation
- changes in weight
- difficulty sleeping
- anxiety
- cough
- chest pain

WELIREG[®] can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how WELIREG[®] is affecting your blood.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness / tiredness, dizziness		X	
COMMON			
Hypoxia (low oxygen in your body): trouble breathing, shortness of breath, chest pain, dizziness, headaches, weakness of limbs, ringing/buzzing/clicking/		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
hissing in ears			
Eye problems: blurred vision, loss of vision in eye, decreased sharpness of vision, blocked eye veins, increased sensitivity of the eyes to light, eye pain or redness, floaters in field vision, eye irritation, swelling and itching of the eyelids		X	
LESS COMMON			
Blood clot (blocked artery): weakness, drooping of face, numbness			X
Intracranial hemorrhage (bleeding within the skull): sudden tingling, weakness, numbness in face, arm, or leg			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store WELIREG® at room temperature (15°C to 30°C).
- Keep out of reach and sight of children.

If you want more information about WELIREG®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1 800 567-2594.

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