Package leaflet: Information for the patient

Welireg® 40 mg film-coated tablets
belzutifan

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In addition to this leaflet, you will receive a patient card, which contains important safety information that you need to be aware of. Keep this patient card with you.

What is in this leaflet

1. What Welireg is and what it is used for

Welireg contains the active ingredient belzutifan.

Welireg is a medicine used to treat adults with von Hippel-Lindau (VHL) disease who need treatment for a type of kidney cancer called renal cell carcinoma (RCC), tumours in the brain and spinal cord called central nervous system hemangioblastomas, or a type of pancreatic cancer called pancreatic neuroendocrine tumours, and for whom surgery or other local procedures are unsuitable or undesirable.

How belzutifan works
Welireg is a hypoxia-inducible factor 2 alpha (HIF-2α) inhibitor which may slow or stop the growth of tumors in patients with VHL disease.

2. What you need to know before you take Welireg

Do not take Welireg if:
- You are allergic to belzutifan or any of the other ingredients of this medicine (listed in section 6). Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Welireg if:
- You have breathing problems
- You have heart problems
- You have low levels of red blood cells (anaemia)
- You are pregnant or plan to be pregnant
- Welireg may affect fertility, which may affect your ability to have children. Talk to your doctor if this is a concern for you.

If any of the above apply to you (or you are not sure) talk to your doctor before taking this medicine.

Welireg may decrease your red blood cell level. Common symptoms include shortness of breath, fatigue, dizziness, and pale skin.

Welireg may also decrease the oxygen level in your blood. Common symptoms include shortness of breath, increased heart rate, rapid breathing, and feeling anxious or restless. Although symptoms vary from person to person, low oxygen levels in your body that can be serious may require you to stop treatment with Welireg, receive oxygen therapy or be hospitalised. Contact your doctor immediately if you develop any of the following symptoms: bluish discoloration of the skin around your mouth, inability to speak in full sentences without catching your breath, unusual tiredness, and confusion. In light of this risk, you should stop smoking while taking Welireg.

Your doctor will regularly measure your oxygen level and do blood tests to check your red blood cell level during your treatment with Welireg.

Children and adolescents
Do not give this medicine to children and adolescents below the age of 18 years.

Other medicines and Welireg
Tell your doctor or pharmacist about all the medicines you take. This is because Welireg can affect the way some other medicines work. Also, some other medicines can affect the way Welireg works.

Some medicines may increase the risk of side effects with Welireg, for example:

- imatinib (used to treat cancer)
- fluconazole (used to treat fungal infections)
- fluoxetine, fluvoxamine (used to treat depressive disorders)

Welireg may affect the way other medicines work, for example:

- hormonal contraceptives such as desogestrel, ethinylestradiol and levonorgestrel
- alfentanil (used as a supplement before or during anesthesia)
- lurasidone (used to treat schizophrenia or bipolar depression)
- sirolimus, tacrolimus (used as prophylaxis of organ rejection in transplants)

Your doctor will decide if the dose needs to be changed.

Pregnancy information for women and men
If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Your doctor will carry out a pregnancy test before you start taking the medicine.
Welireg may harm your unborn baby and cause a miscarriage. This means:

- You should not become pregnant while taking Welireg
- You should not take Welireg if you are pregnant.

Contraception in women and men
Women
If you are a woman who could get pregnant:

- Birth control methods that contain hormones (such as birth control pills, injections, or transdermal system patches) may not work as well during treatment with Welireg. You should use an effective form of non-hormonal birth control (contraception) or have your male partner use a condom during treatment with Welireg and for 1 week after your last dose.

Talk to your doctor or pharmacists about birth control methods that may be right for you during this time.

If you become pregnant while using Welireg, talk to your doctor straight away.

Men
Welireg may be passed on to an unborn baby and harm it. If you are a man whose female partner could get pregnant:
- You and your partner should use effective contraception while taking Welireg.
- Also do this for at least 1 week after your last dose of Welireg.

If your partner becomes pregnant while you are using Welireg, talk to your doctor straight away.
If you are a man whose female partner is pregnant:
Use a barrier method of contraception during treatment with belzutifan and 1 week after last dose.

Breast-feeding
Do not breast-feed during treatment with Welireg. It is not known if Welireg passes into your breast milk; it may harm your baby.
You should not breast feed for at least one week after your last dose of Welireg.

Fertility
Welireg may impair fertility. If you are planning to have a baby with your partner - talk to your doctor about family planning before taking Welireg.

Driving and using machines
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.

Welireg contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Welireg

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
The recommended dose of Welireg is 120 mg (three 40 mg tablets):
- Take your prescribed dose once a day, at the same time each day.
- Your doctor may change your dose if needed.

How to take
Swallow the tablet whole - do not break, crush, or chew the tablet.
You can take Welireg with or without food.

If you take more Welireg than you should
If you take too many tablets contact a doctor or hospital for advice. Medical treatment may be necessary.

If you forget to take Welireg
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 a double dose to make up for forgotten or vomited dose.

If you are not sure how to take Welireg, call your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects are:

Very Common: may affect more than 1 in 10 people
- low red blood cells (anaemia)
- feeling tired
- feeling dizzy
- have difficulty breathing
- feeling sick (nausea)
- weight gain

Tell your doctor if you notice any of the side effects listed above.

Common: may affect up to 1 in 10 people
- abnormally low oxygen levels in the blood

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Welireg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after "EXP". The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.

Do not use this medicine if the packaging is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Welireg contains
The active substance is belzutifan. Each film-coated tablet contains 40 mg of belzutifan.
The other ingredients are croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, mannitol, cellulose microcrystalline, and colloidal anhydrous silica. The film-coat contains indigo carmine aluminium lake, macrogol, polyvinyl alcohol, talc, titanium dioxide.

What Welireg looks like and contents of the pack
Welireg is a blue, round film-coated tablet, debossed with 177 on one side and plain on the other side.

Welireg is available in HDPE bottles with 90 film-coated tablets and as aluminium/aluminium blisters. Each multipack contains 90 (three packs of 30) film-coated tablets. Not all packaging presentations may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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