WELIREG®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

1. Why am I using WELIREG?

WELIREG contains the active ingredient belzutifan. WELIREG is used to treat adults with von-Hippel Lindau (VHL) disease who need treatment for multiple tumour types, and adults with advanced kidney cancer. For more information, see Section 1. Why am I using WELIREG? in the full CMI.

2. What should I know before I use WELIREG?

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use WELIREG? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with WELIREG and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take WELIREG?

Take your prescribed dose once per day. Take your prescribed dose at the same time each day. You can take WELIREG with or without food. Swallow the tablet whole. Do not break, crush or chew.

More instructions can be found in Section 4. How do I use WELIREG? in the full CMI.

5. What should I know while using WELIREG?

Things you should do	• Tell your doctor if you get any symptoms of low red blood cell counts including tiredness, feeling cold, shortness of breath, chest pain, or fast heartbeat. • Tell your doctor or get medical help right away if you get symptoms of low oxygen in your body, including shortness of breath or fast heart rate. • For female patients who are able to become pregnant, your healthcare provider will do a pregnancy test before you start treatment with WELIREG. You should use an effective form of non-hormonal birth control (contraception) during treatment with WELIREG and for 1 week after your last dose. • Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with WELIREG and for 1 week after your last dose.
Driving or using machines	• You may feel dizzy or tired while taking WELIREG. If this happens, do not drive or use machines until you no longer feel dizzy or tired.
Looking after your medicine	• Store below 30°C

For more information, see Section 5. What should I know while using WELIREG? in the full CMI.

6. Are there any side effects?

Common side effects of WELIREG include: feeling tired, headache, feeling dizzy, nausea, and weight gain.

WELIREG may decrease the oxygen level in your blood and red blood cell level. This may cause serious side effects including shortness of breath, trouble breathing, chest pain, or a very fast heartbeat. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WELIREG®

Active ingredient: *belzutifan* (bel-zu-ti-fan)

Consumer Medicine Information (CMI)

This leaflet provides important information about using WELIREG. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using WELIREG.**

Where to find information in this leaflet:

1. Why am I using WELIREG?
2. What should I know before I use WELIREG?
3. What if I am taking other medicines?
4. How do I use WELIREG?
5. What should I know while using WELIREG?
6. Are there any side effects?
7. Product details

1. Why am I using WELIREG?

WELIREG contains the active ingredient belzutifan.

WELIREG blocks a protein called hypoxia-inducible factor 2 alpha (HIF-2α) which is involved in the growth of some kinds of tumours, it is 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 haemangioblastomas, or a type of pancreatic cancer called pancreatic neuroendocrine tumours, that does not require surgery right away.
- kidney cancer that has spread (advanced RCC) following treatment with a PD-1 or PD-L1 and VEGF cancer medicines.

2. What should I know before I use WELIREG?

Warnings

Do not use WELIREG if:

- you are allergic to belzutifan, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as breathing problems, heart problems/heart disease, low levels of red blood cells (anaemia), or, allergies
- have any other medical conditions
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

- WELIREG can harm your unborn baby and may also cause miscarriage.
- Your doctor will do a pregnancy test before you start treatment with WELIREG.
- You should use an effective form of non-hormonal birth control during treatment with WELIREG and for 1 week after your last dose.
- WELIREG may cause hormonal forms of birth control to not work as well. Unplanned pregnancies can happen.
- Talk with your doctor about birth control methods that may be right for you during this time
- If you become pregnant or suspect you might be pregnant, tell your doctor right away.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

- It is not known if WELIREG passes into your breast milk; it may harm your baby.
- You and your doctor should decide together if you will take WELIREG or if you will breastfeed, but you should not do both at the same time.
- If you intend to breastfeed, wait 1 week after your last dose of WELIREG before you start breastfeeding.

Men with female partners who are able to become pregnant

If you have a partner who is pregnant or could get pregnant:

- Use an effective form of birth control during treatment with WELIREG and for 1 week after your last dose.
- Talk to your doctor about birth control methods that may be right for you during this time.
- Tell your doctor right away if your partner becomes pregnant or thinks she might be pregnant while you are taking WELIREG.

WELIREG may impair fertility. If you are planning to have a baby with your partner, talk to your doctor before taking WELIREG.

Children

It is not known if WELIREG is safe and effective for use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect WELIREG.

4. How do I use WELIREG?

How much to take

- The recommended dose is 120 mg (three 40 mg tablets)
- Take WELIREG exactly as your doctor tells you to
- Your doctor may change your dose if needed
- You can take WELIREG with or without food
- Swallow each tablet whole. Do not break, crush or chew

When to take WELIREG

- Take your prescribed dose once a day
- Take your prescribed dose at the same time each day

If you forget to take WELIREG

- WELIREG should be taken at the same time each day.
- If you miss a dose of WELIREG, take the missed dose as soon as possible on the same day. Take your next dose of WELIREG at your regular time the next day. Do not take extra tablets to make up for the missed dose.
- If you vomit after taking WELIREG, do not take an extra dose. Take your next dose at your regular time the next day.
- If you are not sure how to take WELIREG, call your doctor or pharmacist.

If you take too much WELIREG

If you think that you have taken too much WELIREG, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using WELIREG?

Things you should do

WELIREG may cause serious side effects, including:

- **Low red blood cell counts (anaemia).** Low red blood cell counts are common with WELIREG and can be severe. You may need a blood transfusion if your red blood cell counts drop too low. Your doctor will do blood tests to check your red blood cell counts before you start and during treatment with WELIREG.

  Tell your doctor if you get any symptoms of low red blood cell counts, including tiredness, feeling cold, shortness of breath, chest pain, or fast heartbeat.

- **Low oxygen levels in your body.** WELIREG can cause low oxygen levels in your body that can be severe and may require you to stop treatment with WELIREG, receive oxygen therapy, or be hospitalised. Your doctor will monitor your oxygen levels before you start and during treatment with WELIREG.

  Tell your doctor or get medical help right away if you get symptoms of low oxygen in your body, including shortness of breath or increased heart rate.

WELIREG may cause harm to unborn baby. Treatment with WELIREG during pregnancy can cause harm to your unborn baby. 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. Females who could get pregnant and males with female partners who are able to become pregnant should use effective contraception during treatment with WELIREG and for 1 week after your last dose. Tell your doctor right away if you, or your partner becomes pregnant or thinks she is pregnant while you are taking WELIREG.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how WELIREG affects you.

You may feel dizzy or tired while taking WELIREG. If this happens, do not drive or use machines until you no longer feel dizzy or tired.

Looking after your medicine

Follow the instructions on the packaging on how to take care of your medicine properly.

Store it below 30°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
• Low red blood cells (anaemia) • Low oxygen levels in body which may cause (observed less frequently in people with VHL associated tumours): o shortness of breath or trouble breathing o chest pain o heart feels like it's beating very fast, skipping beats, racing or fluttering	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Less serious side effects

Less serious side effects	What to do
• Feeling like you're going to throw up • Feeling tired • Feeling dizzy • Weight gain (observed less frequently in people with kidney cancer that has spread)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What WELIREG contains

Active ingredient (main ingredient)	• belzutifan
Other ingredients (inactive ingredients)	• croscarmellose sodium • hypromellose acetate succinate • magnesium stearate • mannitol • microcrystalline cellulose • silicon dioxide • indigo carmine aluminium lake • macrogol • polyvinyl alcohol • purified talc • titanium dioxide

What WELIREG looks like

WELIREG 40 mg tablet is a blue, oval, film-coated tablet, with "177" on one side (Bottle pack-Aust R 355338) (Blister pack-Aust R 482705).

Who distributes WELIREG

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park, NSW, 2113

msd-australia.com.au

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