swissmedic

Summary report on authorisation dated 3 December 2025

Welireg® (active substance: belzutifan)

Indication extension in Switzerland: 1 July 2025

Medicinal product (film-coated tablets) for the treatment of adults with advanced renal cell carcinoma (RCC) after at least 2 previous therapies

About the medicinal product

The medicinal product Welireg contains the active substance belzutifan and is administered in the form of film-coated tablets.

Swissmedic first authorised Welireg temporarily on 21 March 2024. The medicinal product is intended for the treatment of adults with Von Hippel-Lindau (VHL)[1] disease, who require therapy for VHL-associated tumours of the kidneys (renal cell carcinomas), the brain and spinal cord (haemangioblastomas of the central nervous system), or the pancreas (pancreatic neuroendocrine tumours), and do not require immediate surgery.

The indication extension of 1 July 2025 means that Welireg is now also authorised for the treatment of adults with advanced renal cell carcinoma (RCC). The cancer is unresectable (cannot be removed by surgery) and has progressed in the patients to be treated, despite 2 or more previous lines of therapy (including PD-(L)1 and VEGF tyrosine kinase inhibitors).

Mode of action

The active substance belzutifan is an inhibitor of hypoxia-inducible factor 2 alpha (HIF-2α)[2]. Belzutifan binds to HIF-2α and in this way blocks regulatory mechanisms in specific genes capable of triggering the formation of tumours. This mechanism of action enables tumour growth to be slowed or stopped in patients.

Administration

Welireg, containing the active substance belzutifan, is a prescription-only medicine.

[1] Von Hippel-Lindau (VHL) disease: Rare, hereditary disorder in which benign or malignant tumours can form in various organs.

[2] Hypoxia-inducible factor 2 alpha (HIF-2α): A regulatory protein capable of triggering specific mechanisms in genes by binding to regions in their DNA.

It is available as film-coated tablets in the dosage strength of 40 mg. The recommended dose is 120 mg (3 film-coated tablets of 40 mg) once daily. The film-coated tablets are not to be chewed and can be taken with or without food.

Treatment with Welireg is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments.

The doctor will advise patients to continue the therapy until the disease progresses or severe side effects occur.

Women of child-bearing age should use a highly effective method of contraception during treatment with Welireg and for at least 1 week after the last dose as the active substance belzutifan can harm the unborn child.

Efficacy

The efficacy of the indication extension for Welireg was investigated in the LITESPARK-005 clinical trial, which compared Welireg (belzutifan) with everolimus (authorised cancer medicine). It included a total of 746 patients with unresectable renal cell carcinoma (RCC), whose disease had progressed despite previous therapies with PD-(L)1 and VEGF tyrosine kinase inhibitors.

The trial showed a statistically significant improvement in progression-free survival (PFS)[3] throughout the entire trial observation period under treatment with Welireg, although the median PFS was identical for both treatment groups (5.6 months). The objective response rate (ORR)[4] was also significantly higher for Welireg treatment (22% versus 3.5% for everolimus).

Precautions, undesirable effects, & risks

Welireg must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects of Welireg, affecting more than 10% of patients, were anaemia, fatigue/exhaustion, musculoskeletal pain, nausea, headache, increased liver function tests, shortness of breath, constipation, dizziness, and low levels of oxygen in body tissues (hypoxia).

It is important to monitor oxygen levels and blood count regularly. Dose adjustments may be required, particularly in the event of more severe undesirable effects.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

There are currently only limited treatment options for patients with advanced renal cell carcinoma (RCC), particularly after unsuccessful treatments with PD-(L)1 and VEGF tyrosine kinase inhibitors. Welireg, containing the active substance belzutifan, offers a new treatment option with a different mechanism of action than the currently available systemic therapies. Clinical trials showed that Welireg can slow disease progression. Welireg demonstrated lower rates of unde-

[3] Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[4] Objective response rate (ORR): The objective response rate is defined as the percentage of patients with a clinically relevant reduction in tumour size.

sirable effects that resulted in discontinuation of treatment or death versus the comparator therapy, everolimus.

Taking all the risks and precautions into account, and based on the available data, the benefits of this treatment outweigh the risks.

Swissmedic has therefore authorised the indication extension of Welireg in Switzerland for the treatment of adults with advanced renal cell carcinoma (RCC) after at least 2 previous therapeutic approaches.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Welireg®

Information for patients (package leaflet): Information for patients Welireg®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.