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Summary report on authorisation dated 10 October 2025

Balversa® (active substance: erdafitinib)

Authorisation in Switzerland: 14 January 2025

Film-coated tablets for the treatment of advanced urothelial carcinoma with specific genetic alterations in adults

About the medicinal product

Balversa contains the active substance erdafitinib and is used to treat adults with unresectable or metastatic urothelial carcinoma[1], if a genetic alteration has been identified in FGFR3 (fibroblast growth factor receptor 3).

Balversa is used if the disease has progressed after immunotherapy and after platinum-based chemotherapy, if the patients were eligible for these treatments.

Since Balversa should be used only for treating a urothelial carcinoma with the FGFR3 gene alteration, the doctor should arrange a test for this alteration before initiating treatment to ensure that this medicinal product is suitable.

Mode of action

Balversa is a tyrosine kinase inhibitor, a group of medicinal products that work by blocking certain enzymes on cells, particularly the FGFR receptors (fibroblast growth factor receptors). This slows or stops the growth of the cancer cells.

Administration

Balversa is a prescription-only medicine and should be prescribed by a doctor with experience in administering cancer treatments.

Balversa is available as film-coated tablets taken by mouth.

The recommended starting dose is 8 mg once daily. Depending on tolerability and the results of a blood test, the dose can be increased to 9 mg once daily if recommended by the doctor.

[1] Urothelial carcinoma (UC): Urothelial cancer refers to bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra).

The tablets can be taken with or without food and should be swallowed whole.

Efficacy

The efficacy of Balversa was investigated in study BLC3001 (THOR), which recruited 266 patients with advanced urothelial carcinoma harbouring specific genetic alterations (FGFR) and with disease progression despite immunotherapy.

In the study the patients were divided into two treatment groups: one group received Balversa and the other group chemotherapy (docetaxel or vinflunine).

The treatment with Balversa showed a statistically significant improvement in overall survival[2] compared to the chemotherapy. Patients survived for a median[3] period of 12.1 months compared to 7.8 months in the chemotherapy group. Progression-free survival – i.e. the period until the disease continues to progress – was also prolonged (5.55 months versus 2.73 months). Furthermore, Balversa showed a higher response rate[4] of 35.3 % compared to 8.5 % with the chemotherapy.

Precautions, undesirable effects, & risks

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

The most common undesirable effects in all patients treated with Balversa (occurring in more than 10 % of all patients) include the build-up of fluid under the retina and detachment of the retina from the back of the eye (central serous retinopathy (CSR)), high blood phosphate levels (hyperphosphataemia), skin disorders such as swelling, redness or peeling (palmar-plantar erythrodysaesthesia syndrome), diarrhoea, inflammation of the lining of the mouth, dry mouth, reduced appetite, taste disturbance, elevated AST/ ALT[5] levels, hair loss, decreased weight and nail disorders.

Regular ophthalmological examinations are recommended since the use of Balversa can lead to eye disorders such as CSR.

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

2 Overall survival: Overall survival (OS) refers to the period between the start of treatment and the death of the patient.

3 Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

4 Response rate: Proportion of patients who respond positively and discernibly to a treatment (in this case the response rate corresponds to a radiologically measurable reduction in the size of tumour lesions)

5 AST/ ALT: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are enzymes produced mainly in the liver. Elevated levels of activity of these enzymes in the blood may indicate liver-related diseases.

Why the medicinal product has been authorised

There is a great need for new treatment options for patients with advanced urothelial carcinoma whose disease continues to progress despite immunotherapy or chemotherapy. Balversa is a targeted treatment that acts against alterations in the FGFR3 receptor. In the pivotal trial, Balversa significantly prolonged overall and progression-free survival and improved the response rate. Taking all the risks and precautions into account, and based on the available data, the benefits of Balversa outweigh the risks. Swissmedic has therefore authorised the medicinal product Balversa, containing the active substance erdafitinib, for use in Switzerland for this patient group.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Balversa®

Information for patients (package leaflet): Information for patients Balversa®
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.