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Balversa (erdafitinib)

An overview of Balversa and why it is authorised in the EU

What is Balversa and what is it used for?

Balversa is used to treat urothelial cancer (cancer of the bladder and urinary system) in adults. It is used on its own when the cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body).

Balversa is given to patients whose tumours have changes in the fibroblast growth factor receptor 3 (*FGFR3*) gene and have worsened after treatment known as immunotherapy.

Balversa contains the active substance erdafitinib.

How is Balversa used?

Balversa can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in treating cancer.

Balversa is available as tablets to be taken by mouth once daily. Phosphate levels in the blood will be assessed before the first dose and then monitored monthly. If the phosphate levels in the blood increase, the doctor may either reduce the dose, give another medicine known as a phosphate binder to lower phosphate levels in the blood or stop treatment. In case of serious side effects, the doctor may have to stop the medicine. Treatment should continue for as long as the patient benefits from it and side effects are manageable.

For more information about using Balversa, see the package leaflet or contact your doctor or pharmacist.

How does Balversa work?

Genetic changes to the *FGRF3* gene can produce an abnormal form of the FGRF3 protein, which causes the uncontrolled growth of cancer cells. The active substance in Balversa, erdafitinib, is an FGFR tyrosine kinase inhibitor and works by blocking the activity of abnormal FGFR3 on the surface of cancer cells, stopping the protein from functioning and thereby slowing the growth and spread of the cancer.

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What benefits of Balversa have been shown in studies?

Balversa was investigated in a main study in adults with urothelial cancer with *FGFR3* alterations that had spread or could not be removed by surgery and had been previously treated with one or two therapies, including immunotherapy. In the study, 136 people who received Balversa lived for an average of 12.1 months compared with an average of around 7.8 months for people who received other cancer medicines called docetaxel or vinflunine. People who received Balversa lived an average of 5.6 months before their disease got worse compared with an average of 2.7 months for those who received docetaxel or vinflunine alone.

What are the risks associated with Balversa?

For the full list of side effects and restrictions with Balversa, see the package leaflet.

The most common side effects with Balversa (which may affect more than 1 in 10 people) include hyperphosphataemia (high blood phosphate levels), diarrhoea, stomatitis (inflammation of the lining of the mouth), dry mouth, reduced appetite, dry skin, anaemia (low levels of red blood cells), constipation, dysgeusia (taste disturbance), palmar-plantar erythrodysaesthesia syndrome (rash and numbness on the palms and sole), hair loss, increased blood levels of liver enzymes, onycholysis (separation of a fingernail or toenail from its nail bed), nausea (feeling sick), decreased weight, dry eye, nail discolouration, vomiting, increased blood creatinine levels (a sign of kidney problems), hyponatraemia (low blood sodium levels), paronychia (nailbed infection), nail dystrophy (abnormal changes in the shape, colour, texture, and growth of the fingernails or toenails), onychomadesis (condition where the nail stops growing or falls off), nosebleeds and nail disorder.

The most common serious side effects with Balversa include stomatitis, hyponatraemia, palmar-plantar erythrodysaesthesia syndrome, onycholysis, diarrhoea, hyperphosphataemia, decreased appetite and nail dystrophy.

Why is Balversa authorised in the EU?

At the time of approval, more treatment options were needed for people with advanced urothelial carcinoma after one to two previous treatments.

The main study showed that in people with urothelial cancer with changes in the *FGFR3* gene and in whom immunotherapy had failed, treatment with Balversa increased the time they lived before their disease got worse.

Regarding the safety profile, side effects are considered manageable with treatment interruption and dose modifications.

The European Medicines Agency therefore decided that Balversa's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Balversa?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Balversa have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Balversa are continuously monitored. Suspected side effects reported with Balversa are carefully evaluated and any necessary action taken to protect patients.

Other information about Balversa

Balversa received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Balversa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/balversa

This overview was last updated in 08-2024.