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EPAR summary for the public

Vectibix

panitumumab

This is a summary of the European Public Assessment Report (EPAR) for Vectibix. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Vectibix.

For practical information about using Vectibix, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vectibix and what is it used for?

Vectibix is a medicine for treating colorectal (bowel) cancer that has spread to other parts of the body.

Vectibix is used alone or with other cancer medicines in patients with a type of tumour that has normal ('wild-type') copies of a gene known as *RAS*.

It contains the active substance panitumumab.

How is Vectibix used?

Vectibix can only be obtained with a prescription. Treatment with Vectibix should be supervised by a doctor who has experience in the use of cancer therapy. It should only be started after the presence of wild-type *RAS* has been confirmed by an experienced laboratory using a validated test method.

Vectibix is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The recommended dose of Vectibix is 6 mg per kilogram body weight given once every two weeks. The recommended infusion time is approximately 60 minutes, but larger doses may need 90 minutes. The dose may need to be modified if severe skin reactions occur.

How does Vectibix work?

The active substance in Vectibix, panitumumab, is a monoclonal antibody, a type of protein that has been designed to attach to and block a target called EGFR on the surface of certain cells, including in



some tumours. As a result, these tumour cells can no longer receive the messages transmitted via EGFR that they need to grow and spread to other parts of the body.

Panitumumab does not seem to work against tumour cells that contain mutated (abnormal) *RAS* genes. This is because growth of these types of cells does not depend on EGFR and they can continue to grow uncontrollably even when EGFR is blocked.

What benefits of Vectibix have been shown in studies?

Several bowel cancer studies have shown that Vectibix is effective at prolonging life or slowing disease progression in patients with 'wild-type' *RAS* tumours that have spread. The studies show Vectibix can be effective when used alone and together with the standard chemotherapy regimens FOLFOX (a combination of 5-fluorouracil with folinic acid and the cancer medicine oxaliplatin) or FOLFIRI (5-fluorouracil with folinic acid and a different cancer medicine, irinotecan).

Here are some of the main results from these studies:

- Patients receiving Vectibix in combination with FOLFOX lived for an average of 10.1 months without the disease getting worse in a study of 1,183 previously untreated patients compared with 7.9 months for those receiving FOLFOX alone.
- Around 59% of patients who received Vectibix plus FOLFIRI in a study of 154 previously untreated had some reduction in signs of cancer. Patients in this study (there was no comparator treatment) lived for an average of 11.2 months without their disease getting worse.
- Around 73% of patients given Vectibix plus FOLFIRI and 78% of those given Vectibix with FOLFOX had some reduction in signs of cancer in a study of 80 previously untreated patients. Patients given these combinations lived for an average of 14.8 months and 12.8 months respectively without their disease getting worse.
- Patients given Vectibix in combination with FOLFIRI lived for 16.2 months in a study of 1,186 previously treated patients compared with 13.9 months in patients receiving FOLFIRI alone. Patients receiving Vectibix also had a longer period of time without their disease getting worse: 6.4 months versus 4.6 months.
- Patients with wild-type tumours who received Vectibix alone had no disease progression for an average of 16 weeks in a study of 463 patients, compared with 8 weeks in those who did not receive Vectibix and only had supportive care. This study involved patients with either wild-type or mutant *RAS* whose disease had got worse despite treatments that included a fluoropyrimidine, oxaliplatin and irinotecan. It was later confirmed that benefit is limited only to patients with wild-type *RAS* tumours.

What are the risks associated with Vectibix?

In studies, 93% of the patients receiving Vectibix had side effects affecting the skin, although most of these were mild or moderate. The most common side effects with Vectibix (seen in more than 2 patients in 10) were diarrhoea, nausea (feeling sick), vomiting, constipation, abdominal pain (stomach ache), fatigue (tiredness), pyrexia (fever), lack of appetite, paronychia (nail bed infection), rash, acneiform dermatitis (skin inflammation resembling acne), pruritus (itching), erythema (reddening of the skin) and dry skin. For the full list of all side effects reported with Vectibix, see the package leaflet.

Vectibix must not be used in patients who have had a severe or life-threatening hypersensitivity (allergic) reaction to panitumumab or any of the other ingredients in the past. It must not be used in

patients with interstitial pneumonitis or pulmonary fibrosis (lung diseases). Vectibix must not be used with oxaliplatin-containing chemotherapy in patients whose tumour contains the mutated *RAS* gene or for whom the *RAS* status is not known.

Why is Vectibix approved?

The CHMP concluded that Vectibix's benefits are greater than its risks and recommended that it be given marketing authorisation.

Vectibix was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

The company that markets Vectibix will ensure that all doctors who are expected to prescribe Vectibix are provided with educational material informing them of the importance of carrying out a *RAS* test before treatment with Vectibix and only using Vectibix in patients whose tumour is confirmed to contain the wild-type *RAS* gene.

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

Other information about Vectibix

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Vectibix on 3 December 2007. This was switched to a full marketing authorisation on 15 January 2015.

The full EPAR for Vectibix can be found on the Agency's website ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Vectibix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.