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Imbruvica (*ibrutinib*)

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

What is Imbruvica and what is it used for?

Imbruvica is a medicine used to treat adults with certain cancers that affect B cells (a type of white blood cell).

Mantle cell lymphoma (MCL)

Imbruvica is used in patients with previously untreated MCL who would be able to undergo autologous stem cell transplantation (ASCT). ASCT is a procedure where the patient's bone marrow is replaced by their own stem cells to form new bone marrow that produces healthy cells. Instead of undergoing ASCT, patients may receive Imbruvica with a combination of medicines containing rituximab, chemotherapy and corticosteroids, alternating with another medicine combination containing rituximab, chemotherapy and corticosteroids without Imbruvica; they then receive Imbruvica alone.

Imbruvica is also used on its own in patients whose disease does not respond to or has come back after previous treatment.

Chronic lymphocytic leukaemia (CLL)

Imbruvica is used in both previously treated and untreated patients with CLL; in previously treated patients with CLL it can be taken on its own but can also be taken with bendamustine and rituximab. In previously untreated patients, it can be taken on its own but can also be taken with rituximab or obinutuzumab or venetoclax.

Waldenström's macroglobulinaemia (also known as lymphoplasmacytic lymphoma)

For patients with Waldenström's macroglobulinaemia, Imbruvica is taken on its own or with rituximab.

Imbruvica contains the active substance ibrutinib.

How is Imbruvica used?

Imbruvica can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in using cancer medicines.

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Imbruvica is available as capsules and tablets to be taken by mouth once a day.

How long and how often Imbruvica is taken depends on the cancer being treated and whether it is used alone or in combination with other medicines.

If the patient is taking other medicines that may interact with Imbruvica or gets severe side effects, the doctor may lower the dose or interrupt treatment.

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

How does Imbruvica work?

The active substance in Imbruvica, ibrutinib, works against cancerous B lymphocytes, a type of white blood cells. It does this by blocking an enzyme called Bruton's tyrosine kinase (Btk), which helps B lymphocytes survive and migrate to organs where they normally multiply. By blocking Btk, ibrutinib reduces the survival and migration of B lymphocytes, thereby delaying progression of the cancer.

What benefits of Imbruvica have been shown in studies?

Mantle cell lymphoma not treated before

In a study involving 870 patients with previously untreated MCL who could receive ASCT, patients were split in 3 groups. The first 2 groups received Imbruvica with or without ASCT:

- in group 1, patients received Imbruvica with a combination of medicines containing rituximab, chemotherapy and corticosteroids called R-CHOP, alternating with another medicine combination containing rituximab, chemotherapy and corticosteroids called R-DHAP, without Imbruvica, for a total of six 21-day cycles; this was followed by 2 years of daily treatment with Imbruvica;
- patients in group 2 received the same treatments as those in group 1 but they also underwent ASCT before the 2-year-long treatment with Imbruvica.

The third group did not receive Imbruvica but underwent ASCT: patients received alternately the R-CHOP and R-DHAP combinations for a total of six 21-day cycles; this was followed by ASCT.

After an average of 55 months of follow up, about 23% of patients in the first group (61 out of 268) had either died or their disease got worse or stabilised (did not improve) compared with 32% of patients in the third group (87 out of 269). Results from the second group were similar to those from the first group, indicating no additional benefit when ASCT was added to Imbruvica compared with Imbruvica treatment without ASCT.

Mantle cell lymphoma treated before

In a study in 111 patients with mantle cell lymphoma that did not respond to or had come back after previous treatment, 21% of patients taking Imbruvica had a complete response and 47% had a partial response (decrease in tumour size). The average duration of response to treatment was 17.5 months.

A second study in 280 such patients compared Imbruvica with another cancer medicine, temsirolimus. The average time patients lived without their disease getting worse was 15 months with Imbruvica, compared with 6 months with temsirolimus.

Chronic lymphocytic leukaemia

In one study involving 391 patients whose disease did not respond to or had come back after previous treatment, 66% of patients receiving Imbruvica were still alive after one year with their disease not having progressed compared with around 6% of patients receiving another cancer medicine, ofatumumab.

In a study involving 269 patients who had not been treated before, around 90% of patients receiving Imbruvica were still alive with their disease not having progressed after 1.5 years of treatment compared with around 52% of patients receiving a cancer medicine called chlorambucil.

In a study involving 578 patients whose disease had not responded to or had come back after previous treatment, death or signs that the cancer was progressing occurred in 19% of patients who took Imbruvica together with the cancer medicines bendamustine and rituximab compared with 63% in those who took bendamustine and rituximab without Imbruvica.

In a study involving 229 previously untreated patients, after 31 months, 79% of patients treated with Imbruvica and obinutuzumab were alive with their disease not having progressed compared with 36% of patients who took chlorambucil and obinutuzumab.

In another study involving 529 previously untreated patients, after 3 years around 12% of patients treated with Imbruvica and rituximab had a worsening of their disease or died compared with 25% of those treated with chemotherapy plus rituximab.

In a study involving 211 previously untreated patients, after 28 months, death or signs that the cancer was progressing occurred in 21% of patients who received Imbruvica with venetoclax compared with 64% of patients given chlorambucil and obinutuzumab.

Another study involving 159 previously untreated patients showed that 55% of patients treated with Imbruvica plus venetoclax had a complete response (no detectable signs of cancer).

Waldenström's macroglobulinaemia

In one main study involving 63 patients who had previously received another treatment for Waldenström's macroglobulinaemia, the disease responded to treatment with Imbruvica in 87% of patients. Response to treatment was measured as a reduction in the blood levels of the protein IgM, which is present in high levels in patients with Waldenström's disease.

In a study involving 150 patients with Waldenström's macroglobulinaemia, after 26 months, death or signs that the cancer was progressing occurred in 19% of patients who took Imbruvica together with rituximab compared with 56% of patients who took only rituximab.

What are the risks associated with Imbruvica?

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

The most common side effects with Imbruvica (which may affect more than 1 in 5 people) include diarrhoea, neutropenia (low levels of neutrophils, a type of white blood cell), pain in muscles and bones, haemorrhage (bleeding), rash, nausea (feeling sick), joint pain, nose and throat infections, and thrombocytopenia (low blood platelet counts).

The most serious side effects (which may affect more than 1 in 20 people) include neutropenia, thrombocytopenia, lymphocytosis (high levels of white blood cells known as lymphocytes), high blood pressure and pneumonia (lung infection).

St. John's wort (a herbal remedy used for depression and anxiety) must not be used in patients treated with Imbruvica.

Why is Imbruvica authorised in the EU?

Imbruvica was effective in patients with mantle cell lymphoma that did not respond to or had come back after previous treatment, a group of patients with poor prognosis and few other treatment options. In patients with previously untreated mantle cell lymphoma, Imbruvica was shown to benefit patients when used with combination therapies containing rituximab, chemotherapy and corticosteroids, and may therefore replace ASCT. Imbruvica was also shown to be effective at delaying progression of chronic lymphocytic leukaemia, both in untreated patients and in those who had received treatment previously. In addition, Imbruvica was shown to be effective in patients with Waldenström's macroglobulinaemia. The side effects of the medicine were considered acceptable.

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

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

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

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

Other information about Imbruvica

Imbruvica received a marketing authorisation valid throughout the EU on 21 October 2014.

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

This overview was last updated in 07-2025.