EMA/694589/2020
EMEA/H/C/005026

# Inrebic (*fedratinib*)

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

## What is Inrebic and what is it used for?

Inrebic is a medicine used to treat adults with myelofibrosis (a rare form of blood cancer) who have enlarged spleen or other symptoms related to the disease.

Inrebic can be used in three types of the disease: primary myelofibrosis (also known as chronic idiopathic myelofibrosis, where the cause is unknown), post-polycythaemia vera myelofibrosis (where the disease is linked to an overproduction of red blood cells) and post-essential thrombocythaemia myelofibrosis (where the disease is linked to an overproduction of platelets, components that help the blood to clot).

Inrebic is used both in patients who have not been treated with medicines known as Janus kinase (JAK) inhibitors before and in those who have been treated with the JAK inhibitor ruxolitinib.

These diseases are rare, and Inrebic was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the European Medicines Agency's website (primary myelofibrosis: 1 October 2010; post-polycythaemia vera myelofibrosis: 26 November 2010; post-essential thrombocythaemia myelofibrosis: 26 November 2010).

Inrebic contains the active substance fedratinib.

## How is Inrebic used?

The medicine can only be obtained with a prescription. Treatment with Inrebic should be started and supervised by doctors experienced in the use of cancer medicines.

Inrebic is available as capsules; the recommended dose is 400 mg once daily. Patients may also be given other medicines to stop them feeling sick or vomiting.

Treatment should continue for as long as the patient benefits from it. The doctor may reduce the dose, interrupt treatment or stop it altogether if the patient has certain side effects.

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

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## How does Inrebic work?

The active substance in Inrebic, fedratinib, works by blocking an enzyme known as JAK2, which is involved in the production and growth of blood cells. In myelofibrosis, there is too much JAK activity, leading to the abnormal production of blood cells. These blood cells migrate to organs, including the spleen, causing them to become enlarged. By blocking JAK2, Inrebic reduces the abnormal production of blood cells, thereby reducing symptoms of the disease.

## What benefits of Inrebic have been shown in studies?

In 2 main studies in patients with myelofibrosis, Inrebic was effective at reducing the size of patients' spleen.

In the first study, in patients with myelofibrosis who had not been treated with a JAK inhibitor before, 36% of patients (35 out of 97) given Inrebic had at least a 35% reduction in spleen size measured by a scan, compared with 1% (1 out of 96) of patients who received placebo. In this study, 40% of patients (36 out of 89) given Inrebic had at least 50% reduction in symptoms, measured using a myelofibrosis symptom rating scale, compared with 9% (7 out of 81) of patients who received placebo.

A second study involved patients with myelofibrosis who had already been treated with the JAK inhibitor ruxolitinib; for most of them, ruxolitinib treatment had not worked or could not be continued due to side effects, or the disease had come back. In this study, about 23% of patients (22 out of 97) receiving Inrebic 400 mg once daily had at least 35% reduction in spleen size.

## What are the risks associated with Inrebic?

The most common side effects with Inrebic (which may affect more than 1 in 10 people) are diarrhoea, nausea (feeling sick), vomiting, anaemia (low red blood cell counts) and thrombocytopenia (low blood platelet counts). The most common serious side effects (which may affect up to 1 in 10 people) are anaemia and diarrhoea.

Inrebic must not be used by pregnant women. For the full list of side effects and restrictions of Inrebic, see the package leaflet.

## Why is Inrebic authorised in the EU?

Inrebic has been shown to reduce spleen size in patients with myelofibrosis who had not been treated with JAK inhibitors before and in those who had previously been treated with ruxolitinib. Reduction in spleen size and associated symptoms is considered of major clinical relevance for patients with myelofibrosis. In terms of safety, side effects of Inrebic are considered manageable.

The European Medicines Agency therefore decided that Inrebic'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 Inrebic?

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

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

## Other information about Inrebic

Inrebic received a marketing authorisation valid throughout the EU on 8 February 2021.

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

This overview was last updated in 02-2021.