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EPAR summary for the public

Sprycel

dasatinib

This document is a summary of the European public assessment report (EPAR) for Sprycel. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Sprycel.

What is Sprycel?

Sprycel is a medicine that contains the active substance dasatinib. It is available as tablets (20, 50, 70, 80, 100 and 140 mg).

What is Sprycel used for?

Sprycel is an anticancer medicine. It is used to treat adults with the following types of leukaemia (cancer of the white blood cells):

- chronic myeloid leukaemia (CML) in the 'chronic' phase in newly diagnosed patients who are 'Philadelphia chromosome positive' (Ph+). CML is a leukaemia where granulocytes (a type of white blood cell) start growing out of control. Ph+ means that some of the patient's genes have rearranged themselves to form a special chromosome called the Philadelphia chromosome which produces an enzyme, Bcr-Abl kinase, that leads to the development of leukaemia.
- CML in 'chronic', 'accelerated' and 'blast' phases. Sprycel is used when patients cannot tolerate, or when their disease is not responding to, other treatments including imatinib (another anticancer medicine);
- Ph+ acute lymphoblastic leukaemia (ALL), where lymphocytes (another type of white blood cell) multiply too quickly, or in 'lymphoid blast' CML. Sprycel is used when patients cannot tolerate, or when their disease is not responding to, other treatments.

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Because the number of patients with CML and ALL is low, the diseases are considered ‘rare’, and Sprycel was designated an ‘orphan medicine’ (a medicine used in rare diseases) on 23 December 2005.

The medicine can only be obtained with a prescription.

How is Sprycel used?

Treatment with Sprycel should be started by a doctor who has experience in the diagnosis and treatment of leukaemia.

Sprycel is taken once a day, consistently either in the morning or in the evening. For chronic phase CML, the starting dose is 100 mg. For advanced (accelerated or blast) phase CML and for Ph+ ALL, it is 140 mg. The dose can be increased or decreased on the basis of the patient’s response to the medicine. Treatment is continued until either the disease gets worse or until the patient cannot tolerate the medicine any longer. Patients must be monitored during treatment to check their blood levels of platelets (components that help the blood to clot) and neutrophils (the white blood cells that fight infection). Doctors may recommend a lower dose or a break from treatment if these values change or if patients have certain side effects. Sprycel tablets must be swallowed whole. See the summary of product characteristics (also part of the EPAR) for full details.

How does Sprycel work?

The active substance in Sprycel, dasatinib, belongs to a group of medicines called ‘protein kinase inhibitors’. These compounds act by blocking types of enzymes known as protein kinases. Dasatinib acts mainly by blocking the Bcr-Abl protein kinase. This enzyme is produced by leukaemia cells, and causes them to multiply uncontrollably. By blocking Bcr-Abl kinase, as well as other kinases, Sprycel helps to control the spread of leukaemia cells.

How has Sprycel been studied?

The five main studies of Sprycel, taken twice a day, involved 515 patients, all of whom had received prior treatment with imatinib and had either failed to respond or become resistant to it. None of these studies included a head-to-head comparison of Sprycel with any other medicine. Two studies were carried out in chronic CML (198 and 36 patients), one was in accelerated CML (120 patients), one was in myeloid blast CML (80 patients), and one was in Ph+ ALL and lymphoid blast CML (81 patients).

Two further studies compared the effects of Sprycel taken once or twice a day, one in 670 patients with chronic phase CML and the other in 611 patients with advanced phase CML or Ph+ ALL.

All of the studies assessed the patients’ responses by measuring the levels of white cells and platelets in the blood, to see if they were returning to normal, and by measuring the number of white blood cells that contained the Philadelphia chromosome, to see if it was decreasing.

A further study involving 519 patients compared Sprycel with imatinib in treating newly diagnosed Ph+ patients with chronic phase CML who had not received any previous treatment. The main measure of effectiveness was the number of patients whose blood cells no longer contained the Philadelphia chromosome within one year of treatment.

What benefit has Sprycel shown during the studies?

In the larger main study of patients with chronic phase CML, 90% of the patients responded to treatment, with blood levels of platelets and white blood cells returning to within predefined, normal

values. In patients with CML in other phases (accelerated, myeloid blast and lymphoid blast) and in ALL, between a quarter and a third of the patients showed a complete response. In addition, between one and two thirds of the patients in the five main trials showed a reduction in the number of white blood cells containing the Philadelphia chromosome. In the additional studies, once- and twice-daily Sprycel had similar rates of effectiveness, but the once-daily dose caused fewer side effects.

In the study on newly diagnosed Ph+ patients with chronic phase CML, Sprycel was more effective than imatinib: within one year, 77% of patients receiving Sprycel no longer had the Philadelphia chromosome in their blood cells, compared with 66% of patients receiving imatinib.

What is the risk associated with Sprycel?

In studies, the most common side effects with Sprycel (seen in more than 1 patient in 10) were infection, suppression of the bone marrow (decreasing numbers of blood cells), headache, haemorrhage (bleeding), pleural effusion (fluid around the lungs), dyspnoea (difficulty breathing),, diarrhoea, vomiting, nausea (feeling sick), abdominal pain (stomach ache), skin rash, musculoskeletal pain, fatigue (tiredness), swelling in the extremities and the face, pyrexia (fever), neutropenia (low levels of neutrophils), thrombocytopenia (low blood platelet counts) and anaemia (low red blood cell counts). For the full list of all side effects and restrictions with Sprycel, see the package leaflet.

Why has Sprycel been approved?

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

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

A risk management plan has been developed to ensure that Sprycel is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Sprycel, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Sprycel:

The European Commission granted a marketing authorisation valid throughout the European Union for Sprycel on 20 November 2006.

The summaries of opinion of the Committee for Orphan Medicinal Products for Sprycel can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/Rare disease designation:

- CML;
- ALL.

The full EPAR for Sprycel 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 Sprycel, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.