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Sprycel (*dasatinib*)

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

What is Sprycel and what is it 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.

Sprycel is also used to treat children who have newly diagnosed Ph+ CML in the 'chronic' phase, or who have Ph+ CML and cannot be given treatment including imatinib or whose disease has not responded to such treatment.

Sprycel contains the active substance dasatinib.

How is Sprycel used?

Sprycel can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of leukaemia.

Sprycel is available as tablets (20, 50, 70, 80, 100 and 140 mg) and a powder to make up a suspension (10 mg/ml) to be taken by mouth. It is taken once a day, consistently either in the morning or in the evening. For chronic phase CML, the starting dose in adults is 100 mg. For adult advanced (accelerated or blast) phase CML and for Ph+ ALL, it is 140 mg. The starting dose for children with chronic phase CML is based on their body weight and on whether the dose is given as the tablets or the suspension, which have different doses. The dose can be increased or decreased on the

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

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 reduce the number of leukaemia cells.

What benefits of Sprycel have been shown in studies?

The five main studies of Sprycel in adults, 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).

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.

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. Once- and twice-daily Sprycel had similar rates of effectiveness, but the once-daily dose caused fewer side effects.

Another main study looked at the effectiveness of Sprycel in 113 children with Ph+ chronic phase CML, including 29 patients who could not use or had not responded to imatinib as well as 84 newly diagnosed children who had not been previously treated. A response was seen in around 90% of patients who could not use or did not respond to imatinib, and in 94% of newly diagnosed patients.

All of these 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. 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 are the risks 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 side effects and restrictions with Sprycel, see the package leaflet.

Why is Sprycel authorised in the EU?

The European Medicines Agency decided that Sprycel'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 Sprycel?

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

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

Other information about Sprycel

Sprycel received a marketing authorisation valid throughout the European Union on 20 November 2006.

Further information on Sprycel can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 06-2018.