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EPAR summary for the public

Onsenal

celecoxib

This document is a summary of the European Public Assessment Report (EPAR) for Onsenal. 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 Onsenal.

What is Onsenal?

Onsenal is a medicine that contains the active substance celecoxib. It is available as white capsules (200 and 400 mg).

What is Onsenal used for?

Onsenal is used to reduce the number of polyps in patients with familial adenomatous polyposis (FAP). This is a genetic disease that causes 'adenomatous intestinal polyps', growths that project from the lining of the colon or rectum (large intestine). Onsenal is used in addition to surgery (to remove the polyps) and endoscopic monitoring (to check if polyps are developing, using an endoscope, a thin tube that allows a doctor to look inside the gut).

Because the number of patients with FAP is low, the disease is considered 'rare', and Onsenal was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 November 2001.

The medicine can only be obtained with a prescription.

How is Onsenal used?

The recommended dose of Onsenal is 400 mg twice a day with food. The usual medical care for FAP patients should be continued.

In patients with moderate liver disease, the dose of Onsenal should be halved. Onsenal must not be given to patients with severe liver or kidney problems. A lower starting dose may be needed in

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patients whose bodies may break Onsenal down slowly. The maximum recommended daily dose of Onsenal is 800 mg.

How does Onsenal work?

The active substance in Onsenal, celecoxib, is a 'non-steroidal anti-inflammatory drug' (NSAID) that belongs to the group 'cyclo-oxygenase 2 (COX-2) inhibitors'. It blocks the COX-2 enzyme, resulting in a reduction in the production of prostaglandins, substances that are involved in processes such as inflammation and the activity of smooth muscle (muscle that performs automatic tasks such as the opening and closing of blood vessels). COX-2 is found at high levels in adenomatous colorectal polyps. By blocking the activity of COX-2, celecoxib helps to slow down the formation of polyps by stopping them developing their own blood supply and by increasing the rate of cell death.

How has Onsenal been studied?

Onsenal has been studied in one main study involving 83 adults (aged 18 years or over) with FAP, in which two doses of Onsenal were compared with placebo (a dummy treatment). In the study, 25 patients had an intact colon, but the remainder had had some or all of their colon removed through surgery. The main measure of effectiveness was the reduction in the number of polyps in a defined area of the colon or rectum wall after six months of treatment. An additional study looked at the effects of Onsenal in 18 patients aged 10 to 14 years with FAP.

What benefit has Onsenal shown during the studies?

Onsenal at a dose of 400 mg twice a day was more effective than placebo. In adults, Onsenal had reduced the average number of polyps by 28% after six months, while the number had fallen by 5% in the patients taking placebo. Onsenal also reduced the number of polyps in patients aged 10 to 14 years with FAP.

What is the risk associated with Onsenal?

The most common side effects with Onsenal (seen in more than 1 patient in 10) are hypertension (high blood pressure) and diarrhoea. For the full list of all side effects reported with Onsenal, see the Package Leaflet.

Onsenal should not be used in people who may be hypersensitive (allergic) to celecoxib, to any of the other ingredients, or to sulphonamides (such as some antibiotics). It must not be used in patients who have an active ulcer or bleeding in the stomach or gut, or in patients who have had allergic-type reactions after taking aspirin or an NSAID, including another COX-2 inhibitor. Onsenal must not be given to pregnant women or women who could become pregnant unless they are using an effective method of contraception, or to women who are breast-feeding. It must not be given to patients with severe liver or kidney disease, patients with a disease causing inflammation of the bowel, or patients with certain problems affecting the heart or blood vessels. For the full list of restrictions, see the Package Leaflet.

Why has Onsenal been approved?

The CHMP decided that Onsenal's benefits are greater than its risks but noted that no effect of Onsenal on the risk of developing cancer of the intestine had been shown. The Committee recommended that Onsenal be given marketing authorisation.

Onsenal has been authorised under 'exceptional circumstances'. This means that because the disease is rare, it has not been possible to obtain complete information about Onsenal. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Onsenal?

The company that makes Onsenal has committed to carrying out a study in patients with FAP, in order to collect more information on the medicine's safety and effectiveness. The company will submit a progress report on the study, including all safety information and details of how it is ensuring that patients are being recruited quickly enough. The company will also submit a full report on the study once it has finished.

Other information about Onsenal:

The European Commission granted a marketing authorisation valid throughout the European Union for Onsenal on 17 October 2003. The marketing authorisation holder is Pfizer Limited. After five years, the marketing authorisation was renewed for a further five years.

The full EPAR for Onsenal can be found here. For more information about treatment with Onsenal, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Onsenal is available here.

This summary was last updated in 05-2010.