EMA/902533/2022
EMEA/H/C/000175

Iscover (*clopidogrel*)

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

What is Iscover and what is it used for?

Iscover is a medicine used to prevent problems caused by blood clots in adults who have:

- recently had a myocardial infarction (heart attack). Iscover can be started between a few days and 35 days after the attack;
- recently had an ischaemic stroke (stroke caused by failure of the blood supply to part of the brain). Iscover can be started between seven days and six months after the stroke;
- peripheral arterial disease (problems with blood flow in the arteries);
- a condition known as 'acute coronary syndrome', when it should be given with acetylsalicylic acid (also known as aspirin). Acute coronary syndrome is a group of heart problems that includes heart attacks and unstable angina (a severe type of chest pain).
  Some of these patients may be undergoing percutaneous coronary intervention (a procedure that unblocks blood vessels of the heart to restore its blood supply) and may have had a stent inserted (a short tube in an artery to prevent it closing up). Others may benefit from thrombolytic or fibrinolytic treatment (treatments to dissolve blood clots).
- atrial fibrillation (irregular rapid contractions of the upper chambers of the heart), when it should be given with acetylsalicylic acid. It is used in those patients who have at least one risk factor for vascular events such as a heart attack or stroke, cannot take vitamin K antagonists (other medicines that prevent blood clots) and are at low risk of bleeding.

Iscover contains the active substance clopidogrel.

How is Iscover used?

Iscover is available as tablets and can only be obtained with a prescription.

Iscover is taken once a day as a 75 mg tablet. Use of a loading dose (an initial higher dose) and the duration of treatment depend on the age of the patient and the disease being treated. For patients undergoing a percutaneous coronary intervention or eligible for thrombolytic or fibrinolytic therapy, treatment should start as early as possible after start of symptoms.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

How does Iscover work?

The active substance in Iscover, clopidogrel, is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. Blood clots are caused by cells in the blood called platelets sticking together. Clopidogrel stops the platelets sticking together by blocking a substance called ADP from attaching to a receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent another heart attack or stroke.

What benefits of Iscover have been shown in studies?

Iscover was more effective than acetylsalicylic acid at preventing new ischaemic events. In a study in around 19,000 patients who had recently had a heart attack or an ischaemic stroke, or who had established peripheral artery disease, 939 patients who were given Iscover experienced a new ischemic event (heart attack, ischaemic stroke or death) over a period of one to three years, compared with 1,020 patients who were given acetylsalicylic acid. This corresponds to a relative reduction in risk of 9% compared with acetylsalicylic acid and means that fewer patients will have new ischaemic events if they receive Iscover than if they receive acetylsalicylic acid.

In three studies involving over 61,000 patients with non-ST segment elevation acute coronary syndrome, 2,172 of whom had a stent inserted during the study, Iscover was given in combination with acetylsalicylic acid and compared with placebo (a dummy treatment). In these studies, which differed in duration from up to 8 days to up to one year, the overall relative risk of an event such as a blocked artery, another heart attack or death, was reduced by 20% when patients were given Iscover and acetylsalicylic acid compared with placebo. There was also a reduction in the patients who had a stent inserted. In 2 studies in 49,000 patients with ST segment elevation myocardial infarction, fewer patients on Iscover had events than patients on placebo (262 against 377 in the CLARITY study, and 2,121 against 2,310 in the COMMIT study).

In a study in around 7,500 patients with atrial fibrillation who had at least one risk factor for vascular events and who could not take vitamin K antagonist therapy, patients were given Iscover together with acetylsalicylic acid or placebo for an average of three years. In this study, Iscover plus acetylsalicylic acid reduced the risk of new events by 11% compared with placebo taken with acetylsalicylic acid, with the largest reduction (28%) seen for stroke.

Study results published in medical journals showed that Iscover was effective for up to 12 months at reducing the occurrence of heart attack, stroke or death in patients treated for heart attack with ST-segment elevation who are having a percutaneous coronary intervention.

What are the risks associated with Iscover?

Bleeding reactions are the most common side effects reported with Iscover. The most common of these (which may affect up to 1 in 10 people) are haematoma (a collection of blood under the skin), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), bruising and bleeding where the skin is punctured.

Other side effects (which may affect up to 1 in 10 people) are diarrhoea, abdominal pain (stomach ache) and dyspepsia (heartburn).

For the full list of side effects of Iscover, see the package leaflet.

Iscover must not be used in people who may be hypersensitive (allergic) to clopidogrel or any of the other ingredients. It must not be used in patients who have severe liver disease or a disease that may cause bleeding such as a stomach ulcer or bleeding in the brain.

Why is Iscover authorised in the EU?

The European Medicines Agency decided that Iscover'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 Iscover?

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

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

Other information about Iscover

Iscover received a marketing authorisation valid throughout the EU on 14 July 1998.

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

This summary was last updated in 12-2022.