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Clopidogrel Zentiva[1] *(clopidogrel)*

An overview of Clopidogrel Zentiva and why it is authorised in the EU

What is Clopidogrel Zentiva and what is it used for?

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

- recently had a myocardial infarction (heart attack). Clopidogrel Zentiva 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). Clopidogrel Zentiva 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 (another medicine that prevents blood clots). Acute coronary syndrome is a group of heart problems that include severe heart attacks (known as ST-elevation myocardial infarction) 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 placed 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.

Clopidogrel Zentiva contains the active substance clopidogrel.

How is Clopidogrel Zentiva used?

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

Clopidogrel Zentiva is taken once a day . Use of a loading dose (an initial higher dose) and the duration of treatment depend on the age of the patient and the condition 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.

[1] Previously known as Clopidogrel Winthrop

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 Clopidogrel Zentiva, see the package leaflet or contact your doctor or pharmacist.

How does Clopidogrel Zentiva work?

The active substance in Clopidogrel Zentiva, 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 Clopidogrel Zentiva have been shown in studies?

Clopidogrel Zentiva 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 Clopidogrel Zentiva 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 Clopidogrel Zentiva than if they receive acetylsalicylic acid.

In three studies involving over 61,000 patients with unstable angina, 2,172 of whom had a stent inserted during the study, Clopidogrel Zentiva 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 Clopidogrel Zentiva 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 Clopidogrel Zentiva 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 Clopidogrel Zentiva together with acetylsalicylic acid or placebo for an average of three years. In this study, Clopidogrel Zentiva 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 Clopidogrel Zentiva was effective for up to 12 months at reducing the occurrence of heart attack, stroke or death in patients treated for ST-elevation myocardial infarction who are having a percutaneous coronary intervention.

What is the risk associated with Clopidogrel Zentiva?

For the full list of side effects and restrictions with Clopidogrel Zentiva, see the package leaflet.

Bleeding reactions are the most common side effects reported with Clopidogrel Zentiva. The most common of these (which may affect up to 1 in 10 people) include 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) include diarrhoea, abdominal pain (belly pain) and dyspepsia (heartburn).

Clopidogrel Zentiva 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 Clopidogrel Zentiva authorised in the EU?

The European Medicines Agency decided that Clopidogrel Zentiva's benefits are greater than its risks and recommended that it be authorised for use in the EU.

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

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

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

Other information about Clopidogrel Zentiva

Clopidogrel Zentiva received a marketing authorisation valid throughout the EU on 16 July 2008. This authorisation was based on the authorisation granted to Plavix in 1998 ('informed consent'). The name of the medicine was changed to Clopidogrel Zentiva on 23 August 2011.

Further information on Clopidogrel Zentiva can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/clopidogrel-zentiva

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