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EPAR summary for the public

DuoPlavin

clopidogrel and acetylsalicylic acid

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

What is DuoPlavin?

DuoPlavin is a medicine that contains two active substances, clopidogrel and acetylsalicylic acid (also known as aspirin). It is available as oval tablets containing 75 mg clopidogrel, either with 75 mg (yellow) or 100 mg acetylsalicylic acid (pink).

What is DuoPlavin used for?

DuoPlavin is used to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries), such as a heart attack, in adults who are already taking both clopidogrel and acetylsalicylic acid. It can be used in the following groups of patients who have a condition known as 'acute coronary syndrome':

- patients who are having 'unstable angina' (a severe type of chest pain) or a myocardial infarction (heart attack) with no 'ST-segment elevation' (an abnormal reading on the ECG or electrocardiogram), including in patients having a stent (a short tube) inserted into an artery to prevent it from closing up;
- patients being treated for heart attack with ST-segment elevation, when the doctor thinks that they would benefit from thrombolytic treatment (treatment to dissolve blood clots).

The medicine can only be obtained with a prescription.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How is DuoPlavin used?

DuoPlavin is taken as one tablet once a day in place of the clopidogrel and acetylsalicylic acid tablets that the patient has already been taking separately.

How does DuoPlavin work?

Both active substances in DuoPlavin, clopidogrel and acetylsalicylic acid, are 'inhibitors of platelet aggregation'. This means that they help to prevent cells in the blood called platelets from aggregating (sticking together) and forming clots. Clopidogrel stops the platelets aggregating by blocking a substance called ADP from attaching to a special receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming. Acetylsalicylic acid stops the platelets aggregating by blocking an enzyme called prostaglandin cyclo oxygenase. This reduces the production of a substance called thromboxane, which normally helps clots to form by binding platelets together. When taken together, the two active substances can reduce the risk of problems due to blood clots forming, helping to prevent another heart attack.

Both active substances have been available in the European Union (EU) for a number of years. Clopidogrel has been authorised as Plavix and Iscover since 1998 for reducing platelet aggregation, and is often used in combination with acetylsalicylic acid. Acetylsalicylic acid has been available for over 100 years.

How has DuoPlavin been studied?

Because the two active substances have been used together for a number of years, the company presented the results of studies showing that the active substances in DuoPlavin are absorbed in the body in the same way as the two medicines taken separately. It also presented the results of previous studies involving over 60,000 patients with acute coronary syndrome, which showed that the combination of clopidogrel and acetylsalicylic acid taken as separate tablets was effective at preventing atherothrombotic events such as heart attacks.

What benefit has DuoPlavin shown during the studies?

DuoPlavin was shown to be comparable to clopidogrel and acetylsalicylic acid taken separately, and can therefore be used in place of the clopidogrel and acetylsalicylic acid tablets that the patients have already been taking.

What is the risk associated with DuoPlavin?

The most common side effects with DuoPlavin (seen in between 1 and 10 patients in 100) are haematoma (a collection of blood under the skin), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), diarrhoea, abdominal pain (stomach ache), dyspepsia (heartburn), bruising, and bleeding where the skin is punctured. For the full list of all side effects reported with DuoPlavin, see the Package Leaflet.

DuoPlavin should not be used in people who may be hypersensitive (allergic) to clopidogrel, non steroidal anti-inflammatory drugs (such as acetylsalicylic acid) or any of the other ingredients in DuoPlavin. It must not be used in patients who have a disease that is causing bleeding, such as stomach ulcer or bleeding in the brain. It must not be used in patients who have severe liver or kidney problems, or who have a medical condition that includes a combination of asthma, rhinitis (stuffy and runny nose) and nasal polyps (growths in the lining of the nose). DuoPlavin must not be used during the last three months of pregnancy.

Why has DuoPlavin been approved?

The Committee for Medicinal Products for Human Use (CHMP) noted that DuoPlavin is comparable to clopidogrel and acetylsalicylic acid tablets taken separately, and concluded that combining both active substances in a single DuoPlavin tablet simplifies treatment for patients as they will need to take fewer tablets. The Committee therefore decided that DuoPlavin's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about DuoPlavin:

The European Commission granted a marketing authorisation valid throughout the EU for DuoPlavin to Sanofi Pharma Bristol Myers Squibb SNC on 15 March 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for DuoPlavin can be found here. For more information about treatment with DuoPlavin, read the Package Leaflet (also part of the EPAR).

This summary was last updated in 01-2010.