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EPAR summary for the public

DuoPlavin

clopidogrel / 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 tablets containing 75 mg clopidogrel, either with 75 mg or 100 mg acetylsalicylic acid.

What is DuoPlavin used for?

DuoPlavin is used to prevent 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 as separate tablets. It can be used in the following groups of patients who have a condition known as 'acute coronary syndrome':

- patients who have 'unstable angina' (a severe type of chest pain) or who have had a heart attack with no 'ST-segment elevation' (an abnormal reading on the ECG or electrocardiogram), including those who are 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.

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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 antiplatelet medicines. This means that they help to prevent blood cells called platelets from sticking together and forming clots, thus helping to prevent another heart attack.

Clopidogrel stops the platelets sticking together 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 sticking together by blocking an enzyme called prostaglandin cyclo-oxygenase. This reduces the production of a substance called thromboxane, which normally helps clots to form by attaching platelets together. The combination of the two active substances has an additive effect, reducing the risk of blood clots forming, more than either medicine alone.

Both active substances have been available in the European Union (EU) for a number of years. Clopidogrel has been authorised 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 when taken in a single tablet as when the two medicines are taken separately. It also presented the results of 3 previous studies involving over 61,000 patients with unstable angina or who had had a heart attack.

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.

Results from the 3 studies in patients with unstable angina or who had had a heart attack showed that the combination of clopidogrel and acetylsalicylic acid taken as separate tablets was more effective at preventing events such as heart attacks than acetylsalicylic acid alone.

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 must not be used in people who are 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 or in patients with mastocytosis (high blood levels of certain white blood cells called mast cells). It must not be used in patients who have severely reduced liver or kidney function, 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 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 on 15 March 2010.

The full EPAR for DuoPlavin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with DuoPlavin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.