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DuoPlavin (*clopidogrel / acetylsalicylic acid*)

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

What is DuoPlavin and what is it used for?

DuoPlavin is a medicine used to prevent problems caused by blood clots and hardening of the arteries, such as a myocardial infarction (heart attack), in adults who are already taking both clopidogrel and acetylsalicylic acid (also known as aspirin) 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 in an artery to prevent it closing up) inserted as part of a percutaneous coronary intervention (a procedure that unblocks blood vessels of the heart to restore its blood supply);
- patients being treated for heart attack with ST-segment elevation who are having a percutaneous coronary intervention or for whom the doctor thinks that they would benefit from thrombolytic or fibrinolytic treatment (treatments to dissolve blood clots).

DuoPlavin contains the active substances clopidogrel and acetylsalicylic acid.

How is DuoPlavin used?

DuoPlavin is available as a tablet and can only be obtained with a prescription.

DuoPlavin is taken once a day as one tablet containing 75 mg clopidogrel and either 75 mg or 100 mg acetylsalicylic acid and is taken in place of the clopidogrel and acetylsalicylic acid tablets that the patient has already been taking separately. The medicine can be taken for up to 12 months.

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

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 heart problems, such as heart attack.

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

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

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 EU for a number of years. Clopidogrel has been authorised since 1998 and is often used in combination with acetylsalicylic acid. Acetylsalicylic acid has been used for over 100 years.

What benefits of DuoPlavin have been shown in the studies?

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 taken separately.

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.

In addition, the company presented the results from 3 previous studies in 61,000 patients with unstable angina or who had had a heart attack, which 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.

A further study also showed that DuoPlavin was effective at reducing the occurrence of heart attack, stroke or death in patients undergoing percutaneous coronary intervention.

What are the risks associated with DuoPlavin?

Bleeding reactions are the most common side effects reported with DuoPlavin. The most common of these (which may affect up to 1 and 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 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 is DuoPlavin authorised in the EU?

The European Medicines Agency noted that DuoPlavin is comparable to clopidogrel and acetylsalicylic acid tablets taken separately, and concluded that combining both active substances in a single tablet

simplifies treatment for patients as they will need to take fewer tablets. The Agency therefore decided that DuoPlavin'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 DuoPlavin?

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

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

Other information about DuoPlavin:

DuoPlavin received a marketing authorisation valid throughout the EU on 14 March 2010.

Further information on DuoPlavin can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/duoplavin-0

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