



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Clopidogrel/Acetylsalicylic acid Teva

## clopidogrel / acetylsalicylic acid

This is a summary of the European public assessment report (EPAR) for Clopidogrel/Acetylsalicylic acid Teva. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Clopidogrel/Acetylsalicylic acid Teva.

For practical information about using Clopidogrel/Acetylsalicylic acid Teva, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Clopidogrel/Acetylsalicylic acid Teva and what is it used for?

Clopidogrel/Acetylsalicylic acid Teva is a blood thinning medicine that contains two active substances, clopidogrel and acetylsalicylic acid. It is used to prevent problems caused by blood clots, such as a heart attack, in adults who are already taking both clopidogrel and acetylsalicylic acid (known commonly 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 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 treatment to dissolve blood clots.

### How is Clopidogrel/Acetylsalicylic acid Teva used?

Clopidogrel/Acetylsalicylic acid Teva is available as tablets containing 75 mg clopidogrel, either with 75 mg or 100 mg acetylsalicylic acid. The medicine is taken as a single tablet daily in place of the clopidogrel and acetylsalicylic acid tablets that the patient has already been taking separately.

Clopidogrel/Acetylsalicylic acid Teva can only be obtained with a prescription.



## **How does Clopidogrel/Acetylsalicylic acid Teva work?**

Both active substances in Clopidogrel/Acetylsalicylic acid Teva, 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 binding 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.

## **What benefits of Clopidogrel/Acetylsalicylic acid Teva have been shown in 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 Clopidogrel/Acetylsalicylic acid Teva 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 in total over 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.

## **What are the risks associated with Clopidogrel/Acetylsalicylic acid Teva?**

The most common side effects with Clopidogrel/Acetylsalicylic acid Teva (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), 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 Clopidogrel/Acetylsalicylic acid Teva, see the package leaflet.

Clopidogrel/Acetylsalicylic acid Teva must not be used in people who are hypersensitive (allergic) to clopidogrel, non-steroidal anti-inflammatory drugs (NSAIDs, used to relieve pain and inflammation) such as acetylsalicylic acid, or any of the other ingredients in Clopidogrel/Acetylsalicylic acid Teva. 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). Clopidogrel/Acetylsalicylic acid Teva must not be used during the last three months of pregnancy.

## **Why is Clopidogrel/Acetylsalicylic acid Teva approved?**

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Clopidogrel/Acetylsalicylic acid Teva's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP noted that both active substances in Clopidogrel/Acetylsalicylic acid Teva have been used for several years to reduce the risk of heart attack and when taken together they can reduce the risk more than each component can alone. The Committee also considered that combining both active substances in a single tablet simplifies treatment for patients as they will need to take fewer tablets.

### **What measures are being taken to ensure the safe and effective use of Clopidogrel/Acetylsalicylic acid Teva?**

A risk management plan has been developed to ensure that Clopidogrel/Acetylsalicylic acid Teva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Clopidogrel/Acetylsalicylic acid Teva, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

### **Other information about Clopidogrel/Acetylsalicylic acid Teva**

The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel/Acetylsalicylic acid Teva on 01 September 2014.

The full EPAR and risk management plan summary for Clopidogrel/Acetylsalicylic acid Teva can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find medicine/Human medicines/European public assessment reports). For more information about treatment with Clopidogrel/Acetylsalicylic acid Teva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2014.