

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Hjercatyl is indicated for the treatment of acute and chronic heart disease (including myocardial infarction, stroke, angina, Coronary Artery Bypass Grafting (CABG) and coronary angioplasty) and for the prevention of thrombosis.

Myocardial Infarction (MI)

Each year the number of new heart attacks (or MI) that occur in the US is 600,000.¹ In Europe, a study from Denmark reported that about 20,414 new patients were diagnosed with MI in 1 year.² Overall, surveys show that 7% of the people in the US and 4.8% in Europe have had MI.³ The percentage of MI that result in death ranges from 7% to 13%.^{4,5,6} The risk of MI increases with age, smoking, diabetes, high cholesterol levels and high blood pressure.

Stroke

Stroke is a leading cause of death and disability in the US and Europe. Each year in the US, about 780,000 people experience new or recurrent stroke.¹ In a large study in Europe, new cases of stroke increased with age, and were reported more frequently in men in most of the age groups.⁷ Stroke causes 9% of all deaths around the world⁸ and in 2004, it was the third leading cause of death in the US. The risk of stroke increases with factors such as age, diabetes, and past history of cardiovascular disease.

Angina (stable or unstable)

Angina pectoris is a form of severe chest pain that is cardiac in nature and relates to a reduction of oxygen to the heart and could be due to obstruction of the coronary arteries. Overall in the US, angina is found in 3.3% of white men, 2.8% of white women, 2.4% of black men and 5.4% of black women.⁹ In Europe, the percentage of angina ranges from 3.57% in France to 4.12% in Italy.¹⁰ Similar to MI, the risk of angina increases with age, smoking, diabetes, high cholesterol and high blood pressure.

Coronary Artery Bypass Grafting (CABG) or Infra-inguinal bypass surgery

Coronary artery bypass grafting (CABG) is a type of surgery to treat people with severe heart disease.¹¹ Risk of heart disease increases with factors such as high blood pressure, diabetes, smoking and age.^{12,13} A study in Europe conducted within six countries found that 63% of cardiac patients had received CABG from September to November 1995.¹⁴ In 2010 in the US, about 0.4 million CABG were performed, of which 40% were in those aged 45-64 years and 60% were in those over 65 years of age.¹⁵ One study reported that the percentage of death in those who received CABG was 3% between 1999 to 2001 in California and 2% in New York.¹⁶ In a study from Scotland, death rate from CABG was 6.7% from 1997 to 1999.¹⁷

Infra-inguinal bypass surgery (IIBS) is used as treatment for patients with peripheral arterial disease, especially in those with obstruction to blood flow in the arteries leading to the legs.¹⁸ The risk of peripheral arterial disease increases with age, diabetes, smoking and high blood pressure.¹⁹ In Europe the number of IIBS performed per year between 2005 and 2009 ranged from 369 in Finland to 3,426

in Italy.²⁰ In the US a study done in private hospitals found that IIBS was performed more among whites (68% of procedures) than blacks (19%).²¹ The overall death rate among IIBS patients was 2.7% and major complications have been reported in 18.7% of those who had this surgery.²²

Coronary Angioplasty, with the exception of the acute phase

Coronary angioplasty (also called balloon angioplasty) is a type of surgery to treat people with severe heart disease. The risk of heart disease increases with high blood pressure, diabetes, smoking and age.^{12,13} In the US, about 500,000 balloon angioplasties were performed in 2010 of which 220,000 were in those aged 45-64 years and 257,000 were in those over 65 years of age.¹⁵ The percentage of those surviving three years after a coronary angioplasty is 94.6% in a US study.²³

Thrombosis

Venous thrombosis, including deep vein thrombosis and pulmonary embolism, occurs at an annual incidence of about 1 per 1000 adults. Rates increase sharply after around age 45 years, and are slightly higher in men than women in older age. Major risk factors for thrombosis, other than age, include exogenous factors such as surgery, hospitalization, immobility, trauma, pregnancy and the puerperium and hormone use, and endogenous factors such as cancer, obesity, and inherited and acquired disorders of hypercoagulation.²⁴

VI.2.2 Summary of treatment benefits

Hjercatyl contains acetylsalicylic acid (ASA), which belongs to a group of medicines called anti-platelet agents. Platelets are cell fragments in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery, it stops the blood flow and cuts off oxygen supply to the areas of the body beyond the clot. When this happens in the heart, it can cause a heart attack or angina; in the brain it can cause a stroke.

Hjercatyl is taken to reduce the risk of blood clot formation and thereby prevent heart attack, stroke, and cardiovascular problems in patients who suffer from stable or unstable angina.

Hjercatyl is also used to prevent the formation of blood clots after certain types of heart surgery that are performed to widen or to unblock the blood vessels.

Effectiveness

ASA is well-established as an effective and well tolerated treatment for secondary prevention of cardiovascular events in the proposed indications.

VI.2.3 Unknowns relating to treatment benefits

ASA has been marketed for over 100 years and has been in well-established medicinal use for secondary prevention of cardiovascular (heart-related) events for over 20 years. During this time, the clinical efficacy and safety have been thoroughly investigated and well understood as documented in published literature. There is no evidence to suggest that efficacy is reduced or enhanced in any target subpopulation.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
<ul style="list-style-type: none"> Bleeding in the gut (Gastrointestinal Haemorrhage), sore (ulceration) and perforations, including interactions with medications that can increase the risk of bleeding 	Drugs like Hjercatyl, as a class, can cause bleeding in the gut.	Patients who have had bleeding in their gut should not use Hjercatyl.
<ul style="list-style-type: none"> Bleeding (Haemorrhage) including lack of blood supply to the brain (cerebrovascular events) 	Drugs like Hjercatyl, as a class, can cause bleeding. There is an increased risk of bleeding particularly during or after surgeries (even in cases of minor procedures, e.g. pulling teeth) or in patients who have certain conditions that affect blood clotting.	Use with caution before surgery, including pulling teeth. It may be necessary to stop treatment for a period of time before surgery. Certain medications should not be taken together with Hjercatyl.
<ul style="list-style-type: none"> Allergic-type response (Hypersensitivity Reactions) 	Drugs like Hjercatyl may cause breathing difficulties, rash or itchy skin reactions.	Patients who have had allergic responses to ASA or other non-steroidal anti-inflammatory medicines (NSAIDS) should not use Hjercatyl.
<ul style="list-style-type: none"> Serious allergic-type skin reactions (Stevens-Johnson syndrome, epidermal necrolysis) 	Drugs like Hjercatyl, as a class, may cause serious allergic skin reactions.	Seek medical advice at the first sign of allergic-type skin reactions.
<ul style="list-style-type: none"> Use during pregnancy and breastfeeding (lactation) 	Drugs like Hjercatyl may cause injuries in the unborn child or the newborn if used during pregnancy or breastfeeding.	Do not use or use with caution during pregnancy and breastfeeding. Seek medical advice.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
<ul style="list-style-type: none"> Brain and liver disease (Reye's Syndrome) in children 	Hjercatyl is not recommended for use in adolescents/children under 15 years. ASA may be a contributory factor in the causation of Reye's syndrome, a potentially fatal disease that can damage the brain and the liver, in some children.

Missing information

Risk	What is known
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VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Hjercatyl can be found in the Hjercatyl EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the initial risk management plan.