VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Fungal infections that are resistant to drugs commonly used to treat them are increasing in occurrence and this has led to the need to develop new therapies (i.e. antifungal drugs). More serious fungal infections (those that have entered the bloodstream) have also become increasingly common in recent years. Once thought of as a relatively rare, a type of fungus named C*andida,* are the fourth leading cause of bloodstream infections in hospitalised patients. Advances in transplantation technology and cancer treatment, as well as the extensive use of antibiotics have resulted in more patients being put at risk for such infections.

The serious infections that enter the bloodstream, known as invasive candidiasis and candidemia, are usually found in people with severely depressed immune systems from diseases such as cancer, AIDS, bone marrow or organ transplants. Although less common than C*andida,* infections with *Aspergillus* (other type of fungus), has increased as well. The number of deaths related to these infections is high. Due to the serious nature of underlying disease in many of the patients suffering from these infections, the overall deaths rates may be as high as 61% for *Candida* infections and up to 88% in patients with severe *Aspergillus* infections.

VI.2.2 Summary of treatment benefits

Based on the available data from clinical studies and clinical experience of several years, anidulafungin represents an effective drug in the treatment of invasive candidiasis in adult patients.

If administered as indicated in the Summary of Product Characteristics and taking into account the contraindications, the warnings and precautions, anidulafungin can be considered effective in the approved indications.

VI.2.3 Unknowns relating to treatment benefits

There are no adequate data from the use of anidulafungin in pregnant/lactating women to recommend its use during pregnancy and lactation.

Experience of anidulafungin use in elderly is limited.

Data in paediatric population is limited. Based on currently available information, no recommendation on a posology can be made.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergic reactions (anaphylaxis and infusion-related reactions)	Adverse reactions related to infusion with anidulafungin have been reported, such as rash, itching, hot flush and hives. These side effects are common (may affect up to 1 in 10 people). Life-threatening allergic reactions that might include difficult breathing with wheezing or worsening of an existing rash have been reported with anidulafungin.	Patients are advised to contact their physician or another healthcare professional should any of the following reactions occur: flushing, rash, itching, hot flush, hives, sudden contractions of the muscles around the airways resulting in wheezing or coughing or difficulty in breathing. Patients allergic to drugs like anidulafungin or other ingredients of this medicine should not use this product.
Liver-related events	Liver problems, such as change in blood tests of liver function, are common in patients treated with anidulafungin. In some patients with other serious medical conditions who were receiving additional medicines along with anidulafungin, significant liver problems have occurred, such as: abnormal flow of bile from the gallbladder into the intestine with uncommon frequency (up to 1 in 100 people).	Liver functions should be closely monitored in patients developing liver problems during treatment.

Important potential risks

Risk	What is known (including reason why it is considered a potential risk)
Seizures	Although there is no clear evidence that the risk of seizures is caused by anidulafungin, seizures have been observed in patients treated with other drugs in this class. The frequency of this event is common (up to 1 in 10 people). Patients are advised to immediately contact their doctor or another healthcare professional.
Worsening of infusion associated allergic reactions because of anaesthesia	Rats given high doses of anidulafungin experienced a worsening of allergic reactions related to infusion of anidulafungin and anaesthesia. The cause is unknown. Although the relevance of this finding to humans is unknown, any patient experiencing allergic reactions related to infusion and anaesthesia might be at risk. These patients should be closely monitored during anidulafungin treatment. No instances of anaesthesia-exacerbated infusion-associated reactions have been observed in humans.

Risk	What is known (including reason why it is considered a potential risk)
Abnormalities in electrocardiogram/ Heart disease (QT prolongation/ torsade de pointes)	Patients treated with anidulafungin often are seriously ill with other risk factors, such as heart disease or abnormalities in heart function. QT prolongation (an abnormal pattern seen on an electrocardiogram) or torsade de pointes (a rare heart disease) have not been reported in patients with candidemia or other forms of Candida infections, regardless of treatment with anidulafungin or another drug in the same class.

Missing information

Risk	What is known
Limited information on use in children and adolescents	The safety and the benefits of anidulafungin in children have not yet been established. To date, experience with anidulafungin in the paediatric population is limited. Twenty-five children with a low count of one type of white blood cells (neutrophils) at risk for invasive fungal infections in one study showed that anidulafungin was well tolerated; however, the study was not designed to assess effectiveness.
Limited information on use in elderly	A limited number of elderly patients were studies in clinical trials. More severe adverse reactions were reported among elderly patients, but their frequency was similar to that of younger patients, except that respiratory distress was reported to more patients over 65 years.
Use in pregnant women	Pregnant women were not allowed in anidulafungin studies. There are insufficient safety data in pregnancy to recommend the use of anidulafungin during pregnancy without clear potential benefit.
Resistance	Anidulafungin is fungicidal for *Candida* species. Resistance to anidulafungin was not observed in laboratory experiments designed to detect it, including *in vitro* passage experiments and animal infection experiments.

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 Patient Information Leaflet (PIL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post-authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable for pre-approval versions.