Elements for a Public Summary

Overview of disease epidemiology

Increases in life expectancy and ageing populations are expected to make osteoarthritis the fourth leading cause of disability by the year 2020. For women, the highest risk to start suffering from osteoarthritis is among those aged 65–74 years, reaching approximately 13.5 new diagnosis per 1000 population per year; for men, the highest risk starting to suffer from osteoarthritis occurs among those aged ≥75 years (approximately 9 new diagnoses per 1000 population per year). The overall risk to fall ill with osteoarthritis increases with age, because the condition is not reversible. Men are affected more often than women among those aged <45 years, whereas women are affected more frequently among those aged >55 years). Worldwide estimates are that 9.6% of men and 18.0% of women aged ≥60 years have symptomatic osteoarthritis.

Because of its prevalence and the frequent disability that accompanies disease in the knee and hip, osteoarthritis accounts for more trouble with climbing stairs and walking than any other disease. Osteoarthritis is the most common reason for total hip and total knee replacement.

Summary of treatment benefits

There is some good evidence to support the efficacy of Cartexan as an effective symptomatic treatment for the knee and hip OA, with a favourable safety profile.

Unknowns relating to treatment benefits

There are no reports that CS acts different with regards to palliation of symptoms of osteoarthritis and potential side effects in different ethnic groups.

Children do not represent a target population for osteoarthritis treatment.

Elderly persons being the main target population for osteoarthritis treatment are well represented in the population of the conducted clinical trials.

Summary of safety concerns

Important identified risks

None.

Important potential risks

Risk	What is known	Preventability
Anticoagulation effect (Platelet aggregation inhibition)	There have been signs of platelet aggregation inhibition in rats with substantially higher doses than the recommended ones.	Yes, by monitoring for changes in blood coagulation parameters when used at the same time with blood thinning drugs

Risk	What is known	Preventability
Nausea	Some patients start to suffer from nausea in temporal coincidence with taking Cartexan. As symptoms are usually mild, no action has to be taken and treatment should not be stopped.	Yes, sometimes it can disappear by taking the drug after a meal
Abdominal pain upper	Some patients start to suffer from abdominal pain upper in temporal coincidence with taking Cartexan. As symptoms are usually mild, no action has to be taken and treatment should not be stopped.	Yes, sometimes it can disappear by taking the drug after a meal
Gastrointestinal disorder	Some patients start to suffer from gastrointestinal disorders in temporal coincidence with taking Cartexan. As symptoms are usually mild, no action has to be taken and treatment should not be stopped.	Yes, sometimes it can disappear by taking the drug after a meal
Diarrhoea	Some patients start to suffer from diarrhoea in temporal coincidence with taking Cartexan. As symptoms are usually mild, no action has to be taken and treatment should not be stopped. This effect is thought to be due to the soaking up of water by CS.	Yes, sometimes it can disappear by taking the drug after a meal
Erythema	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions such as erythema can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan.
Irritant dermatitis	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions such as irritant dermatitis can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan.
Papular skin eruption	Cartexan is CS from non-human sources. Hence there is a potential possibility that	If you have had allergic symptoms after prior exposure to CS, you should

Risk	What is known	Preventability
	allergic reactions such as popular skin eruption can develop.	not take Cartexan.
Urticaria	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions such as urticaria can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan.
Eczema	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions such as can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan.
Itching (Pruritus)	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions such as pruritus can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan.
Allergic reaction	Cartexan is CS from non-human sources. Hence there is a potential possibility that allergic reactions can develop.	If you have had allergic symptoms after prior exposure to CS, you should not take Cartexan
Oedema	In very few patients with comorbidity of cardiac failure and / or renal impairment, some patients may start to suffer from oedema or other signs of water retention in temporal coincidence with taking Cartexan. This effect is known to be due to the soaking up of water by CS.	

Important missing information

Risk	What is known
Limited information on use in patients with liver impairment	It is recommended that patients with impaired hepatic function are monitored carefully.

Summary of additional 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.

This medicine has no additional risk minimisation measures.

Planned post authorisation development plan

No post authorisation development is planned.

Summary of changes to the Risk Management Plan over time

Changes from version 1 to version 2:

Update the document with new available information:

- Data exposition from clinical trials (data from new study, CS/IV-RMF-01, available), exposition from post marketing experience.
- Amend S.VII.3 Potential and important safety risks according to available information.
- New ICSR report form.

This summary was last updated updated in 01-2016.