

RISK MANAGEMENT PLAN

CHLORAMPHENICOL SANTEN
5 mg/ml eye drops, solution
5 mg/ml eye drops, solution in single-dose container
10 mg/g eye ointment
chloramphenicol

DATE: 23.9.2015, VERSION 1.0

SANTEN OY
CONFIDENTIAL

Part VI: Summary of the risk management plan by product: Chloramphenicol Santen 5 mg/ml eye drops, solution

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Chloramphenicol Santen 5 mg/ml eye drops are used for bacterial eye infections, such as conjunctivitis (inflammation of conjunctival mucosa covering the white of the eyes and the inner side of the eyelids), blepharitis (inflammation of eye lids), dacryocystitis (inflammation of tear sac at the inner corner of the eye) and keratitis (inflammation of cornea, which is the transparent front part of the eye). The product can also be used for preventing infections after eye injuries and surgeries and after removal of foreign bodies.

Symptoms of bacterial eye infections include red eye, swelling, irritation and/or watering of the eyes. Eye infections are most commonly caused by viruses, bacteria or allergens. Bacterial infections can be caused by a range of different bacteria and therefore they are treated with antibiotics, such as chloramphenicol, that are effective against different types of bacteria.

The incidence of bacterial conjunctivitis has been estimated to be 135 in 10 000 and it is more common in young children and the elderly than in other age groups. The possibility of bacterial keratitis is high in people wearing contact lenses, while dacryocystitis is often caused by an obstruction of the nasolacrimal duct. Blepharitis most commonly starts in the fourth and fifth decades of life.

VI.2.2 Summary of treatment benefits

Chloramphenicol eye drops have been widely used in the treatment and prevention of superficial eye infections for decades because chloramphenicol inhibits the growth and reproduction of many different types of bacteria. Direct application of chloramphenicol delivers high drug concentrations to the surface of the eye quickly and with minimal exposure of the other parts of the body to the drug.

Mild eye infections often resolve by themselves but chloramphenicol accelerates the rate of clinical resolution and decreases the risk of contagious spread, for example, in the case of bacterial conjunctivitis.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Decreased ability of the bone marrow to produce blood cells (bone marrow depression)	Topical use of a medicinal product containing chloramphenicol for months may cause changes in the blood count in very rare cases (less than 1/10,000) and in patients who have earlier suffered from bone marrow dysfunction. The evidence to support this, however, is conflicting. Chloramphenicol Santen 5 mg/ml eye drops should not be used by

	patients with personal or family history of changes in blood count. The product should not be used for prolonged periods or simultaneously with medicines which can suppress the functioning of the bone marrow. Chloramphenicol should be used with caution during pregnancy and breastfeeding.
Severe allergic reactions	Allergic reactions may uncommonly appear during the use of ocular chloramphenicol. Angioedema (sudden localised swelling of the skin, mucosa or internal organs) and anaphylactic reactions (rapid, severe, potentially life-threatening allergic reactions) have occurred in a small number of people but their exact frequency is unknown. Chloramphenicol Santen 5 mg/ml eye drops should not be used by people who are allergic to chloramphenicol or any of the other ingredients of the medicine.

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 Chloramphenicol Santen 5 mg/ml eye drops can be found in the national authority's web page.

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.

Part VI: Summary of the risk management plan by product: Chloramphenicol Santen 5 mg/ml eye drops, solution in single-dose container

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Chloramphenicol Santen 5 mg/ml eye drops are used for bacterial eye infections, such as conjunctivitis (inflammation of conjunctival mucosa covering the white of the eyes and the inner side of the eyelids), blepharitis (inflammation of eye lids), dacryocystitis (inflammation of tear sac at the inner corner of the eye) and keratitis (inflammation of cornea, which is the transparent front part of the eye). The product can also be used for preventing infections after eye injuries and surgeries and after removal of foreign bodies.

Symptoms of bacterial eye infections include red eye, swelling, irritation and/or watering of the eyes. Eye infections are most commonly caused by viruses, bacteria or allergens. Bacterial infections can be caused by a range of different bacteria and therefore they are treated with antibiotics, such as chloramphenicol, that are effective against different types of bacteria.

The incidence of bacterial conjunctivitis has been estimated to be 135 in 10 000 and it is more common in young children and the elderly than in other age groups. The possibility of bacterial keratitis is high in people wearing contact lenses, while dacryocystitis is often caused by an obstruction of the nasolacrimal duct. Blepharitis most commonly starts in the fourth and fifth decades of life.

VI.2.2 Summary of treatment benefits

Chloramphenicol eye drops have been widely used in the treatment and prevention of superficial eye infections for decades because chloramphenicol inhibits the growth and reproduction of many different types of bacteria. Direct application of chloramphenicol delivers high drug concentrations to the surface of the eye quickly and with minimal exposure of the other parts of the body to the drug.

Mild eye infections often resolve by themselves but chloramphenicol accelerates the rate of clinical resolution and decreases the risk of contagious spread, for example, in the case of bacterial conjunctivitis.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Decreased ability of the bone marrow to produce blood cells (bone marrow depression)	Topical use of a medicinal product containing chloramphenicol for months may cause changes in the blood count in very rare cases (less than 1/10,000) and in patients who have earlier suffered from bone marrow dysfunction. The evidence to support this, however, is conflicting.

	Chloramphenicol Santen 5 mg/ml eye drops should not be used by patients with personal or family history of changes in blood count. The product should not be used for prolonged periods or simultaneously with medicines which can suppress the functioning of the bone marrow. Chloramphenicol should be used with caution during pregnancy and breastfeeding.
Severe allergic reactions	Allergic reactions may uncommonly appear during the use of ocular chloramphenicol. Angioedema (sudden localised swelling of the skin, mucosa or internal organs) and anaphylactic reactions (rapid, severe, potentially life-threatening allergic reactions) have occurred in a small number of people but their exact frequency is unknown. Chloramphenicol Santen 5 mg/ml eye drops should not be used by people who are allergic to chloramphenicol or any of the other ingredients of the medicine.

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 Chloramphenicol Santen 5 mg/ml eye drops can be found in the national authority's web page.

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.

Part VI: Summary of the risk management plan by product: Chloramphenicol Santen 10 mg/g eye ointment

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Chloramphenicol Santen 10 mg/g eye ointment is used for bacterial eye infections, such as conjunctivitis (inflammation of conjunctival mucosa covering the white of the eyes and the inner side of the eyelids), blepharitis (inflammation of eye lids), dacryocystitis (inflammation of tear sac at the inner corner of the eye) and keratitis (inflammation of cornea, which is the transparent front part of the eye). The product can also be used for preventing infections after eye injuries and surgeries and after removal of foreign bodies.

Symptoms of bacterial eye infections include red eye, swelling, irritation and/or watering of the eyes. Eye infections are most commonly caused by viruses, bacteria or allergens. Bacterial infections can be caused by a range of different bacteria and therefore they are treated with antibiotics, such as chloramphenicol, that are effective against different types of bacteria.

The incidence of bacterial conjunctivitis has been estimated to be 135 in 10 000 and it is more common in young children and the elderly than in other age groups. The possibility of bacterial keratitis is high in people wearing contact lenses, while dacryocystitis is often caused by an obstruction of the nasolacrimal duct. Blepharitis most commonly starts in the fourth and fifth decades of life.

VI.2.2 Summary of treatment benefits

Chloramphenicol eye ointment has been widely used in the treatment and prevention of superficial eye infections for decades because chloramphenicol inhibits the growth and reproduction of many different types of bacteria. Direct application of chloramphenicol delivers high drug concentrations to the surface of the eye quickly and with minimal exposure of the other parts of the body to the drug.

Mild eye infections often resolve by themselves but chloramphenicol accelerates the rate of clinical resolution and decreases the risk of contagious spread, for example, in the case of bacterial conjunctivitis.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Decreased ability of the bone marrow to produce blood cells (bone marrow depression)	Topical use of a medicinal product containing chloramphenicol for months may cause changes in the blood count in very rare cases (less than 1/10,000) and in patients who have earlier suffered from bone marrow dysfunction. The evidence to support this, however, is conflicting. Chloramphenicol Santen 10 mg/g eye ointment should not be used

	by patients with personal or family history of changes in blood count. The product should not be used for prolonged periods or simultaneously with medicines which can suppress the functioning of the bone marrow. Chloramphenicol should be used with caution during pregnancy and breastfeeding.
Severe allergic reactions	<p>Allergic reactions may uncommonly appear during the use of ocular chloramphenicol. Angioedema (sudden localised swelling of the skin, mucosa or internal organs) and anaphylactic reactions (rapid, severe, potentially life-threatening allergic reactions) have occurred in a small number of people but their exact frequency is unknown.</p> <p>Chloramphenicol Santen 10 mg/g eye ointment should not be used by people who are allergic to chloramphenicol or any of the other ingredients of the medicine.</p>

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 Chloramphenicol Santen 10 mg/g eye ointment can be found in the national authority's web page.

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.