SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gentamicin <TRADE NAME> <STRENGTH> Eye Drops, Solution

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each <mL> solution contains <STRENGTH> of Gentamicin

For the full list of excipients, see section 6.1.

<REGARDING THE APPROVAL>

1. PHARMACEUTICAL FORM

Eye Drops, Solution <REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Genticin eye drops are indicated in adults and children:

1. For the treatment of superficial eye infections caused by organisms sensitive to gentamicin.

2. For prophylaxis against infection in trauma of the eye.

* 1. Posology and method of administration

**Posology**

**Adults, the elderly and the paediatric population**

Eyes: 1 or 2 drops should be instilled in the affected eye up to six times a day, or more frequently if required. (Severe infections may require 1 or 2 drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

**Method of administration**

For topical ocular use.

* 1. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Myasthenia gravis.

* 1. Special warnings and precautions for use

Long-term continuous topical therapy should be avoided. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross sensitivity with other aminoglycoside antibiotics may occur.

In severe infections, topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment.

Gentamicin may cause irreversible partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose-related and is enhanced by renal and/or hepatic impairment and is more likely in the elderly.

Contact lenses should be removed during the period of treatment of ocular infections.

Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic gentamicin therapy. Although these effects have not been reported following topical otic use of gentamicin, caution is advised when used concomitantly with systemic aminoglycosides. There have been observed cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where the patient’s aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. Mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

Patients should be monitored in case of prolonged use.

**Excipient information**

<REGARDING THE APPROVAL>

* 1. Interaction with other medicinal products and other forms of interaction

Potent diuretics such as ethacrynic acid and furosemide are believed to enhance any risk of ototoxicity whilst amphotericin B, cisplatin and cyclosporine and cephalosporins are potential enhancers of nephrotoxicity.

Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician.

Neuromuscular blockade and respiratory paralysis have been reported in patients from the administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia.

* 1. Fertility, pregnancy and lactation

**Pregnancy**

Safety for use in pregnancy has not been established. Gentamicin should only be used in pregnancy when considered essential by the physician, after careful assessment of the potential risks and benefits.

**Breast-feeding**

Safety for use in lactation has not been established. In the absence of gastrointestinal inflammation, the amount of gentamicin ingested from the milk is unlikely to result in significant blood levels in breast-fed infants. Gentamicin should only be used in lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

**Fertility**

No data available.

* 1. Effects on ability to drive and use machines

Patients should be advised that the use of Gentamicin in the eye may cause transient blurring of vision. If affected, patients should not drive or operate machinery until vision has cleared.

* 1. Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention: Not known (cannot be estimated from the available data)

|  |  |  |
| --- | --- | --- |
| **System organ class** | **Frequency** | **Undesirable effects** |
| Eye disorders | Not known | - local sensitivity:  - vision blurred  - eye irritation  - burning sensation  - stinging sensation  - itching (eye pruritus) |
| Ear and labyrinth disorders | Not known | - local sensitivity  - ototoxicity  - vestibular disorder:  - hearing loss |
| Skin and subcutaneous tissue disorders | Not known | - burning sensation  - stinging  - itching (pruritus):  - dermatitis. |
| Renal and urinary disorders | Not known | - nephropathy toxic\*  - acute renal failure |

\*Gentamicin may cause nephrotoxicity when given systemically. However, it is likely that systemic absorption following topical administration does not constitute a comparable risk.

In the event of irritation, sensitisation or super-infection, treatment should be discontinued and appropriate therapy instituted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC.

* 1. Overdose

**Symptoms**

The oral ingestion of the contents of one bottle is unlikely to cause any significant adverse effect.

**Management**

Haemodialysis and peritoneal dialysis will aid the removal from blood but the former is probably more efficient. Calcium salts given intravenously have been used to counter the neuromuscular blockade cause by gentamicin.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives. ATC code: S03AA06

Mechanism of action.

Gentamicin is mixture of antibiotic substances produced by the growth of micromonospora purpurea. It is a bactericidal antibiotic which acts by inhibiting protein synthesis. It has greater antibacterial activity than streptomycin, neomycin or kanamycin.

Gentamicin exerts a number of effects on cells of susceptible bacteria. It affects the integrity of the plasma membrane and the metabolism of RNA, but it's most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit.

* 1. Pharmacokinetic properties

**Absorption**

Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.

**Distribution**

Gentamicin is 70-85% bound to plasma albumin following administration. Effective plasma concentration is 4 - 8ug/ml The volume of distribution (VD) is 0.3 1/kg

**Elimination**

> 90% Gentamicin is excreted unchanged in the urine by glomerular filtration. T½ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency. The elimination rate constant is; 0.02 Hr-1 for anuric patients\* 0.30 Hr-1 normal

\*Therefore, in those with anuria care must be exercised.

* 1. Preclinical safety data

Not relevant.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

Not applicable.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>