Bar prints 100mm @ 100%

Santen

COMMERCIAL ARTWORK

Description:	Hialid 0.1% (MY) 5 ml Leaflet
CMO Item Number:	N/A
CMO SPEC Number:	N/A
GLAMS Part Number:	CAW-5803-01
Technical Drawing No:	N/A
Dimension:	254 X 110 mm
Pharma Code:	004620
2D matrix:	N/A
Date:	14-03-2023
Market:	MY
Material Code:	752804
Artwork Version Number:	05
Schawk Job No.:	108421447/403221585

Printable Colours:

Santen PI Blue

Non Print:

Profile Technical Info

SGK

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75280405

004620

Hialid® 0.1 ophthalmic solution

Santen

[Description]

Clear, colourless, viscous, sterile, aqueous ophthalmic solution.

[Composition]

Each mL contains purified sodium hyaluronate 1mg

[Actions and Pharmacology]

Sodium hyaluronate binds to firbonectins and accelerates the adhesion and extension of epithelial cells. Sodium hyaluronate also has an excellent water-holding property because each sodium hyaluronate molecule can retain many H_2O molecules.

Topical application of sodium hyaluronate ophthalmic solution accelerates the wound healing of corneal epithelium in rabbits.

Sodium hyaluronate accelerates the extension of corneal epithelial cells in isolated strips of cultured rabbit cornea.

[Pharmacokinetics]

- *Blood concentration*

Blood concentrations of sodium hyaluronate were determined before topical application as well as on treatment day 3, day 9 (the last day of dosing), and day 10 in 6 healthy adult male volunteers. To the unilateral eye of the subjects, 0.1% (day 1) and 0.5% (day 2-9) ophthalmic solutions of sodium hyaluronate were instilled at a dose of one drop 5 times daily (day 1-2) and one drop 13 times daily (day 3-9). All blood levels determined before, during, and after treatment were less than the detection limit (10 μg/mL).

- *Intraocular distribution*

Following a single topical application of 50 μL of 0.1% ^{14}C-sodium hyaluronate ophthalmic solution in rabbits with a normal cornea, radioactivity was only detected in the outer ocular area. Especially, the radioactivity in the bulbar conjuntiva was high and it was detactable till at least 8 hr after application. In contrast, the radioactivity level in the cornea was low and it was only detectable for 30 min after application. Following topical application of 50 μL of 0.1% ^{14}C-sodium hyaluronate ophthalmic solution in rabbits with injured cornea approximately 408ng/mL of the concentration was detected in the cornea even at 1 hr after application, indicating better penetration of ^{14}C-radioactivity into the injured cornea. Radioactivity was also detected in the aqueous humor.

[Indications]

Indicated for the treatment of keratoconjunctival epithelial disorders resulting from Sjogren's syndrome, sicca syndrome (dry eye) and extrinsic diseases caused by contact lens wearing.

[Contraindications]

This medication should not be used when the following medical problem exist: hypersensitivity to hyaluronate sodium.

[Precautions / Warning]

Hypersensitivity such as blepharitis and eyelid dermatitis, and ophthalmic adverse reactions such as itching, irritation, conjunctivitis, conjunctival injection,corneal disorders including keratitis superficialis diffusa (incidence 0.1% to <5%) may occur. Eye discharge (incidence <0.1%) may be produced.

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[Main Side / Adverse Effects]

Adverse reactions to this drug were reported in 74 of 4,208 patients evaluated before approval and during drug use investigation (1.76%). The major adverse reactions were eyelid itching in 19 patients (0.45%), eye irritation in 15 patients (0.36%), conjunctival injection in 10 patients (0.24%), blepharitis in 7 patients (0.17%), etc. [At the end of reexamination].

[Use During Pregnancy, Delivery or Lactation]

Fertility - No evidence of impairment of fertility was seen in rats and rabbits given hyaluronate sodium in doses of up to 1.43 mg per kg of body weight (mg/kg), approximately 11 times the maximum recommended human dose (MRHD), per treatment cycle.

Pregnancy - Adequate and well-controlled studies in humans have not been done. No evidence of harm to the fetus was seen in rats and rabbits given hyaluronate sodium in doses of up to 1.43 mg/kg, approximately 11 times the MRHD, per treatment cycle.

Breast-feeding - it is not known whether hyaluronate sodium is distributed into breast milk.
However, problems in humans have not been documented.

[Drug Interactions]

Not documented yet.

[Overdose and Treatment]

Safety on repeated cycles and overdose has not been established.

[Dosage and Administration]

Usually, instill one drop a time to the eye 5-6 times daily. The dosage may be adjusted according to the patient's symptoms.

Route of administration: ophthalmic use only.

User Instruction:

- Be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.
- This product is suitable for use with contact lenses.

Storage: Store below 30˚C in a tight container.

Presentation / Packing: 5mL × 1bottle

Date of Revision: March 2023

Manufactured by:
SANTEN PHARMACEUTICAL CO., LTD.
Noto Plant: 2-14, Shikinami, Hodatsushimizu-cho, Hakui-gun, Ishikawa, Japan

Product Registration Holder:
SANTEN PHARMA MALAYSIA SDN. BHD.
(1117719-T)
Unit #23A-10, Q Sentral, No. 2A, Jalan Stesen Sentral 2,
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1HT·MLS

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Approved 26-Mar-2023 23-00 UTC

Username	Full Name	Status	Date/Time (UTC)
GaithriGanesan	Gaithri Ganesan	Approved	21-Mar-2023 00-58 UTC
ShirleyTok	Shirley Tok	Approved	21-Mar-2023 01-16 UTC
KahPeiLau	Kah Pei Lau	Approved	21-Mar-2023 02-54 UTC
CalvinLow	Calvin Low	Approved	21-Mar-2023 06-36 UTC
GraceLou	Grace Lou	Approved	25-Mar-2023 00-46 UTC
KazuhiroNishino	Kazuhiro Nishino	Approved	26-Mar-2023 23-00 UTC