Humamallana DavaBank

Drugs 🔻

# Hypromellose

Targets (1)

#### IDENTIFICATION

| name | нурготтепоѕе |
|------|--------------|
|      |              |

Accession Number DB11075

**Type** Small Molecule

#### **Groups** Approved

#### Description

Hypromellose, or hydroxypropyl methylcellulose (HPMC) [8], is a semisynthetic, inert, and viscoelastic polymer that forms a colloid solution when dissolved in water. It acts as a thickening agent, coating polymer, bioadhesive, solubility enhancer in solid dispersions, and binder in the process of granulation and in modified release formulations [2]. It is a commonly used as a delivery component in oral pharmaceutical products that provides the release of a drug in a controlled fashion, effectively increasing the duration of release of a drug to prolong its therapeutic effects [1]. Hypromellose is also found in eye drops as a lubricant [3].

#### Synonyms

 $\hbox{Cellulose hydroxypropyl methyl ether} \\$ 

Cellulose, 2-hydroxypropyl methyl ether

Hiprome**l**osa

Hydroxypropyl methylcellulose 2208

Hydroxypropyl methylcellulose 2910

Hydroxypropyl methylcellulose 4000

Hydroxypropyl methylcelluloses

Hydroxypropylmethylcellulose

Hypromellose

Hypromelloses

### **Product Ingredients**



| INGREDIENT                            | UNII              | CAS           | INCHI KEY      |
|---------------------------------------|-------------------|---------------|----------------|
| Hypromellose 2208 (100 mpa.s)         | B1QE5P712K        | Not Available | Not applicable |
| Hypromellose 2208 (15000 mpa.s)       | Z78RG6M2N2        | Not Available | Not applicable |
| Hypromellose 2906 (4000 mpa.s)        | <u>5EYA69XGAT</u> | Not Available | Not applicable |
| <u>Hypromellose 2906 (50 mpa.s)</u>   | <u>612E703ZUQ</u> | Not Available | Not applicable |
| <u>Hypromellose 2910 (15 mpa.s)</u>   | 36SFW2JZ0W        | Not Available | Not applicable |
| Hypromellose 2910 (15000 mpa.s)       | 288VBX44JC        | Not Available | Not applicable |
| Hypromellose 2910 (3 mpa.s)           | <u>0VUT3PMY82</u> | Not Available | Not applicable |
| <u>Hypromellose 2910 (4000 mpa.s)</u> | RN31520P35        | Not Available | Not applicable |

#### Prescription Products

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|      |                       |           |             |          |   | MARKETING |                       | MARKETING |                       |                       |    |
|------|-----------------------|-----------|-------------|----------|---|-----------|-----------------------|-----------|-----------------------|-----------------------|----|
| NAME | $\uparrow \downarrow$ | DOSAGE ↑↓ | STRENGTH ↑↓ | ROUTE ↑↓ | $LABELLER \ \!$ | START     | $\uparrow \downarrow$ | END       | $\uparrow \downarrow$ | $\uparrow \downarrow$ | ΛΨ |

4/23/2010

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NAME ↑ DOSAGE ↑ STRENGTH ↑ ROUTE ↑ LABELLER ↑ START ↑ END

TART  $^{\uparrow\downarrow}$  END  $^{\uparrow\downarrow}$   $^{\uparrow\downarrow}$ 

Search

Drugs

Over the Counter Products

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entries

MARKETING MARKETING ROUTE ↑↓ LABELLER DOSAGE ↑↓ STRENGTH ↑↓ NAME START  $\uparrow \downarrow$ **END** 小人 Artelac Solution .32 % Ophthalmic Bausch & Lomb 2005-03-25 2008-07-28 Lubricant Eye Inc Drops Corneo Solution 0.3 % Ophthalmic Orimed Pharma 2015-09-16 Not applicable Hypromellose Corporation Genteal Solution 3 mg Ophthalmic Novartis 1997-10-17 Not applicable Genteal Gel Gel 0.3 % Ophthalmic Alcon, Inc. 2002-10-23 2016-05-30 GenTeal Mild Liquid 0.002 L/1L Ophthalmic Novartis 2009-09-14 Not applicable GenTeal Mild Liquid 0.003 L/1L Ophthalmic Novartis 2009-09-14 Not applicable to Moderate GenTeal Gel .003 g/1g Ophthalmic Novartis 2009-09-14 Not applicable Severe Pharmaceuticals Corporation Goniosoft Liquid 25 mg/1mL Ophthalmic O Cu Soft, Inc. 1989-10-02 Not applicable Ophthalmic Hub Goniovisc Solution / 25 mg/1mL 2011-11-10 Not applicable Ophthalmic Pharmaceuticals drops Lubricant

Ophthalmic Hyalogic Llc

Showing 1 to 10 of 25 entries

%)

Liquid

3 mg/10mL

HylaTears

Search

Not applicable

1 2 3

2018-02-12

**Mixture Products** 

Show 10 entries MARKETING MARKETING INGREDIENTS DOSAGE ↑↓ ROUTE ↑ LABELLER NAME START END Hypromellose Solution / Ophthalmic Preferreed 2010-09-02 Not applicable Advanced Eye Relief/ (5 mg/1mL) + drops Pharmaceuticals Redness **Naphazoline** Inc. <u>hydrochloride</u> Maximum Relief (0.3 mg/1mL) Advanced Hypromellose Solution / Ophthalmic Bauch & Lomb 2010-09-02 Not applicable Eye Relief/ (5 mg/1mL) + drops Incorporated Redness **Naphazoline** Maximum <u>hydrochloride</u> (0.3 mg/1mL) Relief Hypromellose | Solution / Artificial Ophthalmic Geri-Care 2018-06-01 Not applicable (0.002 Pharmaceuticals, Tears drops mg/1mg) + Corp <u>Glycerin</u> (0.002 mg/1mg) +<u>Polyethylene</u> glycol 400 (0.01 mg/1mg) Artificial Hypromellose Solution Ophthalmic Teva 2011-04-19 Not applicable Tears (0.2%) +Glycerin (0.2 %) Hypromellose | Solution Artificial 2009-02-24 Ophthalmic Alcon, Inc. 2005-03-16 (0.3%) +Tears Dextran (0.1

NAME 

| NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME | NAME |

Drugs Tears (2 mg/1mL) + Company Glycerin (2 mg/1mL) + <u>Polyethylene</u> glycol 400 (10 mg/1mL) <u>Hypromellose</u> Solution / **Bion Tears** Ophthalmic ALCON 1992-10-19 Not applicable <u>2910 (4000</u> drops LABORATORIES, <u>mpa.s)</u> (3 INC. mg/1mL) + Dextran 70 (1 mg/1mL) Hypromellose Solution / Ophthalmic Alcon, Inc. **Bion Tears** 1996-10-28 2016-10-20 - Liq Oph (0.3 %) + drops Dextran 70 (0.1 %) CAREALL Hypromellose Solution / Ophthalmic New World 2014-01-01 Not applicable Artifical (2 mg/1mL) + drops Imports, Inc Tears Glycerin (2 mg/1mL) + <u>Polyethylene</u> <u>glycol 400</u> (10 mg/1mL) CAREALL <u>Hypromellose</u> Solution / Ophthalmic New World 2014-06-01 Not applicable Lubricating <u>2910 (4000</u> drops Imports Eye Drops <u>mpa.s)</u> (.3 mg/1mL) + <u>Dextran 70</u> (.1 mg/1mL)

Showing 1 to 10 of 85 entries

Unapproved/Other Products ①

Show 10 entries Search

| NAME ↑↓               | INGREDIENTS  | DOSAGE A | ROUTE ↑↓            | LABELLER ↑↓                        | MARKETING<br>START ↑↓ | MARKETING THE  | ₩ | 1√  |
|-----------------------|--|----------|---------------------|------------------------------------|-----------------------|----------------|---|-----|
| Entrocel              | Hypromellose<br>(18 mg/1mL)  |          | Oral                | Mallinckrodt                       | 2009-06-01            | 2012-10-31     |   | 1 * |
| Gonak<br>Hypromellose | Hypromellose<br>2906 (4000<br>mpa.s) (25<br>mg/1mL) +<br>Hypromellose<br>2906 (50<br>mpa.s) (25<br>mg/1mL) | Solution | Ophthalmic          | Akorn                              | 1997-01-01            | Not applicable |   |     |
| Gonak<br>Hypromellose | Hypromellose<br>2906 (4000<br>mpa.s) (25<br>mg/1mL) +<br>Hypromellose<br>2906 (50<br>mpa.s) (25<br>mg/1mL) | Solution | Ophthalmic          | Akorn                              | 1997-01-01            | Not applicable |   |     |
| Goniosoft             | Hypromellose<br>(25 mg/1mL)  | Liquid   | Ophtha <b>l</b> mic | O Cu Soft, Inc.                    | 1989-10-02            | Not applicable |   |     |
| Goniotaire            | Hypromellose<br>2906 (4000<br>mpa.s) (25<br>mg/1mL)  | Solution | Ophtha <b>l</b> mic | Altaire<br>Pharmaceuticals<br>Inc. | 2002-01-18            | Not applicable |   |     |

<u><</u> 1 ≥

Tears (artificial) [4]

Lubricant (ophthalmic) [4]

Diagnostic aid (contact lens procedures; gonioscopy) [4]

#### Pharmacodynamics

Hypromellose is the most commonly used in hydrophilic matrix fabrication. It allows for controlled release of drug substances, increasing duration of therapeutic effects [3]. The physical characteristics of this drug resemble natural tears, providing lubrication to the ocular surface and maintaining corneal hydration in dry eye syndromes [2].

Hypromellose is considered an inert substance as it has no direct pharmacological activity. The viscosity promoting properties of hypromellose prolong the retention time and improve adhesion of synthetic tears to the cornea and conjunctiva. As a result, the tear film breakdown time is prolonged and/or the tear film stability is enhanced. A stable tear film protects the cornea from dryness and epithelial cells 6.

Hypromellose is a methyl and hydroxypropyl mixed ether of cellulose. It is utilized as artificial tears to prevent conjunctival and corneal damage due to impaired lacrimal secretions. It is also used as a visco-elastic promoting agent by maintaining a deep, viscous chamber and allowing for easier manipulation, helping the vitreous surface to be pushed back, thus preventing the formation of a postoperative flat chamber [5].

#### Mechanism of action

Promotes corneal wetting by the stabilization and thickening the precorneal tear film and prolonging the tear film breakdown time, which is usually shortened in dry eye conditions.

Hypromellose also acts to lubricate and protect the eye [6].

The surface active properties of the vehicles found in artificial tears solutions act to stabilize the

TARGET

In the intact eye, the corneal surface is moistened primarily by the mucin that is produced in the

Drugs

ACTIONS

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ORGANISM

application of artificial tear fluid is highly recommended. Both its surface activity and its adsorptive capacity make hypromellose optimal for this use. Hypromellose has a physical-chemical action and leads to, in an aqueous solution, a reduced surface tension as well as an increased level of viscosity. Hypromellose adheres well to the cornea and conjunctiva and provides ample moisture. Irritation symptoms caused by blinking, which occur in the case of tear fluid deficiency, are therefore decreased and symptoms of epithelial desiccation are also alleviated [6].

<<

| Absorption  Not systemically absorbed 6.  Volume of distribution  Protein binding  Not Available  Metabolism  Not Available | Humans        |  |  |  |  |  |
|---|---------------|--|--|--|--|--|
| Volume of Not Available distribution  Protein binding Not Available   |               |  |  |  |  |  |
| distribution  Protein binding Not Available   |               |  |  |  |  |  |
|   |               |  |  |  |  |  |
| Metabolism Not Available  |               |  |  |  |  |  |
|   | Not Available |  |  |  |  |  |
| Route of Not Available elimination  | Not Available |  |  |  |  |  |
| Half life Not Available   | Not Available |  |  |  |  |  |
| Clearance Not Available   | Not Available |  |  |  |  |  |
| Toxicity LD 50 (Rat): > 5 g/kg [MSDS].  |               |  |  |  |  |  |
| Hypromellose is considered low toxicity to non-toxic $^{\fbox{8}}$ .  |               |  |  |  |  |  |
| Adverse events may include blurred vision and contact dermatitis [4]. Hypersensitivity                                      | and           |  |  |  |  |  |
| intolerance reactions may occur (for example, eye burning, pain, increased lacrimation                                      | on, a         |  |  |  |  |  |
| sensation of foreign body, conjunctival hyperemia, eyelid swelling, pruritus). The stick                                    | kiness        |  |  |  |  |  |
| sensation of the eyelids, the decreased sense of smell, photosensitivity [6].   |               |  |  |  |  |  |
| Affected organisms Not Available  | Not Available |  |  |  |  |  |
| Pathways Not Available  | Not Available |  |  |  |  |  |
| Pharmacogenomic Not Available Effects/ADRs ①  |               |  |  |  |  |  |
| NTERACTIONS   |               |  |  |  |  |  |
| Drug Interactions Not Available   |               |  |  |  |  |  |
| 0   |               |  |  |  |  |  |

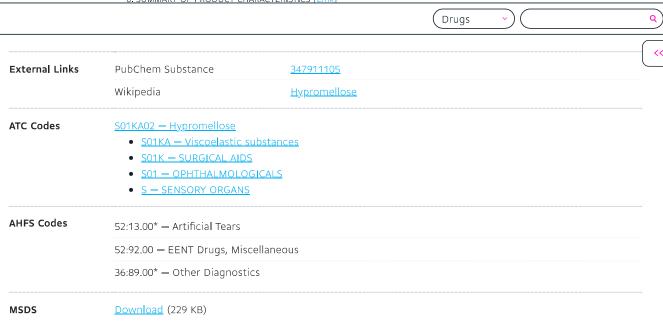
## General References

**Food Interactions** 

- 1. Li CL, Martini LG, Ford JL, Roberts M: The use of hypromellose in oral drug delivery. J Pharm Pharmacol. 2005 May;57(5):533-46. [PubMed:15901342]
- Al-Tabakha MM: HPMC capsules: current status and future prospects. J Pharm Pharm Sci. 2010;13(3):428-42.
   [PubMed:21092714]
- 3. BION TEARS [Link]

Not Available

- 4. Hypromellose [Link]
- 5. MIMS Hypromellose [Link]
- 6. SUMMARY OF PRODUCT CHARACTERISTICS [Link]



#### CLINICAL TRIALS

#### Clinical Trials ①

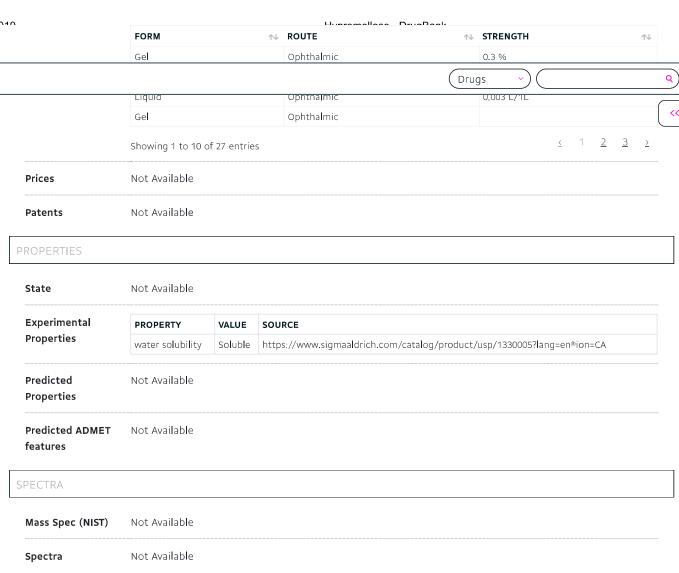
https://www.aragoann.oa/arago/DD 11070

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|----------|------------|------------|--|-------------|-------|---|
| PHASE ↑↓ | STATUS ↑↓  | PURPOSE ↑↓ | CONDITIONS   | $\wedge$    | COUNT | ₩ |
| 1        | Completed  | Treatment  | <u>Dry Eye Syndrome (DES)</u>                            |             | 1     |   |
| 2        | Completed  | Treatment  | Conjunctivitis, Seasonal Allergic                        |             | 1     |   |
| 2        | Completed  | Treatment  | Eye Dryness  |             | 1     |   |
| 2        | Completed  | Treatment  | Macular Edema (ME). / Retinopathy, Diabet                | <u>ic</u>   | 1     |   |
| 2        | Recruiting | Treatment  | Herpes Zoster Keratitis                                  |             | 1     |   |
| 2        | Recruiting | Treatment  | Thyroid Eye Disease                                      |             | 1     |   |
| 2        | Terminated | Treatment  | <u>Dry Eye Syndromes</u>                                 |             | 1     |   |
| 2, 3     | Completed  | Treatment  | Conjunctivitis, Viral                                    |             | 1     |   |
| 3        | Completed  | Treatment  | Conjunctivitis, Viral                                    |             | 1     |   |
| 3        | Completed  | Treatment  | Exfoliation Syndrome / Glaucoma, Primary<br>Angle (POAG) | <u>Open</u> | 1     |   |

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PHARMACOECONOMICS

| Manufacturers | Not Available |            |             |            |
|---------------|---------------|------------|-------------|------------|
| Packagers     | Not Available |            |             |            |
| Dosage forms  | Show 10 enti  | ies        |             | Search     |
|               | FORM          | ↑↓ ROUTE   | ↑↓ STRENGTH | $\uparrow$ |
|               | Solution      | Ophthalmic | .32 %       |            |
|               | Solution      | Ophthalmic |             |            |
|               | Liquid        | Ophthalmic |             |            |
|               | Solution      | Ophthalmic | 0.3 %       |            |
|               | Solution      | Oral       | 18 mg/1mL   |            |
|               | Solution      | Ophthalmic | 3 mg        |            |



TAXONOMY

**Classification** Not classified

TARGETS

https://www.

| 1. Epithelial cell adhesion molecule       | Details   |
|--|---|
| Kind                                       | Protein   |
| Organism                                   | Humans  |
| Pharmacological action<br>General Function | Unknown Protein complex binding   |
| Specific Function                          | May act as a physical homophilic interaction molecule between intestinal epithelial cells (IECs) and intraepithelial lymphocytes (IELs) at the mucosal epithelium for providing immunological barrier |
| Gene Name                                  | EPCAM   |
| Uniprot ID                                 | <u>P16422</u>   |
| Uniprot Name                               | Epithelial cell adhesion molecule   |
| Molecular Weight                           | 34932.005 Da  |

4/23/2010

#### Humamallana DavaDank

1. Geerling G, Daniels JT, Dart JK, Cree IA, Khaw PT: Toxicity of natural tear substitutes in a fully defined culture model of human corneal epithelial cells. Invest Ophthalmol Vis Sci. 2001 Apr;42(5):948-56. [PubMed:11274071]

Drugs

Drug created on December 03, 2015 09:51 / Updated on April 22, 2019 17:13

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