



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Hylira™ Gel (sodium hyaluronate 0.2%) safely and effectively. See full prescribing information for Hylira™ Gel (sodium hyaluronate 0.2%).

Hylira™ Gel (sodium hyaluronate 0.2%) for topical use only.

INDICATIONS AND USAGE

Hylira™ Gel (sodium hyaluronate 0.2%) is a topical gel indicated for

- the treatment of symptoms associated with xerosis (dry, scaly skin).

DOSAGE AND ADMINISTRATION

- Apply to the affected area(s) and rub in thoroughly. Use a liberal amount two to three times daily or as directed by a physician.

DOSAGE FORMS AND STRENGTHS

- Gel; sodium hyaluronate, 0.2% w/w (0.17% at MW 2.0 megadaltons, 0.02% at MW 1.2 megadaltons, and 0.01% at 0.2 megadaltons)

CONTRAINDICATIONS

- Do not administer to patients with known hypersensitivity to the listed ingredients.

WARNINGS AND PRECAUTIONS

- For external use only. Avoid contact with eyes, lips, and mucous membranes.

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Hawthorn Pharmaceuticals, Inc. at (888) 455-5253 or www.hawthornrx.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Pregnancy Category C
- It is not known if Hylira™ Gel is excreted in human milk.

See 17 for PATIENT COUNSELING INFORMATION.

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*Sections or subsections omitted from the full prescribing information are not listed.

1 INDICATIONS AND USAGE

Hylira™ Gel is indicated in the treatment of symptoms associated with xerosis (dry, scaly skin).

2 DOSAGE AND ADMINISTRATION

Apply to the affected area(s) and rub in thoroughly. Use a liberal amount two to three times daily or as directed by a physician. For topical use only. Not for ophthalmic use.

3 DOSAGE FORMS AND STRENGTHS

Gel; sodium hyaluronate, 0.2% w/w (0.17% at MW 2.0 megadaltons, 0.02% at MW 1.2 megadaltons, and 0.01% at 0.2 megadaltons); clear, hypoallergenic, viscoelastic gel.

4 CONTRAINDICATIONS

Do not administer to patients with known hypersensitivity to the listed ingredients.

5 WARNINGS AND PRECAUTIONS

Use of this product should be discontinued if hypersensitivity to any of the ingredients is noted. For external use only. Avoid contact with eyes, lips, and mucous membranes.

6 ADVERSE REACTIONS

If any adverse reaction occurs, discontinue use and seek the attention of a physician.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Hylira™ Gel. It is also not known whether Hylira™ Gel can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

8.3 Nursing Mothers

It is not known if Hylira™ Gel is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Hylira™ Gel is administered to a nursing woman.

11 DESCRIPTION

Hylira™ Gel is a clear, hypoallergenic, viscoelastic gel specially formulated with 0.2% w/w sodium hyaluronate (0.17% at MW 2.0 megadaltons, 0.02% at MW 1.2 megadaltons, and 0.01% at 0.2 megadaltons), a mucopolysaccharide found in high concentrations within mammalian skin, cartilage, and synovial fluid. Hylira™ Gel also contains purified water USP, carbomer, methylparaben, trolamine, and propylparaben. The sodium hyaluronate has the structural formula:

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies of Hylira™ Gel in animals to evaluate the carcinogenic and mutagenic potential of the effect on fertility have not been conducted.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Hylira™ Gel is available in a 340 g (12 fl oz), NDC 63717-034-12, and 113 g (4 fl oz), NDC 63717-034-04, plastic bottles. Samples are available in a 22g (0.78 fl oz), NDC 63717-034-99, plastic bottle.

16.2 Storage

Store at controlled room temperature 20° - 25°C (68° - 77°F); excursions permitted 15°-30°C (59° - 86°F). [See USP Controlled Room Temperature]

16.3 Rx Only

17 PATIENT COUNSELING INFORMATION

Patients using Hylira™ Gel should receive the following information and instructions: Hylira™ Gel is to be used as directed by the physician, and should not be used for any other disorder other than for which it was prescribed. It is for external use only.

Avoid contact with eyes, lips, or mucous membranes. If the skin condition worsens with treatment, Hylira™ Gel should be promptly discontinued.

Manufactured for:

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www.hawthornrx.com



Patent Pending

03/08