HYGEL- dressing, wound, drug
Gentex Pharma

HyGel™

HyGel™

(Sodium Hyaluronate) 2.5% Rx Only

PRODUCT DESCRIPTION

HyGel™ is a clear viscous, odorless, aqueous gel composed principally of sodium hyaluronate, a derivative salt of Hyaluronic acid. The portion of sodium hyaluronate “w/w” in the formulation is 2.5%.

Hyaluronic acid is a molecule which is normally found in various parts of the body. Hyaluronic acid used in HyGel™ is derived from a synthetic source more specifically from a bacterial fermentation process. HyGel™ serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.

INGREDIENT

Sodium hyaluronate (2.5%)

OTHER INGREDIENTS

Other ingredients in HyGel™ are as follows:
Hydroxyethyl cellulose, methylparaben, as well as polyethylene glycol, and purified water, USP.

INDICATIONS FOR USE

Rx Only:
Under the supervision of a healthcare professional;

- HyGel™ is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative and donor sites), mechanically or surgically debrided wounds, and for second degree burns.
- HyGel™ is indicated for the management and relief of burning, itching, and pain associated with various types of dermatoses; including atopic dermatitis, allergic contract dermatitis and radio-dermatitis.

CONTRAINDICATIONS

Do not administer to patients with known hyper-sensitivity to the components of this product.

WARNINGS

- The prolonged use of the product may give rise to a sensitization phenomenon. Should this occur, discontinue use of the product immediately and consult a healthcare professional.
- To prevent the possibility of cross infection, a tube of HyGel™ should be used on one patient only.
- Direct contact with the wound and the container should be avoided.
- Do not use in case of package damage.
- Do not use the product after the expiry date noted on the package.
- Keep out of reach of children.

PRECAUTIONS AND OBSERVATIONS

Rx Only:

Consult a healthcare professional if;

1. Signs of infection occur, increased pain, bleeding or wound drainage.
2. There is a change in wound color and/or odor.
3. The wound does not begin to show signs of healing in a few days.
4. Any other unexpected symptoms occur.

Under the supervision of a healthcare professional;

• The treatment of any leg ulcers, pressure ulcers, diabetic ulcers and surgically debrided wounds should be under the supervision of a healthcare professional.
• Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers).
NOTE: The control of blood glucose as well as appropriate pressure relief measures should be provided with diabetic foot ulcers.
• If the wound becomes infected, please immediately consult with a healthcare professional as to whether use of HyGel™ should be continued.
• HyGel™ is for external use only.

HOW TO USE

For Wounds;

1. First, clean the ulcer or other wound with normal saline solution (other cleaning agents are not recommended). Normal saline solution can be obtained through your location pharmacy.
NOTE: Debridement (surgical cleaning) of the wound may be performed at the discretion of the healthcare professional.
2. Remove excess moisture with a dry gauze.
3. Apply HyGel™ liberally into the cavity of the ulcer or wound site and the surrounding area.
4. Apply a non-stick gauze dressing over the wound site.
NOTE: Once HyGel™ is applied the gel should not be touched.
5. Finally, wrap a self-adhesive bandage over the non-stick gauze dressing.
6. Repeat the entire process of wound cleaning, applying HyGel™, and bandaging daily, or as needed.
7. Visit a healthcare professional as recommended.

For Dermatoses;

1. Using a few gentle strokes to smooth the gel across the skin in the same direction as hair growth, apply to the affected areas of the skin on a regular basis and as often as required.
2. If necessary, allow time for any excess to penetrate into the skin. Do not rub the skin vigorously.
3. You can apply HyGel before and after washing; showering or having a bath to help condition your skin and stop it from drying further.
4. If you are applying another topical treatment to the same areas of skin, try to avoid mixing the two products. You may choose to apply the treatments alternately, leaving sufficient time to allow the previous application to penetrate the skin.

HOW SUPPLIED

HyGel™ is available in a 10 gram single tube with tamper evident seal, NDC 15014-105-10, a carton with four 10 gram tubes with tamper evident seal, NDC 15014-105-40, and a 75 gram tube with tamper evident seal, NDC 15014-105-75. Do not use if tamper evident foil seal is broken or missing.

Lot number and expiry date are located on the crimped end of the tube.

STORAGE

Store in a cool dry place; at room temperature. Temperature should not exceed 35°C/95°F. Protect from freezing.

FURTHER INFORMATION

If further information, contact;
Gentex Pharma
121 Marketridge Drive
Ridgeland, MS 39157
Phone: (601) 990-9497
www.hygeltopical.com

Distributed by:
Gentex Pharma
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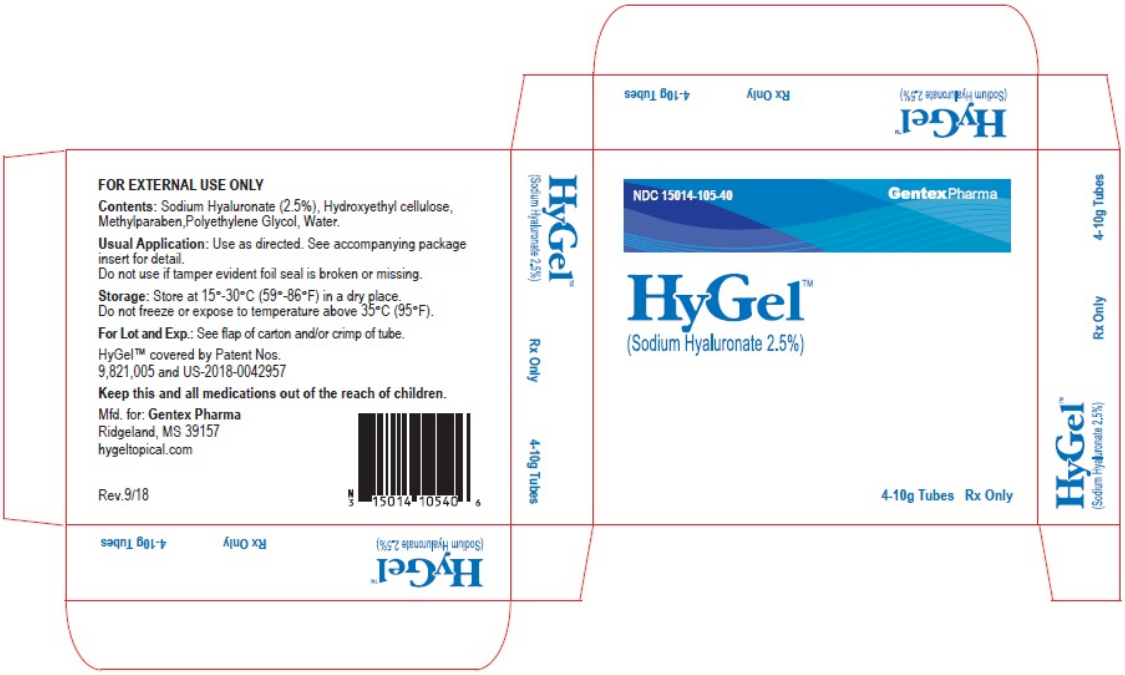
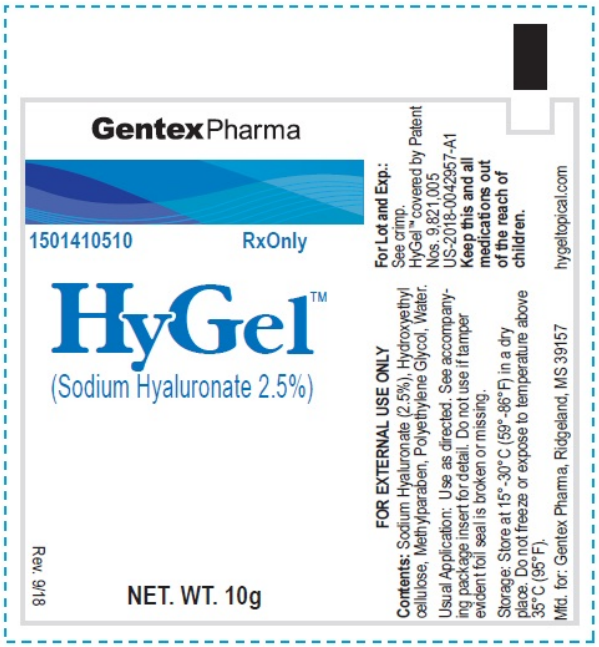
HyGel is covered by US-2018-0042957-A1
HyGel is covered by Patent Filing No. 9,821,005

Packaging

CARTON LABEL



TUBE LABEL



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Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:15014-105

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NHRIC:15014-105-40	4 in 1 CARTON		
1	NHRIC:15014-105-10	10 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NHRIC:15014-105-75	75 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K143527	09/12/2018	

Labeler - Gentex Pharma (625752014)

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