



Approved as is

Date:.....

Henry Schein® Topical Skin Adhesive,
Henry Schein® Topical Skin Adhesive Blue,
Henry Schein® Flexible Topical Skin Adhesive

Signature

Package Insert



Before using product, read the following information thoroughly.

CAUTION: Federal law restricts this device to sale and use by, or on the order of, a physician.

IMPORTANT! This insert is designed to assist in using Henry Schein® Topical Skin Adhesive. It is not a reference to surgical techniques.

DESCRIPTION:

Henry Schein® Topical Skin Adhesive, Henry Schein® Topical Skin Adhesive Blue, and Henry Schein® Flexible Topical Skin Adhesive are sterile, liquid topical skin adhesives composed of n-Butyl-2-Cyanoacrylate monomer. Henry Schein® Flexible Topical Skin Adhesive is a variation of Henry Schein® Topical Skin Adhesive and Henry Schein® Topical Skin Adhesive Blue, the difference is Myristic acid and Triacetin has been added to the Henry Schein® Flexible Topical Skin Adhesive, to allow the film to remain flexible. Henry Schein® Topical Skin Adhesive is provided as a colorless liquid, and Henry Schein® Topical Skin Adhesive Blue and Henry Schein® Flexible Topical Skin Adhesive are colored with D&C Violet #2 dye in order to make it easier to see the thickness of the layer being applied. Henry Schein® Topical Skin Adhesive, Henry Schein® Topical Skin Adhesive Blue, and Henry Schein® Flexible Topical Skin Adhesive topical skin adhesives are supplied in 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within an aluminum pouch so the ampoule can remain sterile. Henry Schein® Topical Skin Adhesive remains liquid until exposed to acidic, basic, alcohol, water or water-containing substances, including tissues. Henry Schein® Topical Skin Adhesive cures (polymerizes exothermically) and forms a film that bonds to the underlying surface. All references to Henry Schein® Topical Skin Adhesive herein refer to Henry Schein® Topical Skin Adhesive (without dye), Henry Schein® Topical Skin Adhesive Blue (with dye) and Henry Schein® Flexible Topical Skin Adhesive unless stated otherwise.

In vitro studies have shown that Henry Schein® Topical Skin Adhesive acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established. See INSTRUCTIONS FOR USE.

INDICATIONS:

Henry Schein® Topical Skin Adhesive, Henry Schein® Topical Skin Adhesive Blue, and Henry Schein® Flexible Topical Skin Adhesive are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Henry Schein® Topical Skin Adhesive, Henry Schein® Topical Skin Adhesive Blue and Henry Schein® Flexible Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS:

- Henry Schein® Topical Skin Adhesive is not to be applied below the surface of the skin. The liquid adhesive will react exothermically with tissue; the polymerized adhesive is not absorbed by any tissues and may elicit a foreign body reaction.

- Henry Schein® Topical Skin Adhesive is not to be applied to any internal organs, blood vessels, nerve tissue, mucosal surfaces or mucocutaneous junctions, areas with dense natural hair, or within the conjunctival sac of the eye.
- Henry Schein® Topical Skin Adhesive is not to be applied to the surface of the eye. If the eyelids are accidentally bonded closed, release eyelashes with warm water by covering with a wet pad. The adhesive will bond to eye protein and will cause periods of weeping which will help to debond the adhesive. Keep the eye covered until debonding is complete – usually within 1 to 3 days. Do not force the eye open.
- Henry Schein® Topical Skin Adhesive is not to be applied to wounds subject to high skin tension or on areas of increased skin tension such as the elbows, knees, or knuckles. Henry Schein® Topical Skin Adhesive is not to be used in areas of skin excision.
- Henry Schein® Topical Skin Adhesive is not to be applied to wounds that show evidence of infection, gangrene or wounds of decubitus etiology.
- Henry Schein® Topical Skin Adhesive is not to be used on patients with known preoperative systemic infections, uncontrolled diabetes, or diseases or conditions that are known to interfere with the wound healing process.
- Henry Schein® Topical Skin Adhesive is not to be used on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, or the dye D&C Violet #2.

WARNINGS:

- Henry Schein® Topical Skin Adhesive should be used only on wounds that have been thoroughly cleaned, debrided and have easily apposed wound edges.
- Henry Schein® Topical Skin Adhesive generates a small amount of heat during polymerization and should not be applied to tissues that may be affected by such heat.
- Henry Schein® Topical Skin Adhesive should always be applied very sparingly, either as minute drops or as a very thin film along the edges of the wound. Heavy application may cause thermal damage to tissues, and delayed healing may result.
- Henry Schein® Topical Skin Adhesive should not be applied to wet wounds. Excess moisture, such as water or alcohol, may accelerate polymerization, resulting in the generation of excess heat.
- Use of Henry Schein® Topical Skin Adhesive may result in localized sensitization or irritation reactions.
- Application and/or migration of either version of the product below the surface of the skin will impair the healing process by forming a barrier between tissue edges.
- Henry Schein® Topical Skin Adhesive Blue and Henry Schein® Flexible Topical Skin Adhesive migration (leak) below the epidermal surface may result in "tattooing" of the underlying tissue.
- Henry Schein® Topical Skin Adhesive will readily adhere to most substrates. Care should be taken to avoid unwanted contact with the adhesive during polymerization. Polymerized adhesive can be removed from metal instruments with acetone. Accidental bonding of materials other than tissues may be reversed by peeling apart the adhered surfaces with the aid of warm soapy water, petroleum gel, saline solution, or 5% solution of sodium bicarbonate.
- Accidental bonding of unwanted skin may occur. Do not pull apart skin. Instead, accidental bonding of unintended areas of skin of the body can be corrected with the use of acetone or by soaking in warm water until the skin may be separated.

PRECAUTIONS:

- Wounds should be kept dry following closure with Henry Schein® Topical Skin Adhesive. Do not apply topical medications following closure.
- In the event of spillage, Henry Schein® Topical Skin Adhesive can be absorbed with talc. Flush area with water to solidify the adhesive.

- Henry Schein® Topical Skin Adhesive has not been evaluated in patients with a history of hypertrophic scarring or keloid information.
- Small quantities of Henry Schein® Topical Skin Adhesive should be used during wound repair because use of excess Henry Schein® Topical Skin Adhesive can result in tissue damage due to the cumulative heat dissipated during device polymerization.

POSSIBLE ADVERSE EVENTS:

Clinical experience with Henry Schein® Topical Skin Adhesive used outside the United States suggests that the following adverse events may occur:

- Dehiscence with the need for re-closure
- Suspected infection
- Bonding to unintended tissues
- Thermal discomfort during polymerization
- Allergic reaction
- Foreign body reaction
- Tattooing
- Chronic non-healing of a wound

HOW SUPPLIED:

Henry Schein® Topical Skin Adhesive is supplied in 0.5 ml single patient use ampoules. Each ampoule is sealed within an aluminum pouch so the exterior of the ampoule can remain sterile. Henry Schein® Topical Skin Adhesive is supplied in boxes of 10 individual ampoules.

INSTRUCTIONS FOR USE:

1. Inspect and clean the wound, provide local anesthesia for adequate cleansing and debridement of any devitalized structures, assure hemostasis, close the dermis as needed, and assure that surface edges are easily apposable before applying Henry Schein® Topical Skin Adhesive.
2. For wounds at risk for tension, provide relief of potential stress along the wound line by approximating wound edges with subcuticular sutures before applying Henry Schein® Topical Skin Adhesive to the skin surface.
3. Open the aluminum pouch to expose the sterile, single patient use ampoule.
4. The ampoule is held at its tip and rigorously shaken downwards to ensure that no adhesive remains within the cannula. Then the ampoule is opened by twisting off the ribbed tip of the cannula. It is advisable to hold the yellow part of the ampoule between two fingers, holding it vertically with the thin end pointing upward, while opening the ampoule. This will prevent any lost Henry Schein® Topical Skin Adhesive from escaping from the ampoule when opening.
5. To express Henry Schein® Topical Skin Adhesive from the ampoule tip, apply light pressure to the ampoule.
6. Appose the tissue edges and hold in apposition while applying Henry Schein® Topical Skin Adhesive tissue adhesive. Hold in apposition for approximately 30 seconds to allow Henry Schein® Topical Skin Adhesive and Henry Schein® Topical Skin Adhesive Blue and 60 seconds for Henry Schein® Flexible Topical Skin Adhesive to polymerize and to prevent migration between wound edges.
7. Apply Henry Schein® Topical Skin Adhesive to the easily apposed wound edges very sparingly, either as minute drops or as a very thin film along the top edges of the wound. Avoid heavy application.
8. After applying Henry Schein® Topical Skin Adhesive and Henry Schein® Topical Skin Adhesive Blue, maintain light pressure along the wound line to maintain apposition for approximately 30 seconds to allow the adhesive to cure. After applying Henry Schein® Flexible Topical Skin Adhesive, maintain light pressure along the wound line to maintain apposition for approximately 60 seconds to allow the adhesive to cure.

9. After Henry Schein® Topical Skin Adhesive application is completed; discard the ampoule with any remaining adhesive by putting the ribbed tip over the thin end of the cannula.

PATIENT INSTRUCTIONS (Available in a separate document for distribution to the patient):

The following information should be shared with the patient:

- Patients may shower and/or bathe but allow only transient wetting of the treatment site. The site should not be soaked or exposed to prolonged wetness for 7–10 days or until polymerized film has sloughed off.
- Do not apply any medications or cream to the wound.
- Do not pull or pick at the wound.
- Avoid extreme physical activity that might dislodge or impact the wound surface.
- Report any unusual discomfort, redness, drainage, swelling and/or other concerns regarding your wound to your doctor.
- If they are recommended by your doctor, you should keep the wound dry with a non-stick, non-medicated and water-resistant bandage. While not required specifically for this product, your doctor in his/her expert opinion may recommend the use of a bandage as a special precaution for your individual circumstance.

STORAGE:

- Henry Schein® Topical Skin Adhesive must be stored in its original sealed aluminum pouch.
- Henry Schein® Topical Skin Adhesive should be kept in the aluminum pouch to maintain stability of the liquid adhesive at room temperature.
- Henry Schein® Topical Skin Adhesive and Henry Schein® Topical Skin Adhesive Blue should be stored at ambient conditions in temperatures at or below 72°F (22° C) away from moisture and direct heat.
- Henry Schein® Flexible Topical Skin Adhesive should be stored at ambient conditions in temperatures at or below 77°F (25° C) away from moisture and direct heat.
- Do not expose Henry Schein® Topical Skin Adhesive to elevated temperatures (i.e., 104–140° F, 40–60° C) for more than eight hours.
- Do not use Henry Schein® Topical Skin Adhesive after the expiration date shown on the aluminum pouch, preceded by the expiration symbol.

STERILITY:

Henry Schein® Topical Skin Adhesive is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged.

CUSTOMER SERVICE

For further information regarding Henry Schein® Topical Skin Adhesive, Henry Schein® Topical Skin Adhesive Blue and Henry Schein® Flexible Topical Skin Adhesive please contact Henry Schein® Topical Skin Adhesive Customer Service at

1-800-PSCHEIN (1-800-772-4346)

MADE IN GERMANY

Distributed by (in US only)

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