exofin®

TOPICAL SKIN ADHESIVE

High Viscosity, 2-Octyl Cyanoacrylate

1.0 g (~1.0 ml)

CHEMENCE

INSTRUCTIONS FOR USE

CE 2797

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BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

exofin® Topical Skin Adhesive (High Viscosity, 2-Octyl Cyanoacrylate)

DESCRIPTION

exofin® Topical Skin Adhesive is a sterile, high viscosity liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colourant D & C Violet #2. It is provided in a 1.0 g single use aluminium collapsible tube and applicator packaged in a rigid PETG blister with Tyvek lid. The applicator is comprised of a self-puncturing cap and a soft elastomeric tip, which allows the adhesive to spread uniformly. As applied to skin, the liquid is syrup-like in viscosity and polymerises within minutes. The increased viscosity in **exofin**® is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site.

INDICATIONS

exofin® is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. **exofin**® may be used in conjunction with, but not in place of, deep dermal sutures. In vitro studies have shown that **exofin**® 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. **exofin**® should be applied by trained medical or nursing staff.

CONTRAINDICATIONS

- **exofin**® is not be applied to any internal organs, on or near mucosal surfaces or across mucocutaneous junctions, on areas with dense natural hair, within the conjunctival sac of the eye or on skin which may be regularly exposed to body fluids.
- **exofin**® is not to be applied to wounds of decubitus etiology or on animal or human bite wounds.
- **exofin**® is not to be used on any wound with evidence of active microbial or fungal infections, or gangrene.
- **exofin**® is not to be used on patients with preoperative systemic infections, uncontrolled diabetes or other diseases or conditions that are known to interfere with wound healing.
- **exofin**® is not to be used on patients with a known hypersensitivity to cyanoacrylate, formaldehyde or benzethonium chloride.

WARNINGS

- **exofin**® is a fast setting adhesive capable of adhering to most body tissues and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerisation of **exofin**® may be accelerated by water or fluids containing alcohol. **exofin**® should not be applied to wet wounds.
- **exofin**® should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with **exofin**®, position the patient so that any run-off of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. **exofin**® will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where **exofin**® is intended to adhere.
- **exofin**® should not be used below the skin because the polymerised material is not absorbed by tissue and can elicit a foreign body reaction.
- **exofin**® should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period or unless skin tension has been removed by application of another wound closure device (e.g., sutures, skin staples, or adhesive wound closure strips) prior to application of **exofin**®.
- **exofin**® treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, oedema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- **exofin**® should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- **exofin**® should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anaesthetic should be used when necessary to assure adequate cleansing and debridement.
- Multiple use of the device in different patients increases the possibility of transfer of infectious agents.
- **exofin**® is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, **exofin**® should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- **exofin**® polymerises through an exothermic reaction in which a small amount of heat is released. With the proper application technique of **exofin**® any potential sensation of heat or pain experienced by the patient is minimised.
- Do not resterilize **exofin**®.
- Do not place **exofin**® in a procedure pack/tray that is to be sterilized prior to use. Exposure of **exofin**®, after its final manufacture, to excessive heat (as in autoclaves) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.
- Potential systemic toxicity of this product is unknown.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with **exofin**®, as these substances can weaken the polymerised film and allow for wound dehiscence. **exofin**® permeability by topical medications has not been studied.
- **exofin**® permeability by fluids is not known and has not been studied.
- **exofin**®, as a liquid, is syrup-like in viscosity. To prevent inadvertent flow of liquid **exofin**® to unintended areas the patient should be positioned so that inadvertent

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flow would be away from unwanted areas.
- Hold applicator horizontal and away from yourself and the patient and squeeze the contents of the tube from the bottom of the tube towards the applicator.
- **exofin®** should be used immediately after applying the applicator and piercing the aluminium tube membrane because the adhesive will polymerise in the applicator, rendering the device unusable.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® antiseptics, HIBICLENS® (chlorhexidene gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of **exofin®** on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of **exofin®** on the following wounds has not been studied: animal or human bites; puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with **exofin®** and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of **exofin®** on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS

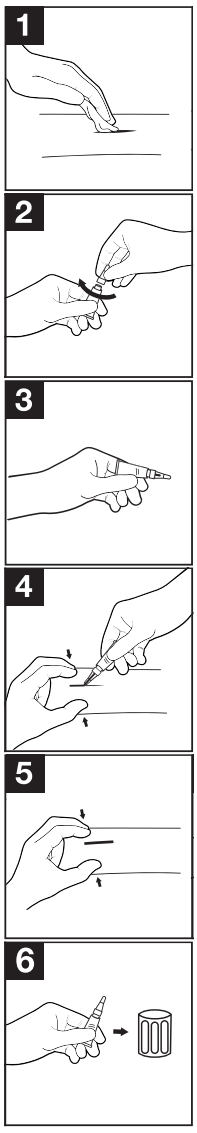
Clinical use of cyanoacrylate-based topical skin adhesives has suggested that the following adverse events may occur: wound dehiscence; infection; acute inflammation including; erythema and oedema; bonding to unintended tissues such as the eye; thermal discomfort during polymerisation; allergic reaction; and foreign body reaction. Reactions may occur in patients who are hypersensitive to cyanoacrylate, formaldehyde or benzethonium chloride. See CONTRAINDICATIONS.

CLINICAL STUDIES

Topical skin adhesives comprised on monomeric 2-octyl cyanoacrylate have been evaluated by numerous organizations in controlled clinical studies in comparison to sutures, staples, adhesive strips and other cyanoacrylate-based topical skin adhesives to close incisions and trauma-induced lacerations. These Instructions for Use have been generated based on the results of these available published studies.

DIRECTIONS FOR USE

1. The incision or trauma site must be clean and dry before applying adhesive. Ensure that the wound edges are easily approximated.
2. Screw the Applicator Tip onto the threaded tube in a clockwise direction until the applicator is tight and seated on the tube. The applicator will puncture the foil membrane on the tube once seated and adhesive will be allowed to flow.
3. While holding the tube horizontal and away from the patient, gently squeeze the tube from the bottom, moving the adhesive upward until it becomes visible through the applicator device.
4. While approximating skin edges, apply adhesive to the wound site by squeezing the aluminium tube gently and continuously in a back and forth motion while spreading over wound site.
5. Continue to hold the wound edges in approximation until the adhesive becomes tacky, typically less than 30 seconds. A smooth and even coat of adhesive is desirable. Once adhesive has completely polymerised (non-tacky) you may cover the site with a secondary bandage. If a secondary bandage is used, DO NOT apply to the adhesive area until it is completely tack free. Applying while tacky may result in adhesive removal when removing secondary bandage and possibly dehiscence of the wound site.
6. Discard adhesive device according to normal protocol after use.



ADDITIONAL INFORMATION

NOTE: **exofin®** polymerises through an exothermic reaction. If the liquid **exofin®** is applied so that large droplets are allowed to remain without being evenly spread, the patient may experience a sensation of heat or discomfort. The sensation may be higher on sensitive tissues.
NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing **exofin®** into the wound. **exofin®** within the wound could delay wound healing and/or result in adverse cosmetic outcome.
NOTE: Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerisation is expected when the **exofin®** layer is no longer sticky.
NOTE: Do not apply liquid or ointment medications onto wounds closed with **exofin®** because these substances can weaken the polymerised film, leading to wound dehiscence.
NOTE: Protective dry dressings such as gauze may be applied only after **exofin®** film is completely solid/polymerised: not tacky to the touch (approximately five minutes after application). Allow the adhesive to fully polymerize before applying a bandage. If a dressing, bandage, adhesive backing or tape is applied before complete polymerisation, the dressing can adhere to the film. The film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur.
NOTE: Patients should be instructed not to pick at the polymerised film of **exofin®**. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.
NOTE: Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
NOTE: Patients should be instructed that until the polymerised film of **exofin®** has sloughed naturally (usually in 5 to 10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.
NOTE: If removal of **exofin®** is necessary for any reason, carefully apply petroleum jelly or acetone to the **exofin®** film to help loosen the bond. Peel off the film, do not pull the skin apart.

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HOW SUPPLIED

exofin® is supplied sterile, in a pre-filled, single-use aluminium tube and applicator. The applicator tube contains the liquid adhesive. The applicator tube and the applicator tip are packaged in a rigid PETG blister with Tyvek lid to maintain the device sterility until opened or damaged. **exofin®** is be available in boxes of 10 devices.

STORAGE — Recommended storage conditions: below 30°C away from direct heat. Do not use after expiry date.

STERILITY — **exofin®** is originally sterilized by dry heat and ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.

STERILE SINGLE USE ONLY

REPORTING — Healthcare Professional should use the following number +1-844-633-4583, when reporting adverse reactions or potentially threatening complications involving **exofin®.**

Not made with natural rubber latex.

Electronic Instructions For Use
www.ifu.chemencemedical.com

Do not re-use

Do not resterilise

Do not use if package is opened or damaged

Keep dry

Temperature limitations

Keep away from sunlight

Use by date

MD Medical Device

STERILE EO Sterilised using ethylene oxide

STERILE Sterilised using dry heat

Importer

Manufacturer

Distributor

EC REP European Authorized Representative

LOT Batch code

REF Catalogue number

CE mark of conformity with European Directive

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