



EPIGLUE
PHARMA PRIVATE LIMITED

N-BUTYL-2-CYANOACRYLATE
EPIGLUE
TOPICAL SKIN ADHESIVE



Room Temperature Storage
High Purity & Product Stability
Great Cosmetic Outcomes
Easy application
Soft Polymer Micro Tip Delivery
Versatile Indicative Uses
Minimal Post-Surgical Infection
Patented Micro Delivery System



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N-BUTYL-2-CYANOACRYLATE EPIGLUE TOPICAL SKIN ADHESIVE

N-BUTYL-2-CYANOACRYLATE

Cyanoacrylate gets polymerized very quickly and becomes in-effective when it gets in contact even with trace moisture content generally present in the atmosphere

This sensitivity of cyanoacrylate tissue adhesive towards atmospheric moisture has been a insurmountable problem for manufacturers as well as for the doctors

The patented micro delivery system package of EPIGLUE, solves the problems in handling of cyanoacrylate both in shipping and handling and as well as in the final usage



ADVANTAGES

Micro Delivery of cyanoacrylate at the wound site helps to just add the right amount to close the wound. Accidental excess application is kept to a minimum when using EPIGLUE which in turn helps in quick healing and decrease in tissue damage due to heat of polymerization

Micro Delivery system provides an option to apply tissue adhesive at hard to reach places as well as incisions and cuts

The crushable ampoule system helps to keep the product from solidifying due to atmospheric moisture. This guarantees the product to remain in liquid form and hence effective and active at time of application

A great convenience to doctors as they have a world class product in their hands

Product is delivered via soft polymer micro tip thus reducing accidental injuries that may happen while applying the product over the wound site

PATENTED MICRO DELIVERY SYSTEM

Applying cyanoacrylate at the site of wound has been a problem with product packaged in plastic ampoule. The product is drawn using a syringe from the container and then the plunger is pushed to release drops of cyanoacrylate over the two edges of the skin

EPIGLUE has a patented micro delivery system which is built into the package itself

When pressed on the plastic jacket firmly between two fingers, the glass ampoule inside is crushed which releases butyl cyanoacrylate into the plastic container

The plastic container contains a built in filter to stop glass particle debris

The product comes out through the needle as micro drops. The flow is easily controlled by applying required pressure on the plastic jacket between the two fingers



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LONG TERM STABILITY

Some products were known to get polymerized (and rendered ineffective), within couple of months of shelf life. It has been also observed some packages getting solidified within days of shipment to the distributors from the manufacturing site

Epiglu is stable with respect to temperature, dust and moisture

The active component, monomer s form of n-butyl-2-cyanoacrylate, remains as clear blue liquid even when left at room temperature

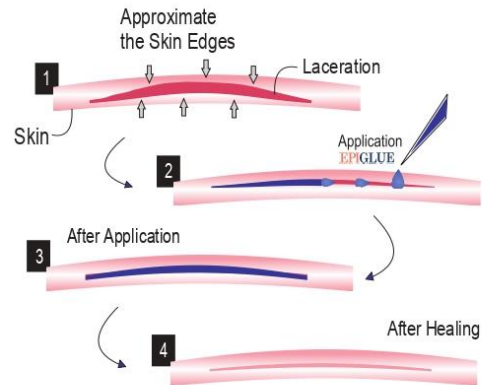
The much needed stability is due to the filling of cyanoacrylate is a hermetically sealed crushable glass ampoule. As the glass walls are impermeable to moisture the product remains in liquid form for a long time even at room temperature storage

The surrounding sheath jacket made up of a polymer gives mechanical strength to the device and doubles as a product usage and handling system

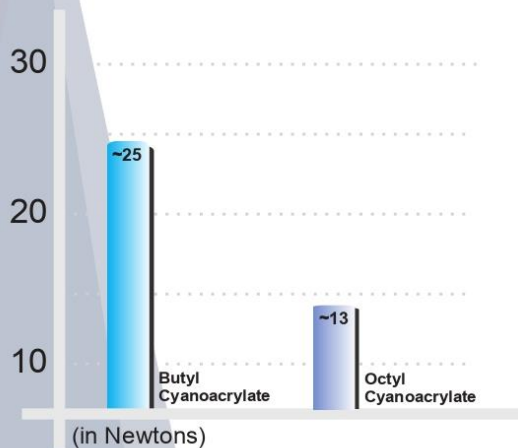


SUGGESTED INDICATIONS

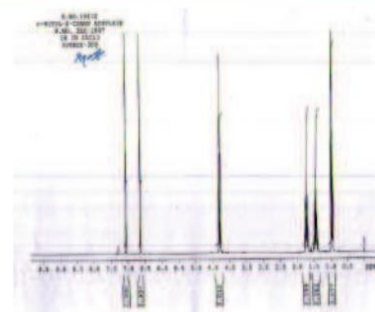
ENT surgery	: Tympanic perforations
Dental surgery	: Dental implants, Periodontal surgery, Gingivectomy, extracting sites.
General surgery	: Laparotomy, Hernia, Appendicitis
Plastic surgery	: Cleft lip, Excision of scars, Skin graft
Gynaecology	: Episiotomy, Cesarean Section, Tubectomy
Orthopaedic	: Tendon repair, bone graft, Cartilage binding
Surgical Oncology	: Thyroid & Breast Malignancy surgery
Pediatric	: Lacerations, Hernia, Cleft palate, Cleft lip



TENSILE STRENGTH COMPARISON



N.M.R CHART



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WARNING

EPIGLUE IS NOT INJECTION
NOT FOR INTRAVENOUS USE
NOT FOR INTRA-MUSCULAR USE
ONLY TO BE USED BY SURGEON OR A
REGISTERED MEDICAL PRACTITIONER
EPIGLUE IS A SINGLE USE MEDICAL DEVICE

PRODUCT INFORMATION

INDICATIONS

Epiglué is indicated for the closure of topical skin cuts, wounds and incisions including laparoscopic incisions, which have easily approximated edges with minimal tension and are thoroughly cleansed and without any evidence of infection

CONTRA-INDICATIONS

Epiglué should not be used internally (Under the tissue or skin) as it may lead to foreign body reaction as the product is not absorbed in the tissues

Epiglué should not be used or applied on any internal organs or vascular bodies or brain tissue

Epiglué is not to be used to close any wounds or cuts that show infection

Epiglué is not to be used on patients that are allergic or hypersensitive to tissue adhesives and any products containing cyanoacrylate products and formaldehyde

Tissue Adhesives are not to be used in patients that have diseases or conditions that are known to interfere in healing process

Epiglué is not to be used on cuts and wounds where extreme skin tensions occur like elbows and knees.

WARNINGS

Epiglué is not an injection and not for intravenous or intramuscular use

Epiglué is to be applied on thoroughly cleansed cuts or wounds that do not show any evidence of infection. Use Epiglué sparingly, as excess application may lead to tissue damage due to heat of polymerization

Do not introduce Epiglué into the wound as it may hinder wound healing

Epiglué is a free flowing blue liquid. If the product appears solidified or not free flowing 'or' the package appears damaged or opened please discard the package immediately

Epiglué is a single use device and should be used immediately after opening the package

STORAGE

Epiglué should be stored below 40°C/104°F. Refrigeration not required. Keep away from moisture and direct heat

PRECAUTIONS

As Epiglué bond to many surfaces, care should be taken so that gloves, surgical instruments do not come into contact during applications

Spilt product can be flushed with water which solidifies the product

Care should be taken not to introduce the product into the eyes as it can bond the eyelids

In case of accidental bonding, do not pull apart the bonded edges. Use copious amount of water to flush out the product

If bonding already occurred, use petroleum products like acetone or dimethyl formamide to dissolve the polymerized product.

Usually within three to four days separation occurs due to the moisture and tears in the eyes

USE OF THE DEVICE

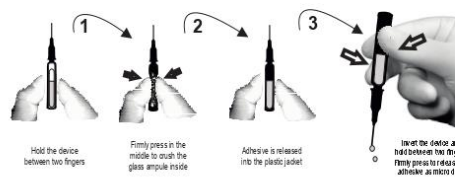
The device is held between forefinger and thumb. Firm pressure is applied on the middle of the plastic jacket to crush the glass ampoule inside. The adhesive is released into the plastic jacket

The device is turned upside down and moved near the site of application. By applying firm pressure using the fingers, micro drops of adhesive are delivered on to the closely approximated skin edges

The tip of the device is not allowed to get in contact with the skin, tissue or open wound during the whole procedure.

Wait for 30 to 60 seconds for the polymerization and bonding to complete

The closed cut or wound can be supplemented with wound tapes or sutures if required especially in case of a long cut or there is a possibility of stretching exists



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