

# Quantity Limit

## Lidocaine, Lidocaine-Prilocaine, Lidocaine -Tetracaine Dermatological Topical

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are included.

Brand Name	Generic Name	Dosage Form
lidocaine HCl 2% (all brands)	lidocaine HCl 2%	gel
lidocaine HCl-collagen-aloe vera 2% (all brands)	lidocaine HCl-collagen-aloe vera 2%	gel
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel prefilled syringe
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	solution
lidocaine 5% (all brands)	lidocaine 5%	ointment
lidocaine 2.5% and prilocaine 2.5% (all brands)	lidocaine 2.5% and prilocaine 2.5%	cream
Pliaglis	lidocaine and tetracaine 7-7%	cream
Synera	lidocaine and tetracaine 70-70 mg	patch

# Indications

## FDA-approved Indications

### Lidocaine HCl 2% Gel

For the local management of skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

### Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

### Lidocaine HCl 4% Gel

Lidocaine 4% Gel is indicated for the following:

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

### Lidocaine HCl Urethral/Mucosal 2% Gel

Lidocaine HCl 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

### Lidocaine HCl Urethral/Mucosal 2% Gel Prefilled Syringe

Lidocaine HCl jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

## Lidocaine HCl 4% Topical Solution

Lidocaine hydrochloride is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

## Lidocaine 5% Ointment

Lidocaine 5% ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx.

It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

## Lidocaine 2.5% and Prilocaine 2.5% Cream

Lidocaine and prilocaine cream, 2.5%/2.5% (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on:

- normal intact skin for local analgesia.
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

Lidocaine and prilocaine cream, 2.5%/2.5% is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

## Pliaglis (lidocaine and tetracaine 7-7% cream)

Pliaglis is indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

## Synera (lidocaine and tetracaine 70-70 mg patch)

Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions.

# Initial Limit Quantity

This quantity limit should accumulate across all products and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

These products are for short-term acute use; therefore, the intent is for prescriptions of the requested product to be filled one month at a time; there should be no 3 month supplies filled.

Product	1 Month Limit	3 Month Limit
lidocaine HCl 2% gel	30 gm or mL / 25 days	Does Not Apply
lidocaine HCl-collagen-aloe vera 2% gel	30 gm or mL / 25 days	Does Not Apply
lidocaine HCl 4% gel	30 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel	60 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel prefilled syringe	60 mL / 25 days	Does Not Apply
lidocaine HCl 4% topical solution	50 mL / 25 days	Does Not Apply
lidocaine 5% ointment	50 gm / 25 days	Does Not Apply
lidocaine-prilocaine 2.5-2.5% cream	30 gm / 25 days	Does Not Apply
Pliaglis 7-7% (lidocaine-tetracaine cream)	30 gm / 25 days	Does Not Apply
Synera 70-70 mg (lidocaine-tetracaine patch)	2 patches / 25 days	Does Not Apply

## References

1. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
4. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; September 2022.
6. Lidocaine HCl 4% topical solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.
7. Lidocaine 5% ointment [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; October 2023.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2018.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
10. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
11. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.

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1329-H

12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
13. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
14. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
15. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed September 2024.

## Document History

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