

# Topi-CLICK® 35 Light SAFE™ Specifications



#### Topi-CLICK® 35 Light SAFE™: 35 mL, 0.25 mL per CLICK

**DESCRIPTION:** Topi-CLICK® 35 Light SAFE™ is USP Compliant to USP671 (250nm to 450 nm) and blocks UVA, UVB and Violet Light.

Topi-CLICK® 35 Light SAFE $^{\mathbb{M}}$  is a smart, effective topical dosing applicator designed to overcome the various limitations associated with pumps, syringes, tubes, tubs and jars. The Topi-CLICK® 35 Light SAFE $^{\mathbb{M}}$  can be used to dispense approximately 5 mL to 35 mL of a topical preparation depending on the volume to weight ratio of base and formula used.

Topi-CLICK® makes it easy to accurately measure the dose and apply topical medications to the intended area, thereby decreasing the risk of improper dosing and contamination while improving compliance and outcomes of therapy.

#### **FEATURES:**

- Each CLICK or turn of the base moves the plunger approximately 0.25 mL of volume space, thereby dispensing 0.25 mL of cream on average. The most common number of CLICKs used for one dose is 2 CLICKs or 0.50 mL volume space.
- Audible, visual and tacticle CLICK registrations for user recognition.
- Lower cost with simplified labeling labels as fast and easily as a prescription bottle.
- Built-in applicator to prevent medication transference to unintended areas.
- "Refill" reminder badge helps patients to reorder in a timely manner.
- Designed to resist accidental discharge in purse, pocket or luggage.

TECHNICAL SPECIFICATIONS: Topi-CLICK® 35 Light SAFE™

Dispenser Volume:Up to 37 mLDelivery Volume:Up to 34 mLDispense per CLICK:0.25 mLApproximate Residual:2.5 mL

**Approximate Priming:** 0.50 mL or 2 CLICKs

**Doses Provided:** When filling with 35 mL, the Topi-CLICK® will provide approximately 32 mL or

64 doses (at 2 CLICKs per dose or 128 CLICKs total).

- Registered FDA device, Class 1 Dispenser.
- Topi-CLICK's FDA Registration # is 3007142798 and the Device Listing Number is D003073.
- Materials compliant with FDA 21.177 code, which is the requirement for United States Phamacopeia (USP <661>).
- Made of FDA grade materials | BPA and Phthalate free.
- Topi-CLICK® 35 Light SAFE™ is USP Compliant to USP671 (250nm to 450 nm) and blocks UVA, UVB and Violet Light.
- Recycling Code is #5 🐴 . Visit http://doselogix.com/recycling-your-topi-click for more information on recycling Topi-CLICK®.

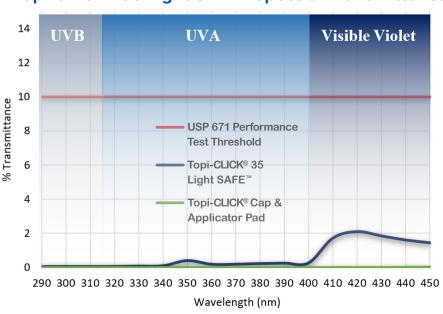
\*Volumes are approximate. As required for compounded prescription pharmaceuticals dispensed in volume dispensers, verify the weight to volume conversions thoroughly. See dispensing instructions at http://doselogix.com/downloads-how-it-works. One time use only.

<sup>1</sup>Topi-CLICK® 35 is the most accurate topical dosing dispenser among those compared in an independent study titled *Topical Metered Dosing Dispenser Performance Evaluation* by Analytical Research Laboratories. Request study at http://doselogix.com/accuracy\_study/.



## Topi-CLICK® 35 Light SAFE™

### **Topi-CLICK® 35 Light SAFE™ Spectral Transmittance**





#### SPECTRAL TRANSMITTANCE TEST REPORT: UVB to VISIBLE

#### **INDEPENDENT TEST RESULTS**

Material Tested N = 2	Average % UVB Spectrum Blocked	Average % UVA Spectrum Blocked	Average % Visible Violet Spectrum Blocked
Topi-CLICK® 35 Light SAFE™	>99.96%	>99.98%	>98.26%
Topi-CLICK® 35 Cap & Applicator Pad	>99.99%	>99.98%	>99.98%

#### **SUMMARY OF FINDINGS**

· Blocks light most likely to damage medications: UVA, UVB, and Violet Light.

#### STANDARDS AND QUALIFYING PROCEDURES

The techniques described in the following standards, as they apply to Moisture Vapor Transmission and Light Transmission, were used to test these samples.

- US Pharmacopeia USP39/NF34 Supplement 1 <671> Performance Testing (Light Transmission)
- US Pharmacopeia USP39/NF34 Supplement 2 <671> Performance Testing Method 1 (Moisture Vapor Transmission)

For general laboratory practices concerning UV measurements, the following standards are utilized for guidance in practical methods for the measurement of UV light:

- · ASTM E275 08 Describing the Measuring Performance of Ultraviolet Spectrophotometers
- ASTM E169 04 (2009) Standard Practices for General Techniques of Ultraviolet Quantitative Analysis



**Topical Dosing Applicators** 

### #1 in Accuracy Per Independent Study of Topical Dosing Dispensers



### **Patient, Physician and Pharmacist Benefits**

HRT / BHRT / Low T / Pain Management / Scar Care

- The most accurate topical dosing dispenser in an independent study by Analytical Research Laboratories<sup>1</sup>.
- Accuracy assures patients request refills on-time, every time.
- Built-in applicator for hands-free application, which lessens the risk of cross-contamination.
- Full dose is applied to the intended area.
- Ease-of-use increases patient satisfaction and compliance.
- Multiple colors for differentiating medications.
- Audible, visual and tactile CLICKs make it easy for patients to accurately dose medications.
- Has a Refill Badge<sup>™</sup> for prompting patients to act for on-time refills.
- Made of FDA grade materials | BPA and Phthalate free | UV block and is Recyclable. ♠
- UV block in plastic protects light sensitive topicals.



Topi-CLICK® 35 topical dosing applicators are available in ten vibrant colors.



Topi-CLICK® 140 topical dosing applicators are available in nine colors.



Topi-CLICK® 35 is a smart, effective topical dosing applicator designed to overcome the various limitations associated with pumps, syringes, tubes, tubs and jars. The Topi-CLICK® 35 can be used to dispense approximately 5 mL to 35 mL of a topical preparation. (0.25 mL/ CLICK)



Visit www.DoseLogix.com to view the complete color availability.

### Topi-CLICK® 140

The Topi-CLICK® 140 offers the same great dosing benefits as the Topi-CLICK® 35 but is designed for larger volume topical formulations up to 140 mLs. The friction-free 4Port™ domed applicator design allows dispensing of larger doses with ease and convenience. (0.50 mL / CLICK)

<sup>1</sup>Topi-CLICK® 35 is the most accurate topical dosing dispenser among those compared in an independent study titled Topical Metered Dosing Dispenser Performance Evaluation by Analytical Research Laboratories. Request study at http://doselogix.com/accuracy\_study/.





**Topical Dosing Applicators** 

## **Topi-CLICK® Patient Use Instructions**



#### STEP 1:

Lift off the cap of the Topi-CLICK® container by placing your thumb under the tab on the protective outer cap and pressing upward.



#### STEP 2

Turn the base to dispense the number of CLICKs specified in the instructions on your prescription label.



#### **STEP 3:**

Watch the visual indicators when rotating base. Be sure to leave the base in the registered CLICK position by aligning the base column with the tube node after each use.



#### **STEP 4:**

Apply topical medication by rubbing the area of skin as directed by your pharmacist using the built-in applicator. Continue rubbing until topical is completely absorbed into the skin.

IMPORTANT: The built-in applicator lessens the risk of cross-contamination and ensures the full dose is applied to the intended area.



#### STEP 5:

Replace cap after each dose to prevent evaporation. Be sure cap snaps on tightly.

Note Be sure to align ports when using the Topi-CLICK® 35 3Port™ cap and applicator.



#### STEP 6:

The bottom of the plunger is the indicating line; when it reaches the embossed line below the word "Refill" approximately 32 CLICKs are left. Approximately 12 CLICKs remain at the line above the word "Refill".

Follow instructions on provider's label before using the Topi-CLICK®.

<sup>1</sup>Topi-CLICK® 35 is the most accurate topical dosing dispenser among those compared in an independent study titled *Topical Metered Dosing Dispenser Performance Evaluation* by Analytical Research Laboratories. Request study at http://doselogix.com/accuracy\_study/.







Prescribe the #1 in Accuracy Topical Dosing Dispensers

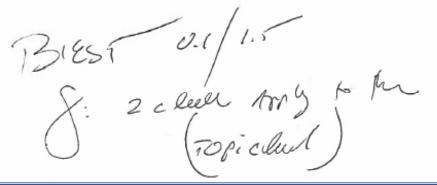
## **Compounded Medication**

Example Generic Name of Active Ingredients(s) / Strength or Dose (i.e., mL or %)

Dosage Form: (i.e., Transdermal Cream, Transdermal Gel)

Quantity:

Directions for Use:





## **Topi Patient Tips**<sup>™</sup>





## **Providing Patient Education**

Providing patient education is a top priority with DoseLogix.

The NEW Easy-Unpack™, 25 package of Topi-CLICK® 35s, contain Topi Patient Tips™ that can be inserted into each prescription to provide simple patient instructions.

Healthcare providers can be assured patients are using the Topi-CLICK® topical dosing applicator properly and receiving an accurate dose every time.







# **Topi-CLICK**® **Filling Instructions** Read all information, specifications and instructions carefully before filling and dispensing Topi-CLICKs.



#### STEP 1:

Fill the Topi-CLICK® dispenser with the desired amount of topical formulations using a Topi-CLICK® Filling Station, a spatula, EMP jar, or nozzle.



#### **STEP 4:**

Prime the Topi-CLICK® by turning the base until topical is dispensed and wipe off topical.

Be sure to leave the base in the registered CLICK position by aligning the base column with the tube node: See Step 3 of the **Patient** Use Instructions.



**Registered Position** 



#### STEP 2:

If needed while filling, stop periodically to tap the Topi-CLICK® on the palm of your hand, counter or Tap-n-CLICK™ to help settle the topical.



#### STEP 5:

Snap on the protective outer cap. (If the cap doesn't fit tight, it's an indication that the built-in applicator in #3 is not "snapped" down all the way.)

Note: Be sure to align ports when using the 3Port<sup>™</sup> cap and applicator.



#### **STEP 3:**

Put the built-in applicator (cap with a hole) on the top of the Topi-CLICK® container by aligning the inside key tabs with the slots on the top of the container tube and snap on.



#### STEP 6:

Apply center of label to the side of the Topi-CLICK® container which is opposite the "REFILL" and graduation marks.

For more information on dispensing amounts per CLICK see the Product Specification's at DoseLogix.com. See Patient User Instructions for information on how to apply topical medications using Topi-CLICK. Verify formulas and weight per volume as required for compounded prescription pharmaceuticals.