

Molluscum can finally be treated at home or on the go

# Because parents have enough to worry about.

Zelsuvmi™
(berdazimer) topical gel, 10.3%



Not an actual patient.

**The FIRST and ONLY FDA-approved at-home topical medication for treating molluscum contagiosum in patients 1 year of age and older.**

## What is ZELSUVMI?

ZELSUVMI is prescription medicine used on the skin (topical) to treat molluscum contagiosum in adults and children 1 year of age and older. It is not known if ZELSUVMI is safe and effective in children under 1 year of age.

## IMPORTANT SAFETY INFORMATION

### What warnings should I know about ZELSUVMI?

ZELSUVMI is for use on the skin (for topical use) only. Do not use ZELSUVMI near or in your eyes, mouth, or vagina.

**Please see additional Important Safety Information throughout and full Prescribing Information.**

Zelsuvmi™
(berdazimer) topical gel, 10.3%

# A proven treatment with an established safety profile that you can apply in the comfort of your home or on the go

**ZELSUVMI is an innovative, nitric oxide–releasing topical gel for treating molluscum contagiosum**

Nitric oxide:

- Occurs naturally in the body
- Has antiviral effects and may increase immune system activity, helping the body attack the virus

The mechanism of action of ZELSUVMI for the treatment of molluscum contagiosum is unknown.

# What to expect from treatment

- Application site reactions, including allergic skin reactions, are common where ZELSUVMI is applied to the skin
- While redness and itching around the bumps may occur, this can be a positive sign that treatment is working
- This sign means the immune system is responding to treatment and beginning to fight the molluscum infection
- Talk to your doctor if you have any concerns about continuing treatment with ZELSUVMI

## IMPORTANT SAFETY INFORMATION (continued)

ZELSUVMI may cause serious side effects, including:

- **Application site reactions.** Application site reactions, including allergic skin reactions, are common where ZELSUVMI is applied to your skin, but can also be severe. **Stop using ZELSUVMI** and tell your healthcare provider right away if you develop pain, burning, stinging, itching, swelling, or redness of your skin that lasts for more than 24 hours after treatment with ZELSUVMI.

**Before using ZELSUVMI, tell your healthcare provider about all your medical conditions, including if you:**

- Have other skin problems.
- Are pregnant or plan to become pregnant. It is not known if ZELSUVMI will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if ZELSUVMI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ZELSUVMI.

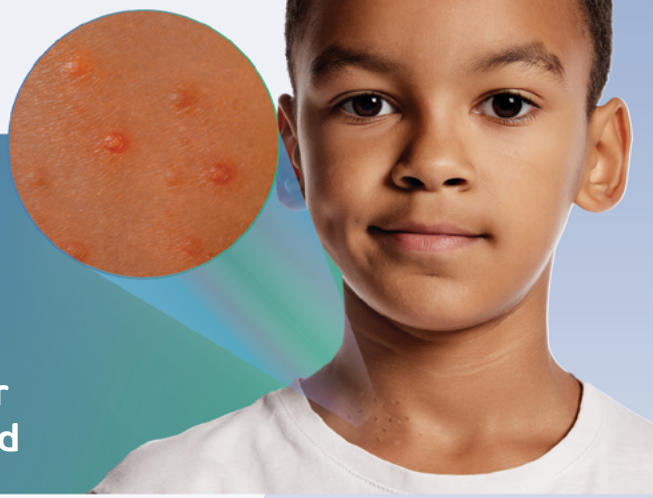
**Please see additional Important Safety Information throughout and full Prescribing Information.**

# What is molluscum contagiosum (or molluscum)?

**A highly contagious skin condition—most common in children—that causes raised bumps, usually found on the trunk/torso (chest, back, and belly), face, arms, legs, and groin**

## What is the impact of molluscum?

- **It can spread to other areas**—a viral infection that starts with a few bumps can expand to dozens of bumps across other parts of the body
- **It is contagious**—bumps can be passed to others in close contact
- **It can persist**—if not treated, the bumps can last for many months or even years
- **It can cause other infections**—scratching or picking the bumps can lead to skin bacterial infections and scarring
- **It is time consuming**—it may take extra cleaning steps to prevent spread and multiple doctor visits for treatment



**4 out of 10 children spread molluscum to another child in their household**

Not an actual patient.

## IMPORTANT SAFETY INFORMATION (continued)

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Please see additional Important Safety Information throughout and full Prescribing Information.**

# Apply ZELSUVMI (berdazimer) once daily at home for up to 12 weeks

**ZELSUVMI is supplied as two tubes and comes with one reusable Dosing Guide**




## ZELSUVMI is applied in just 3 simple steps




Squeeze equal amounts of gel from Tube A and Tube B onto the Dosing Guide as marked.




Using your fingertip, mix the gels on the Dosing Guide to activate ZELSUVMI (must be mixed before application).




Apply ZELSUVMI as a thin, even layer to each molluscum bump once daily for up to 12 weeks.

Wait at least 10 minutes before putting clothes on the skin to allow ZELSUVMI to dry. Avoid swimming, bathing, or washing for 1 hour after applying ZELSUVMI.

Do not use ZELSUVMI near or in your eyes, mouth, or vagina.

For full instructions, see the enclosed Instructions for Use or scan the code to view a helpful video.

## IMPORTANT SAFETY INFORMATION (continued)

Keep ZELSUVMI and all medicines out of the reach of children.

**Please see additional Important Safety Information throughout and full Prescribing Information.**

Zelsuvmi GO

# Getting started with ZELSUVMI

## ZelsuvmiGO—support to help you move forward with treatment

- Financial support options
- Patient assistance program (PAP) enrollment
- Prescription reminders and refill scheduling
- Insurance coverage support

## Copay assistance program

- Patients with commercial insurance may be eligible to receive ZELSUVMI for as little as $0*

## Convenient options to get ZELSUVMI

- At-home delivery using Amazon Pharmacy
- Local pharmacy (eg, Walgreens)
- ASPN Pharmacy

**Visit zelsuvmi.com/support or call ZelsuvmiGO at (888) 309-0186.**




*Patients are not eligible for copay savings if they participate in a state- or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veteran Affairs healthcare, or a state prescription drug assistance program. Commercially insured patients on a plan that does not cover ZELSUVMI are also not eligible. Program terms and conditions apply. Visit zelsuvmi.com/copay for complete terms and conditions.

Zelsuvmi™
(berdazimer) topical gel, 10.3%

# The FIRST and ONLY FDA-approved at-home or on-the-go topical medication for molluscum contagiosum

### Effective
ZELSUVMI can treat bumps on the body, including sensitive areas such as the face, groin, or underarms.

### Generally well tolerated
The most common side effects with ZELSUVMI were application-site reactions, including pain, redness, itching, flaking, and inflammation. The majority of side effects were mild or moderate.

### Convenient
ZELSUVMI is a once-daily prescription treatment that you can apply in the comfort of your home.

**Talk to your doctor about getting started with ZELSUVMI today. Visit zelsuvmi.com for more information.**

## IMPORTANT SAFETY INFORMATION (continued)

### What are the possible side effects of ZELSUVMI?
The most common side effects are application site reactions, including pain, burning, stinging, redness, itching, peeling or flaking, itchy dry skin rash, swelling, breakdown of the outer layer of the skin (erosion), lightening or darkening of the skin, blisters, irritation, and infection. These are not all of the possible side effects of ZELSUVMI.

**You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.**

**Please see additional Important Safety Information throughout and full Prescribing Information, Patient Information, and Instructions for Use.**

Zelsuvmi™
(berdazimer) topical gel, 10.3%

Pelthos Therapeutics

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ZELSUVMI is a trademark of LNHC, Inc.
MAT-0148 10/25



Not an actual patient.

# ZELSUVMI- berdazimer
# LNHC, Inc.

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use ZELSUVMI safely and effectively. See full prescribing information for ZELSUVMI.**

**ZELSUVMI™ (berdazimer) topical gel**
**Initial U.S. Approval: 2024**

**INDICATIONS AND USAGE**

ZELSUVMI™ is a nitric oxide (NO) releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older. (1)

**DOSAGE AND ADMINISTRATION**

- Dispense equal amounts from Tube A and Tube B per the dosing guide. (2.2)
- Mix together and immediately apply a thin layer of ZELSUVMI. (2.2)
- Apply once daily to each MC lesion for up to 12 weeks. (2.2)
- For topical use only and not for ophthalmic, oral, or intravaginal use. (2.2)

**DOSAGE FORMS AND STRENGTHS**

Topical gel: 10.3% berdazimer supplied as two tubes. Tube A contains berdazimer gel and Tube B contains hydrogel. (3)

**CONTRAINDICATIONS**

None. (4)

**WARNINGS AND PRECAUTIONS**

*Application Site Reactions:* Application site reactions, including allergic contact dermatitis, occurred. Discontinue ZELSUVMI and initiate appropriate therapy. (5.1)

**ADVERSE REACTIONS**

The most commonly reported adverse reactions (≥1%) are application site reactions, including pain (such as burning or stinging sensations, 18.7%), erythema (11.7%), pruritus (5.7%), exfoliation (5.0%), dermatitis (4.9%), swelling (3.5%), erosion (1.6%), discoloration (1.5%), vesicles (1.5%), irritation (1.2%), and infection (1.1%). (6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact LNHC, Inc. at 1-855-330-7546 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.***

**See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.**

**Revised: 1/2024**

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## FULL PRESCRIBING INFORMATION

## 1 INDICATIONS AND USAGE

ZELSUVMI™ is indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Important Preparation and Administration Instructions

- ZELSUVMI is supplied in a carton containing the following:
  - Tube A containing berdazimer gel
  - Tube B containing hydrogel
  - Dosing guide
- Mix together equal amounts of gel from Tube A and Tube B before application *[see Dosage and Administration (2.2)]*.
- Do not premix or store mixed ZELSUVMI.
- Instruct the patient to refer to the ZELSUVMI “Instructions for Use” for detailed instructions on the preparation and administration of ZELSUVMI *[see Instructions for Use]*.

### 2.2 Recommended Dosage and Administration

- Dispense equal amounts (0.5 mL) of gel from Tube A and Tube B on the dosing guide.
- Immediately put the caps back on Tube A and Tube B tightly.
- Mix together on the dosing guide.
- Immediately apply ZELSUVMI as an even thin layer. Apply ZELSUVMI once daily to each MC lesion for up to 12 weeks.
- Wash hands after applying ZELSUVMI, unless hands are being treated.
- Allow ZELSUVMI to dry for 10 minutes after application.

- Avoid application to uninvolved skin and avoid transfer of applied ZELSUVMI to other areas, including the eye.
- Avoid swimming, bathing, or washing for 1 hour after application of ZELSUVMI.
- ZELSUVMI is for topical use only and not for ophthalmic, oral, or intravaginal use.

## 3 DOSAGE FORMS AND STRENGTHS

Topical gel: 10.3% berdazimer in an opaque white to off-white gel. ZELSUVMI is supplied as two tubes. Tube A with a blue label contains 14 grams of berdazimer gel and Tube B with a yellow label contains 17 grams of hydrogel.

## 4 CONTRAINDICATIONS

None.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Application Site Reactions

Application site reactions, including allergic contact dermatitis, have occurred in patients treated with ZELSUVMI. Suspect allergic contact dermatitis in the event of pain, pruritus, swelling or erythema at the application site lasting longer than 24 hours. If allergic contact dermatitis occurs, discontinue ZELSUVMI and initiate appropriate therapy.

## 6 ADVERSE REACTIONS

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In three double-blind, vehicle-controlled clinical trials (Trial 1, and Trial 2 and Trial 3, which were similarly designed to Trial 1), 1596 adult and pediatric subjects were treated with ZELSUVMI or vehicle gel topically once daily for up to 12 weeks [see *Clinical Studies (14)*]. In these trials 3% of subjects were less than 2 years of age, and 96% of subjects were 2 to 17 years of age. The trial population included 51% male, 88% White, 6% Black, and 6% Other; for ethnicity, 21% of subjects identified as Hispanic/Latino, 78% as non-Hispanic/Latino, and 1% were not reported. Adverse reactions reported by ≥1% of subjects and more frequently than vehicle-treated subjects are listed in Table 1.

**Table 1: Adverse Reactions Reported by ≥ 1% of Subjects with MC Treated with ZELSUVMI (and Greater than Vehicle) Day 1 through Week 12 in Trials 1, 2, and 3**

| | **ZELSUVMI N=916** | | | **Vehicle Gel N=680** | | |
|---|---|---|---|---|---|---|
| ***Adverse Reaction*** | **Mild n (%)** | **Moderate n (%)** | **Severe n (%)** | **Mild n (%)** | **Moderate n (%)** | **Severe n (%)** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Subjects with any TEAE*** | **220 (24.0)** | **192 (21.0)** | **16 (1.7)** | **118 (17.4)** | **47 (6.9)** | **4 (0.6)** |
| Application Site Pain† | 113 (12.3) | 56 (6.1) | 2 (0.2) | 30 (4.4) | 3 (0.4) | 0 |
| Application Site Erythema | 48 (5.2) | 55 (6.0) | 4 (0.4) | 7 (1.0) | 2 (0.3) | 0 |
| Application Site Pruritus | 36 (3.9) | 15 (1.6) | 1 (0.1) | 5 (0.7) | 2 (0.3) | 0 |
| Application Site Exfoliation | 18 (2.0) | 26 (2.8) | 2 (0.2) | 0 | 0 | 0 |
| Application Site Dermatitis | 16 (1.7) | 26 (2.8) | 3 (0.3) | 3 (0.4) | 2 (0.3) | 0 |
| Application Site Swelling | 17 (1.9) | 14 (1.5) | 1 (0.1) | 3 (0.4) | 1 (0.1) | 0 |
| Pyrexia | 14 (1.5) | 6 (0.7) | 0 | 6 (0.9) | 1 (0.1) | 0 |
| Application Site Erosion | 7 (0.8) | 5 (0.5) | 3 (0.3) | 1 (0.1) | 0 | 0 |
| Application Site Discoloration | 13 (1.4) | 1 (0.1) | 0 | 1 (0.1) | 0 | 0 |
| Application Site Vesicles | 5 (0.5) | 9 (1.0) | 0 | 0 | 1 (0.1) | 0 |
| Vomiting | 5 (0.5) | 7 (0.8) | 0 | 1 (0.1) | 0 | 0 |
| Application Site Irritation | 7 (0.8) | 4 (0.4) | 0 | 0 | 0 | 0 |
| Upper Respiratory Tract Infection | 6 (0.7) | 5 (0.5) | 0 | 4 (0.7) | 1 (0.1) | 0 |
| Application Site Infection | 4 (0.4) | 4 (0.4) | 2 (0.2) | 2 (0.3) | 1 (0.1) | 0 |
| * TEAE – treatment emergent adverse events<br>† Application site pain also includes application site burning and stinging. | | | | | | |

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

There are no available data on ZELSUVMI use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of berdazimer to pregnant rats and rabbits increased malformations in the presence of severe maternal toxicity (*see Data*). The clinical relevance of this finding is unknown given the bioavailability of berdazimer following oral administration is significantly higher than topical application.

The available data do not allow the calculation of relevant comparisons between the systemic exposure of berdazimer observed in animal studies and the systemic exposure that would be expected in humans after topical use of ZELSUVMI.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

*Animal Data*

Systemic embryo-fetal development studies were conducted in rats and rabbits. In an embryofetal development study in rats, oral dose levels of 28, 95, or 189 mg/kg/day

berdazimer were administered during the period of organogenesis. Maternal mortality and elevated methemoglobin levels were noted in dams receiving doses of 95 and 189 mg/kg/day. The maternal no observable adverse effect level (NOAEL) was 28 mg/kg/day. Fetal skeletal malformations (changes in the lumbar and thoracic centra or arches, missing thoracic arches and centra, additional bone in the thoracic arches, missing lumbar centra and arches, and fused ribs) and visceral malformations (cleft palate) and decreased fetal weights were observed in litters from dams receiving 189 mg/kg/day. The fetal NOAEL was 95 mg/kg/day.

In an embryo-fetal development study in rabbits, oral dose levels of 47, 142, or 284 mg/kg/day berdazimer were administered during the period of organogenesis. Maternal mortality, aborted fetuses, adverse clinical observations, and elevated methemoglobin levels were noted in pregnant rabbits receiving doses of 142 and 284 mg/kg/day. The maternal NOAEL was 47 mg/kg/day. Decreased fetal weights were noted from pregnant rabbits receiving 284 mg/kg/day. The fetal NOAEL was 142 mg/kg/day.

### 8.2 Lactation

Risk Summary

There are no data on the presence of berdazimer or its metabolite in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZELSUVMI and any potential adverse effects on the breastfed infant from ZELSUVMI or from the underlying maternal condition.

### 8.4 Pediatric Use

The safety and effectiveness of ZELSUVMI for the topical treatment of MC have been established in pediatric patients 1 year of age and older. Use of ZELSUVMI for this indication is supported by data from three randomized, vehicle-controlled, double-blind trials involving 1596 subjects of which 1575 were pediatric subjects with MC (904 were exposed to ZELSUVMI; 29 subjects were less than 2 years of age, including one subject less than 1 year of age, and 875 were 2 to 17 years of age) *[see Clinical Studies (14)].*

The safety and effectiveness of ZELSUVMI have not been established in pediatric patients younger than 1 year of age.

### 8.5 Geriatric Use

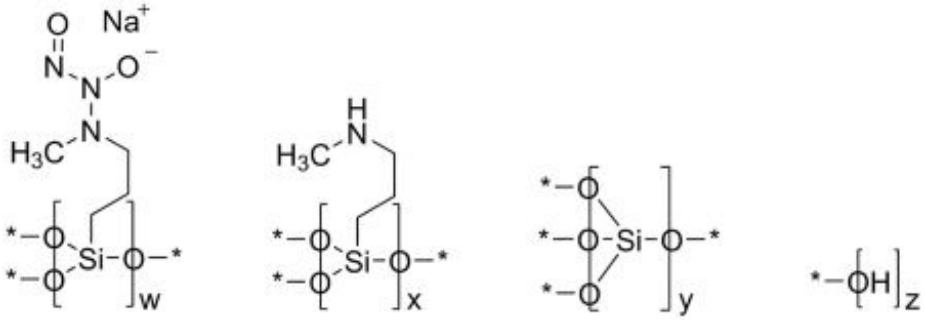
Of the total number of ZELSUVMI-treated subjects in clinical studies for MC, none were 65 to 74 years of age, and one was 75 years of age and older *[see Clinical Studies (14)]*. Clinical studies of ZELSUVMI did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

## 11 DESCRIPTION

ZELSUVMI (berdazimer) topical gel, 10.3%, a nitric oxide releasing agent, contains the drug substance berdazimer sodium, a white to off white powder with the chemical name poly[{[3-(methylamino)propyl]silasesquioxane}-co-{[3-(1-methyl-2-nitroso2-oxidohydrazin-1 yl)propyl]silasesquioxane}-co-silicate (1:3:6 x)], partially hydrolyzed (Si :

OH ~ 10 : 5), and the following structural and empirical formula:

**Structural Formula:**



* Denotes shared oxygen atom between bonded constituents; resulting bonds are Si-O-Si or Si-OH

Empirical formula: $[(C4H9N3NaO3.5Si)3(C4H10NO1.5Si)1(SiO2)6(HO0.5)5]_{0.1n}$

Due to the insoluble nature of berdazimer sodium, the molecular formula, molecular mass, and average molecular weight range cannot be determined.

ZELSUVMI (berdazimer) topical gel is an opaque white to off-white gel containing 10.3% berdazimer (equivalent to 10.9% berdazimer sodium). ZELSUVMI is supplied as two gel components that are mixed before administration:

- Tube A (14 g): an opaque white to off-white gel containing 240 mg of berdazimer sodium per gram of gel and the inactive ingredients cyclomethicone, hexylene glycol, hydroxypropyl cellulose, and isopropyl alcohol.
- Tube B (17 g): a translucent to opaque white to off-white gel containing the inactive ingredients benzoic acid, carboxymethylcellulose sodium, cyclomethicone, ethanol (13% v/v), glycerin, potassium phosphate monobasic, and purified water.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

ZELSUVMI is a nitric oxide releasing agent. The mechanism of action for the treatment of molluscum contagiosum is unknown.

### 12.2 Pharmacodynamics

The pharmacodynamics of ZELSUVMI are unknown.

### 12.3 Pharmacokinetics

Plasma hydrolyzed MAP3 (hMAP3), a structural marker for berdazimer, and nitrate levels were evaluated in n=34 subjects 2 to 12 years of age with MC. Subjects applied ZELSUVMI once-daily for two weeks to a total treatment area of 484 $cm^2$ (mean lesion count=34), applying a mean dose of approximately 3 mL/day. No subjects had quantifiable plasma hMAP3 concentrations on day 1; two subjects had quantifiable concentrations on day 15. Mean plasma nitrate levels were similar on days 1 and 15 and remained relatively flat during the PK sampling period (baseline through 1, 3, and 6 hours post-application).

There were no apparent differences in methemoglobin levels throughout the study.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of berdazimer gel was assessed in a 2-year dermal mouse carcinogenicity study. There were no drug-related tumor findings associated with daily topical administration of berdazimer gel to mice at doses up to 4% berdazimer gel.

Berdazimer was mutagenic in a bacterial mutagenicity assay (Ames assay) but was not clastogenic in an in vitro chromosomal aberration assay in human peripheral blood lymphocytes or in an in vivo micronucleus assay in rats.

There were no berdazimer related effects on male or female fertility and early embryonic parameters in rats at oral doses up to 189 mg/kg/day.

## 14 CLINICAL STUDIES

The efficacy of ZELSUVMI was evaluated in 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials in subjects with MC (Trials 1, 2, and 3; NCT04535531, NCT03927703, and NCT03927716, respectively). Trial 1 enrolled 891 subjects, Trial 2 enrolled 355 subjects, and Trial 3 enrolled 352 subjects. Subjects were randomized 1:1 in Trial 1, and 2:1 in Trials 2 and 3 to receive ZELSUVMI or vehicle applied to MC lesions once daily for up to 12 weeks.

In the three trials, 3% of subjects were less than 2 years of age and 96% of subjects were 2 to 17 years of age. The trial population included 51% male, 88% White, 6% Black, and 6% Other; for ethnicity, 21% of subjects identified as Hispanic/Latino, 78% as non-Hispanic/Latino, and 1% were not reported. Subjects had 3-70 baseline MC lesions. At baseline, the average MC lesion count was 20.2.

The primary efficacy endpoint was the proportion of subjects achieving complete clearance at Week 12. Complete clearance was defined as the subject having a total MC lesion count of 0 at assessment. The key secondary efficacy endpoint was complete clearance rate at Week 8.

Efficacy was demonstrated in Trials 1 and 2. The results are summarized in Table 2.

**Table 2: Complete Clearance Rate at Week 12 and Week 8 in Subjects with MC in Trials 1 and 2**

| | **Trial 1** | | **Trial 2** | |
|---|---|---|---|---|
| | **ZELSUVMI (N=444)** | **Vehicle (N=447)** | **ZELSUVMI (N=237)** | **Vehicle (N=118)** |
| **Complete Clearance Rate at Week 12 (Primary Endpoint)** | 32.4% | 19.7% | 30.0% | 20.3% |
| Treatment Difference (95% Confidence Interval) | 12.8% (7.1%, 18.6%) | | 9.2% (-0.04%, 18.4%) | |
| **Complete Clearance Rate at Week 8 (Secondary Endpoint)** | 19.6% | 11.6% | 13.9% | 5.9% |

| | | |
|---|---|---|
| Treatment Difference<br>(95% Confidence Interval) | 7.5%<br>(3.0%, 12.0%) | 7.8%<br>(1.8%, 13.8%) |

In Trial 3, the complete clearance rates at Week 12 were 26% versus 22% for ZELSUVMI and vehicle, respectively, with 95% confidence interval (-5%, 14%).

## 16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

ZELSUVMI (berdazimer) topical gel, 10.3% is supplied in a carton (NDC 83787-103-31) containing:

- Tube A (14 g) with blue label containing berdazimer sodium in an opaque white to off-white gel (NDC 83787-113-14)
- Tube B (17 g) with yellow label containing translucent to opaque white to off-white gel (UPC 83787-0000-17)
- Dosing Guide

Storage and Handling

- *Prior to Dispensing*: Store ZELSUVMI in a refrigerator between 2°C and 8°C (36°F and 46°F) until dispensed to the patient. Write the “Discard after” date in the space provided on the carton.
- *After Dispensing*: Store ZELSUVMI at room temperature, between 20°C to 25°C (68°F and 77°F) in a dry location.
- Product contains alcohol and should be kept away from open flame.
- Do not freeze.
- Discard 60 days after removal from refrigeration.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient or caregiver to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Application Site Reactions

Advise patients to discontinue ZELSUVMI and seek medical attention immediately if signs or symptoms of application site reactions lasting more than 24 hours occur *[see Warnings and Precautions (5.1)].*

Administration Instructions

Advise patients that ZELSUVMI is for external use only and is not for ophthalmic, oral, or intravaginal use *[see Dosage and Administration (2.2)]*.

Inform patients that ZELSUVMI is supplied with two gel components that must be mixed together immediately before application. Instruct patients not to premix or store mixed ZELSUVMI *[see Dosage and Administration (2.1, 2.2)]*.

Advise patients to wash hands after applying ZELSUVMI (unless hands are being treated) and avoid transfer of the product to other areas of the skin, including the eye *[see Dosage and Administration (2.2)].*

Instruct patients to carefully follow the instructions for preparing and administering ZELSUVMI in the ZELSUVMI FDA-approved patient labeling *[see Instructions For Use].*

Manufactured for:
LNHC, Inc.
Durham, NC 27703

**Patient Package Insert**

**PATIENT INFORMATION**
**ZELSUVMI™ (zel-SOOV-mee)**
**(berdazimer) topical gel**

**Important information: ZELSUVMI is for use on the skin (for topical use) only.** Do not use ZELSUVMI near or in your eyes, mouth, or vagina.

**What is ZELSUVMI?**
ZELSUVMI is a prescription medicine used on the skin (topical) to treat molluscum contagiosum (MC) in adults and children 1 year of age and older.
It is not known if ZELSUVMI is safe and effective in children under 1 year of age.

**Before using ZELSUVMI, tell your healthcare provider about all your medical conditions, including if you:**
- have other skin problems.
- are pregnant or plan to become pregnant. It is not known if ZELSUVMI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZELSUVMI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ZELSUVMI.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use ZELSUVMI?**
- Read the **Instructions for Use** for detailed information about how to properly prepare and apply ZELSUVMI.
- Use ZELSUVMI exactly as your healthcare provider tells you to use it.
- The ZELSUVMI carton contains:
  - 1 tube that contains berdazimer gel (Tube A)
  - 1 tube that contains hydrogel (Tube B)
  - 1 Dosing Guide
- The gels contained in Tube A and Tube B must be mixed together on the Dosing Guide before you apply ZELSUVMI to your skin.
- **Do not** mix the gels until you are ready to apply ZELSUVMI.
- After mixing, apply an even, thin layer of ZELSUVMI right away to each MC bump.
- Apply ZELSUVMI 1 time each day.
- **Do not** apply ZELSUVMI near or in your eyes, mouth, vagina, or areas of your skin where you do not have MC.
- Allow ZELSUVMI to dry for 10 minutes and **do not** swim, take a bath or shower, or wash the areas where you applied ZELSUVMI for 1 hour after you apply it.
- Wash your hands after applying ZELSUVMI, unless your hands are being treated for MC. If someone else applies ZELSUVMI for you, they should wash their hands after

applying ZELSUVMI.

**What are the possible side effects of ZELSUVMI?**
ZELSUVMI may cause serious side effects, including:

- **Application site reactions.** Application site reactions, including allergic skin reactions, are common where ZELSUVMI is applied to your skin, but can also be severe. **Stop using ZELSUVMI** and tell your healthcare provider right away if you develop pain, burning, stinging, itching, swelling, or redness of your skin that lasts for more than 24 hours after treatment with ZELSUVMI.

**The most common side effects of ZELSUVMI include:**

- the following skin side effects at the application site:
  - pain
  - burning
  - stinging
  - redness
  - itching
  - peeling or flaking
  - itchy, dry skin rash
- swelling
- breakdown of the outer layer of the skin (erosion)
- lightening or darkening of the skin
- blisters
- irritation
- infection

These are not all of the possible side effects of ZELSUVMI.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store ZELSUVMI?**

- Store ZELSUVMI at room temperature between 68°F to 77°F (20°C to 25°C) in a dry location.
- Do not premix or store mixed ZELSUVMI.
- Product contains alcohol and should be kept away from open flame.
- Do not freeze ZELSUVMI.
- After use, immediately put caps back on Tube A (berdazimer gel) and Tube B (hydrogel) tightly.
- Throw away if not used within 60 days after receiving ZELSUVMI.

Keep ZELSUVMI and all medicines out of the reach of children.

**General information about the safe and effective use of ZELSUVMI.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZELSUVMI for a condition for which it was not prescribed. Do not give ZELSUVMI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZELSUVMI that is written for health professionals.

**What are the ingredients in ZELSUVMI?**
**Tube A**
**Active ingredient:** berdazimer sodium
**Inactive ingredients:** cyclomethicone, hexylene glycol, hydroxypropyl cellulose, and isopropyl alcohol
**Tube B**

**Inactive ingredients:** benzoic acid, carboxymethylcellulose sodium, cyclomethicone, ethanol, glycerin, potassium phosphate monobasic, and purified water

Manufactured for: LNHC, Inc.
Durham, NC 27703

U.S. Patents: www.pelthos.com/patents
For more information, call 1-855-330-7546 or go to www.Zelsuvmi.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.
Issued: 01/2024

**Instructions For Use**

**INSTRUCTIONS FOR USE**
**ZELSUVMI™ (zel-SOOV-mee)**
**(berdazimer) topical gel, 10.3%**

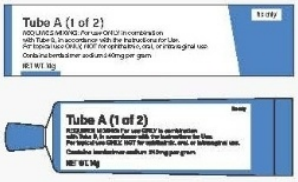
Zelsuvmi™
(berdazimer) topical gel, 10.3%

161545-2

This Instructions for Use contains information on how to prepare and apply ZELSUVMI. Read this Instructions for Use before you start using ZELSUVMI and each time you get a new prescription. Apply ZELSUVMI exactly as your healthcare provider tells you to. Ask your healthcare provider if you have any questions.

**Box Contents (Figure A):**

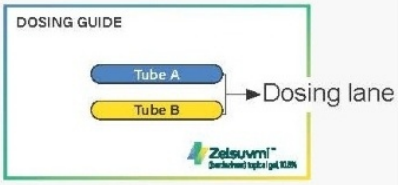
1 Tube A




1 Tube B




1 Dosing Guide




## Important Information You Need to Know Before Applying ZELSUVMI:

- **ZELSUVMI is for use on top of the skin (for topical use only).**
  - **Do not** treat bumps close to your eye or get gel in your eye. If gel gets in your eye, rinse with water.
  - **Do not** eat gel. If gel is swallowed, contact your healthcare provider.
  - **Do not** apply gel to open wounds. If gel gets into an open wound, rinse with water.
  - **Do not** get gel in your mouth, vagina, or on areas of your skin where you do not have bumps.
- ZELSUVMI comes in a box that contains (See Figure A):
  - 1 blue tube that contains berdazimer gel (Tube A)
  - 1 yellow tube that contains hydrogel (Tube B)
  - 1 Dosing Guide
- If you have trouble treating the bumps as the instructions describe, contact your healthcare provider.
- **The gels in Tube A and Tube B must be mixed together on the Dosing Guide before applying to your skin.**
- **Do not mix the gels until you are ready to apply ZELSUVMI.**
- Make sure to put the blue cap back onto the blue tube and put the yellow cap onto the yellow tube. If you mix the caps, wipe caps with **dry** tissue and replace caps on correct tubes.
- Hold tubes gently. If excess gel leaks out, wipe with tissue or cloth.
- Apply mixed gel to clean, dry skin.
- After mixing the gel, apply it to your skin right away.
- Dosing Guide
  - **Only mix gels on Dosing Guide** to ensure the gels are measured accurately and mixed thoroughly. **Do not mix gels directly on skin or in palm of hand.**
  - Always lay Dosing Guide on a flat surface.
  - Always use the Dosing Guide to dispense gels.
  - Throw away any ZELSUVMI remaining on the Dosing Guide after use. **Do not** store mixed ZELSUVMI.
  - **Do not** throw away the Dosing Guide or Instructions for Use. You will re-use the Dosing Guide and Instructions for Use for every application.
  - If your Dosing Guide, Instructions for Use, or tubes are lost or damaged, please contact your healthcare provider, pharmacy, or manufacturer at 1-855-330-7546.

## Preparing to Apply ZELSUVMI

- On a clean, flat surface, open the ZELSUVMI box and remove Tube A and Tube B.
- Break the seal on tubes. You only need to do this the first time you open the tubes.
  - Take cap off Tube A and break seal by pushing the pointed end of the cap into the foil.
  - Put cap back on Tube A tightly.
  - Repeat the above steps with Tube B.

**Turn to the back page for more instructions.**

Instructions begin on the other side.

## Applying ZELSUVMI

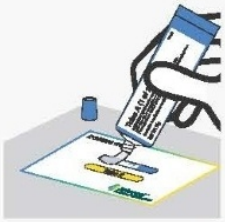
### Step 1. Wash Hands



**Always** wash and dry hands **before** applying gel.

### Step 2. Dispense Gel

Place Dosing Guide on a flat surface.



Remove cap from Tube A. Hold Tube A near blue Tube A dosing lane. Squeeze gel onto blue lane to cover **entire area of the lane**. The gel is white on the Dosing Guide. Screw cap back onto Tube A.



Remove cap from Tube B. Hold Tube B near yellow Tube B dosing lane. Squeeze gel onto yellow lane to cover **entire area of the lane**. The gel is clear to almost clear on the Dosing Guide. Screw cap back onto Tube B.





### Step 3. Mix Gels

Use a fingertip to combine the 2 gels from the blue and yellow lanes. Mix the gels in the center of the Dosing Guide using a circular motion. It is important that the 2 gels get mixed well. Mix the 2 gels together while slowly counting to 20. You may see clumps during mixing and this is normal. Apply the mixed gel right away to the bumps.

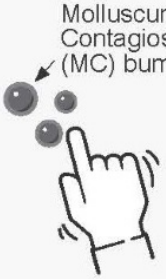


### Step 4. Apply Mixed Gel

Apply an even thin layer of mixed gel to each bump right away.

- All bumps should be treated with gel.

Make sure to cover bumps that are new, hard to reach, or out of sight.



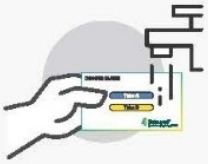

If you run out of mixed gel before you have treated all the bumps, wipe off your Dosing Guide with a **dry** tissue. Follow steps 2, 3, and 4 to apply the mixed gel to the remaining untreated bumps.

After all bumps have been treated:

- **Follow the cleaning and storing steps below.**
- **Wait at least 10 minutes after applying gel before putting clothes on skin to allow ZELSUVMI to dry.**
- **Wait at least 1 hour after applying gel before swimming, washing, bathing, or showering.**

### Step 5. Clean Dosing Guide

Use water and mild soap to remove remaining gel from Dosing Guide. Dry Dosing Guide.





### Step 6. Storing ZELSUVMI

Put dry Dosing Guide and this Instructions for Use back in box. Secure caps on tubes and place back in box.

Store ZELSUVMI at room temperature between 68°F to 77°F (20°C to 25°C) in a dry location. Product contains alcohol and should be kept away from open flame. Do not freeze. Throw away if not used within 60 days after receiving ZELSUVMI.

### Step 7. Wash Hands



**Always** wash hands after you place the contents back in the box unless your hands were treated.

### Disposing of ZELSUVMI



Throw away (dispose of) tubes in household trash when empty or when treatment is stopped.

**Manufactured for:**
LNHC, Inc., Durham, NC 27703

Zelsuvmi™
(berdazimer) topical gel, 10.3%