IOWA | Health and Human Services

Iowa PDL New Drug Review

Proprietary Name: Zelsuvmi®
Common Name: berdazimer
PDL Category: Topical Antivirals

Pharmacology/Usage: Berdazimer, the active ingredient of Zelsuvmi®, is a nitric oxide releasing agent. The mechanism of action for its approved indication is not known.

Indication: For the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

There is no pregnancy category for this medication; however, the risk summary indicates that there are no available data on use in pregnant women to assess for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. The safety and efficacy of use in the pediatric population younger than 1 year of age have not been established.

Dosage Form: Topical gel: 10.3%.

Supplied in a carton containing the following:

- Tube A containing berdazimer gel
- Tube B containing hydrogel
- Dosing guide.

Recommended Dosage: For topical use only. Mix together equal amounts of gel from Tube A and Tube B before application. Immediately put the caps back on the tubes tightly. Mix together on the dosing guide. Do not premix or store mixed Zelsuvmi®.

Immediately apply Zelsuvmi® as an even thin layer, applying once daily to each MC lesion for up to 12 weeks. Wash hands after applying, unless hands are being treated. Allow Zelsuvmi® gel 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®.

Drug Interactions: There are no drug interactions listed with this product.

Box Warning: There is no box warning listed with this product.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Zelsuvmi®) minus reported % incidence for vehicle for mild/moderate/severe adverse reactions. Please note that an incidence of 0% means the incidence was the same as or less than vehicle.* The most frequently reported adverse events included application site pain (7.9%/5.7%/0.2%), application site erythema (4.2%/5.7%/0.4%), application site pruritus (3.2%/1.3%/0.1%), application site exfoliation (2%/2.8%/0.2%), application site dermatitis (1.3%/2.5%/0.3%), application site swelling (1.5%/1.4%/0.1%), pyrexia (0.6%/0.6%/0%), application site erosion (0.7%/0.5%/0.3%), application site discoloration (1.3%/0.1%/0%), application site vesicles (0.5%/0.9%/0%), vomiting

(0.4%/0.8%/0%), application site irritation (0.8%/0.4%/0%), upper respiratory tract infection (0%/0.4%/0%), and application site infection (0.1%/0.3%/0.2%).

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 start appropriate therapy.

Contraindications: There are no contraindications listed with this product.

Manufacturer: LNHC, Inc.

Analysis: The efficacy of Zelsuvmi® was assessed in 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials that included subjects with MC. Trial 1 enrolled 891 subjects, while Trial 2 enrolled 355 subjects and Trial 3 enrolled 352 subjects. In all trials, subjects were randomized to receive Zelsuvmi® or vehicle applied to MC lesions once daily for up to 12 weeks.

In the 3 trials, 3% of subjects were less than 2 years of age while 96% of subjects were between 2 to 17 years of age. The population included 51% who were male, 88% who were White, those who had 3-70 baseline MC lesions, and an average MC lesion count at baseline of 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. Results are presented in the table below, which was adapted from the prescribing information. Efficacy was demonstrated 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)				
Complete clearance week 12	32.4%	19.7%	30.0%	20.3%
Treatment difference	12.8%		9.2%	
NNT *calculated by Optum Rx*	8		11	
Complete clearance rate at week 8 (secondary endpoint)				
Complete clearance week 8	19.6%	11.6%	13.9%	5.9%
Treatment difference	7.5%		7.8%	
NNT *calculated by Optum Rx*	14		13	

In Trial 3, the complete clearance rates at week 12 were 26% for Zelsuvmi® versus 22% for vehicle.

Place in Therapy: Zelsuvmi® is a nitric oxide releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adult and pediatric patients 1 year of age and older. It is for topical use only, to be applied once daily to each MC lesion for up to 12 weeks. The efficacy of Zelsuvmi® was assessed in 3 multicenter, randomized, double-blind, vehicle-controlled trials that included subjects with MC. The primary efficacy endpoint was the proportion of subjects achieving complete clearance at week 12. Efficacy of Zelsuvmi® was demonstrated in Trials 1 and 2. Per the full text study by Browning et al[2] (Trial 1), significantly more in the berdazimer group achieved complete clearance of MC lesions as compared with vehicle at week 12 ($p<0.001$). Berdazimer is listed as a treatment option for MC in immunocompetent patients, along with cryotherapy, curettage, and cantharidin.[3]

Summary

It is recommended that Zelsuvmi® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

PDL Placement: ☐ **Preferred**
☒ **Non-Preferred**

References

[1] Zelsuvmi [package insert]. Durham, NH: LNHC, Inc; 2024.
[2] Browning JC, Enloe C, Cartwright M, et al. Efficacy and safety of topical nitric oxide-releasing berdazimer gel in patients with molluscum contagiosum: A phase 3 randomized clinical trial. *JAMA Dermatol*. 2022; 158(8): 871-878.
[3] Dynamed online. Molluscum contagiosum. Accessed September 2025.