

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	○ swelling
○ burning	○ breakdown of the outer layer of the skin (erosion)
○ stinging	○ lightening or darkening of the skin
○ redness	○ blisters
○ itching	○ irritation
○ peeling or flaking	○ infection
○ itchy, dry skin rash	

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: EPIH SPV, LLC, Wilmington, Delaware 19801

U.S. Patents: www.novan.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.

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