Important Safety Information

CONTRAINDICATIONS

Zingo™ is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type.

WARNINGS AND PRECAUTIONS

Do not use around the eyes.

Do not use Zingo™ on body orifices, mucous membranes, or on areas with a compromised skin barrier. Only use Zingo™ on skin locations where an adequate seal can be maintained.

Patients with severe hepatic disease or pseudocholinesterase deficiency are at a greater risk of developing toxic plasma concentrations of lidocaine.

Patients with bleeding tendencies or platelet disorders could have a higher risk of superficial dermal bleeding.

In clinical trials the most common adverse reactions (>5%) were skin reactions at the site of administration: erythema, petechiae, edema, and pruritus.

Suggestions on how to explain Zingo to a child.

- You might tell the child that Zingo can help “blow away the hurt,” or “blow away the ouchies.”
- If you happen to have a Zingo TRAINER handy, let the kids hold it, even “use” it on a doll or your arm. Allow them to get used to it.
- Perhaps you could explain that some kids say, “Zingo feels like cool air on your skin.” Maybe have the child blow on his/her hand or arm to demonstrate.
- Another suggested technique: Tell patients how children have described Zingo as “breathing medicine onto part of my hand/arm so the skin feels sleepy.”
- Tell the child that they’re going to hear a “popping” sound, but that it’s just a funny noise and won’t hurt.
- Ask them what they think it’ll sound like. “Will it sound like popcorn or hands clapping?”
- Maybe tell your patient that, “Other kids say it sounds kind of like a soda can opening.”
- Have the child sing, “Pop Goes The Weasel” with you.

Ideas on describing how Zingo feels.

- Remind parents that if they remain calm, cool and collected, there’s a better chance their child will, too.
- As a distraction while performing the Zingo procedure, include the parent in a sing-along with the child: perhaps “Pop Goes the Weasel” or “Zingo Was It Name-O.”
- Another possible distraction technique: Have the parent ask the child what rhymes with “Zingo,” or what words start with “Z.”

Possible ways of explaining the “popping” sound.

The role of the parent.

First, clearly and simply explain how Zingo works and its benefits to the child.

LIDOCAINE HYDROCHLORIDE MONOHYDRATE POWDER INTRADERMAL INJECTION SYSTEM 0.5MG.
Point-of-Procedure Preparation

• Examine application site, and use Zingo only on intact skin
• Clean treatment site according to standard practice
• Inspect pouch for tears or visible damage
• Open pouch according to instructions, being careful not to touch the sterile purple outlet
• Do not use if device is dropped or the pouch is damaged or torn

1. POSITION Device

Seal purple Zingo outlet against intact skin

• Seal should be void of visible gaps between application site and purple outlet, as gaps will impede drug delivery
• Application site should be supported to prevent movement

2. PUSH Downward

Apply a downward pressure to release the safety interlock

• Maintain seal between Zingo and skin
• Safety interlock will release only when adequate downward pressure is applied to the application site
• Zingo is ready for administration when the green start button has moved into the upward position

3. PRESS Start Button

Press the green start button while maintaining downward pressure

• Zingo should not be moved from the application site during administration
• A verifying “POP” sound indicates that the lidocaine dose has been discharged

Perform the Procedure

START the peripheral venous access procedure 1–3 minutes after administration

• Analgesia diminishes within 10 minutes of treatment

To report suspected adverse reactions or for questions regarding the product, contact Marathon Pharmaceuticals, LLC, at 1-866-562-4620 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please see inside panels for full prescribing information.

Zingo™ is indicated for use on intact skin to provide topical local analgesia prior to venipuncture or intravenous cannulation.

1 INDICATIONS AND USAGE:

- Zingo™ provides the desired analgesia within one to three minutes prior to needle insertion. (1.2)
- Zingo™ is indicated for use on intact skin to provide topical local analgesia prior to venipuncture in adults. (1.2)
- Zingo™ is indicated for use on intact skin to provide topical local analgesia prior to venipuncture in children 1-18 years of age. (1.2)
- Zingo™ is indicated for use on intact skin to provide topical local analgesia prior to intravenous cannulation in children 1-18 years of age. (1.2)

2 DOSAGE AND ADMINISTRATION:

- When dispensing Zingo™, instruct the patient, hospital staff, or caregiver to read the product information that comes with the device. (2.1)
- Zingo™ is supplied in a system containing a powder intradermal injection system, which contains sterile lidocaine hydrochloride monohydrate. (2.1)
- Zingo™ is supplied in a system containing a powder intradermal injection system, which contains sterile lidocaine hydrochloride. (2.1)

3 DOSAGE FORMS AND STRENGTHS:

- Zingo™ is a single-use, powder-in-liquid intradermal local anesthetic system containing 0.5 mg lidocaine hydrochloride monohydrate. (2.1)

4 CONTRAINDICATIONS:

- Zingo™ is contraindicated in patients with a known history of allergy to local anesthetics of the amide type. (4)

5 WARNINGS AND PRECAUTIONS:

- Do not use Zingo™ on skin where there has been a compromised skin barrier. Only use Zingo™ on skin locations where an adequate local skin barrier is present. (5.1)

6 ADVERSE REACTIONS:

- The most common adverse reactions (≥3%) are skin reactions of the site of administration, erythema, pruritus, edema, and pain. (6.1)
- To report SUSPECTED ADVERSE REACTIONS, contact Marathon Pharmaceuticals, LLC, at 1-866-652-4620 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6.1)

7 PATIENT COUNSELING INFORMATION:

- The most common adverse reactions (≥3%) are skin reactions of the site of administration, erythema, pruritus, edema, and pain. (7.1)

8.5 Geriatric Use:

- Administer Zingo™: (8.5)

11 DESCRIPTION:

- Administer Zingo™: (11)

12.1 Mechanism of Action:

- Administer Zingo™: (12.1)

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility:

- Administer Zingo™: (13.1)

13.2 Mutagenesis:

- Administer Zingo™: (13.2)

13.3 Carcinogenesis:

- Administer Zingo™: (13.3)

13.4 Impairment of Fertility:

- Administer Zingo™: (13.4)

13.5 Nonteratogenic Effects:

- Administer Zingo™: (13.5)

13.6.1 Reproduction:

- Administer Zingo™: (13.6.1)

14 CLINICAL STUDIES:

- Administer Zingo™: (14)

15.1 HOW SUPPLIED/STORAGE AND HANDLING:

- Administer Zingo™: (15.1)

17 PATIENT COUNSELING INFORMATION:

- Administer Zingo™: (17)

17.1 Special Patient Population:

- Administer Zingo™: (17.1)

17.2 Transdermal:

- Administer Zingo™: (17.2)

17.3 Pouch:

- Administer Zingo™: (17.3)

17.4 Application:

- Administer Zingo™: (17.4)

17.5 Disposal:

- Administer Zingo™: (17.5)

17.6 Additional Information:

- Administer Zingo™: (17.6)

17.7 Refills:

- Administer Zingo™: (17.7)

17.8 Other:

- Administer Zingo™: (17.8)

21 CLINICAL PHARMACOLOGY:

- Administer Zingo™: (21)

22.1 Actions:

- Administer Zingo™: (22.1)

22.2 Pharmacokinetics:

- Administer Zingo™: (22.2)

22.3 Special Studies:

- Administer Zingo™: (22.3)

23 NONCLINICAL TOXICOLOGY:

- Administer Zingo™: (23)

23.1 Mutagenesis:

- Administer Zingo™: (23.1)

23.2 Carcinogenesis:

- Administer Zingo™: (23.2)

23.3 Impairment of Fertility:

- Administer Zingo™: (23.3)

24 ADVERSE REACTIONS:

- Administer Zingo™: (24)

24.1 Clinical Trials Experience:

- Administer Zingo™: (24.1)

24.2 Adverse Reactions:

- Administer Zingo™: (24.2)

24.3 Laboratory Tests:

- Administer Zingo™: (24.3)

24.4 Clinical Trials:

- Administer Zingo™: (24.4)

24.5 Post Marketing:

- Administer Zingo™: (24.5)

24.6 Clinical Experience:

- Administer Zingo™: (24.6)

25.1 Comments:

- Administer Zingo™: (25.1)

26.1 Carcinogenesis:

- Administer Zingo™: (26.1)

26.2 Mutagenesis:

- Administer Zingo™: (26.2)

26.3 Impairment of Fertility:

- Administer Zingo™: (26.3)

27.1 Preclinical Studies:

- Administer Zingo™: (27.1)

27.2 Clinical Studies:

- Administer Zingo™: (27.2)

27.3 Post Marketing:

- Administer Zingo™: (27.3)

27.4 Indications:

- Administer Zingo™: (27.4)

27.5 Contraindications:

- Administer Zingo™: (27.5)

27.6 Warnings:

- Administer Zingo™: (27.6)

27.7 Adverse Reactions:

- Administer Zingo™: (27.7)

27.8 Overdosage:

- Administer Zingo™: (27.8)

27.9 Overdose Management:

- Administer Zingo™: (27.9)

27.10 Adverse Reactions:

- Administer Zingo™: (27.10)

28.1 Comments:

- Administer Zingo™: (28.1)

28.2 Indications:

- Administer Zingo™: (28.2)

28.3 Contraindications:

- Administer Zingo™: (28.3)

28.4 Warnings:

- Administer Zingo™: (28.4)

28.5 Adverse Reactions:

- Administer Zingo™: (28.5)

28.6 Overdosage:

- Administer Zingo™: (28.6)

28.7 Overdose Management:

- Administer Zingo™: (28.7)

28.8 Adverse Reactions:

- Administer Zingo™: (28.8)

28.9 Overdosage:

- Administer Zingo™: (28.9)

28.10 Overdose Management:

- Administer Zingo™: (28.10)

28.11 Comments:

- Administer Zingo™: (28.11)
9.3 Nursing Mothers: Lidocaine is secreted into human milk; therefore, caution should be exercised with breastfeeding infants of mothers administered lidocaine.

Because no plasma concentrations of lidocaine were detected following topical administration of Zingo™ in recommended doses, the small amount of lidocaine absorbed orally by a nursing infant is unlikely to cause adverse effects.

9.4 Pediatric Use: Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

9.5 Geriatric Use: In elderly patients, plasma lidocaine concentrations were similar to that of younger adults.

10. OVERDOSAGE:

In adults following a single administration of Zingo™, the plasma levels of lidocaine were below the limit of detection (5 ng/mL). Signs of central nervous system (CNS) toxicity may start at 5000 ng/mL of lidocaine; however, lidocaine levels in the plasma levels of lidocaine were below the limit of detection in human studies. Lidocaine has been used in patients requiring local anesthesia.

11. DESCRIPTION:

Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system contains 0.5 mg sterile lidocaine hydrochloride monohydrate (lidocaine hydrochloride monohydrate), 2% 2',6'-acetoxylidide, monohydrochloride, monohydrate. The molecular formula is C16H20ClN2O4.H2O - HCI - H2O with an molecular weight of 288.1. Lidocaine hydrochloride monohydrate is an aromatic amine, with the amide class. See list of diagram of the structural product in the product insert, containing full prescribing information for Zingo™. Lidocaine hydrochloride monohydrate is a white to light yellow, free-flowing, soluble in alcohol and chloroform, insoluble in ether and, melts around 74-76°C. Lidocaine hydrochloride monohydrate is a white, free-flowing, soluble in alcohol and chloroform, insoluble in ether and, melts at around 74-76°C.

Lidocaine is a local anesthetic that produces local anesthesia by interfering with sodium channel function to block depolarizing pain signals. In adults following a single administration of Zingo™, the plasma levels of lidocaine were below the limit of detection (5 ng/mL). Signs of central nervous system (CNS) toxicity may start at 5000 ng/mL of lidocaine; however, lidocaine levels in the plasma levels of lidocaine were below the limit of detection in human studies. Lidocaine has been used in patients requiring local anesthesia.

12. CLINICAL PHARMACOLGY:

12.1 Mechanism of Action: Zingo™ delivers lidocaine hydrochloride monohydrate into the dermis. lidocaine is an amide-type local anesthetic agent that blocks sodium channel receptors for the initiation and conduction of neural impulses, resulting in local anesthesia.

12.2 Pharmacodynamics: Zingo™ provides local dermal anesthesia within one to three minutes of application. Analgesia diminishes within ten minutes of treatment.

12.3 Pharmacokinetics: Absorption: A single dose of Zingo™ in adults did not produce detectable plasma concentrations of lidocaine at the limit of quantifiable plasma lidocaine concentrations. The chemical derivative of lidocaine 2',6'-acetoxylidide, monohydrochloride, monohydrate, the molecular formula is C16H20ClN2O4.H2O - HCI - H2O with an molecular weight of 288.1. Lidocaine hydrochloride monohydrate is an aromatic amine, with the amide class. See list of diagram of the structural product in the product insert, containing full prescribing information for Zingo™. Lidocaine hydrochloride monohydrate is a white to light yellow, free-flowing, soluble in alcohol and chloroform, insoluble in ether and, melts at around 74-76°C. Lidocaine hydrochloride monohydrate is a white, free-flowing, soluble in alcohol and chloroform, insoluble in ether and, melts at around 74-76°C.

Lidocaine hydrochloride monohydrate is a white, free-flowing, soluble in alcohol and chloroform, insoluble in ether and, melts at around 74-76°C.

13. NONCLINICAL TOXICOLOGY: 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis: Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine.

13.2 Mutagenesis: No mutagenic potential of lidocaine was demonstrated in the in vitro Ames Bacterial Reverse Mutation Assay, the in vitro chromosomal aberration assay, the in vitro lymphocyte somatic cell assay, and the in vivo mouse micronucleus assay.

13.3 Impairment of Fertility: Zingo™ was not formally evaluated for effects on male fertility. Significant systemic exposure to lidocaine is not expected under recommended conditions of use of Zingo™, as lidocaine levels were below the limit of detection in human studies. Lidocaine has been used in patients requiring local anesthesia.

14. CLINICAL STUDIES: Efficacy in Adults: The efficacy of Zingo™ in adults was evaluated in a randomized, double-blind, parallel-arm, sham placebo-controlled trial in which adult patients who required a venipuncture or peripheral venous cannulation. Measurements of pain were made immediately following the procedure. Efficacy was evaluated using a continuous 100-point visual analog scale ranging from 0 (“no pain”) to 100 (“worst possible pain”). Many of the patients had chronic medical problems such as; diabetes, hypertension, hypothyroidism, and peripheral neuropathy and one fourth of the population may have been at higher than average risk of dermal bleeding due to concomitant medications such as NSAIDs, aspirin, or any other medications that affect the blood platelets in less pain compared with placebo. However, efficacy was primarily seen in patients undergoing venipuncture at the antecubital fossa, where Zingo™ was applied and did not demonstrate a difference when active and sham administrations.

Efficacy in Pediatric Patients: The efficacy of Zingo™ in pediatric patients 3 to 18 years of age was evaluated in two randomized, double-blind, parallel-arm, sham placebo-controlled trials in which pediatric patients received either Zingo™ or a sham placebo device. The observed patient population consisted of healthy pediatric patients who required peripheral venipuncture or intravenous cannulation as part of their clinical care. Two efficacy trials (Studies 1 and 2) were conducted during which patients were treated with Zingo™ or a placebo device at the back of an antecubital fossa, between one and three minutes prior to venipuncture or peripheral venous cannulation. Measurements of pain were made immediately following the procedure. Efficacy was measured using a modified version of the Wong-Baker FACES pain rating scale (a categorical 6-point scale containing 6 faces ranging from 0 (“no hurt”) to 5 (“hurts worst”). In both studies, treatment with active drug resulted in less pain, from venipuncture or peripheral venous cannulation, compared with placebo.

16. HOW SUPPLIED/STORAGE AND HANDLING: NDC: 5233-200-20-57 Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system contains 0.5 mg lidocaine hydrochloride monohydrate in a sterile single-use device in a polyolefin foil overwrap. The active ingredient, lidocaine hydrochloride, is a single-use device packaged in an individual clear pouch. Twelve powered devices are placed in labeled cartons. Cartons are stored at controlled room temperature (15-30°C, 59-86°F).

17. PATIENT COUNSELING INFORMATION: Patients should be made aware that a sound similar to that of a popping balloon is emitted at the time Zingo™ is actuated. Patients should be made aware that Zingo™ contains helium and chloroform, insoluble in ether, and melts at around 74–79°C.

19. MEDICINE Industries, Inc., Mundelein, IL 60060, USA

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