Zingo™ is contraindicated in patients with a known history of sensitivity to local anesthetics of 10 mg/kg [360 mg/m²] or 600-fold the SDA).

5 WARNINGS AND PRECAUTIONS
Do not use around the eyes.

5 WARNINGS AND PRECAUTIONS
Do not use Zingo™ on body orces, mucous membranes, or on an uncleaned skin barrier. Only use Zingo™ on skin locations where an adequate seal can be maintained.

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

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.

6.2 Clinical Trials Experience
In pediatric patients, erythema occurred in 53% of Zingo™-treated patients, and in 27% of placebo-treated patients. Petechiae occurred in 46.4% of Zingo™-treated patients, and in 7.0% of placebo-treated patients. In adults, erythema occurred in 67.3% of Zingo™-treated patients, and in 25.0% of placebo-treated patients. Petechiae occurred in 44% of Zingo™-treated patients, and in 5% of placebo-treated patients. Erythema occurred in 8% of Zingo™-treated patients, and 3% of placebo-treated patients. Petechiae occurred in 4% of Zingo™-treated patients, and in 0.5% of placebo-treated patients.

6.2 Clinical Trials Experience
In patients with bleeding tendencies or platelet disorders, Zingo™ should be used with caution.

6.3 Use in Specific Populations
6.3.1 Pregnancy
Zingo™ is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type.

6.3.1 Pregnancy
In animals, Zingo™ should not be used during pregnancy unless clear benefits justify the potential risk to the fetus.

6.3.1 Pregnancy
Zingo™ is a ready-to-use, sterile, single-use, disposable, needle-free delivery system. Zingo™ consists of the following components: a drug reservoir cartridge filled with 5.3 mg lidocaine hydrochloride monohydrate in a powder with a nominal particle size 45 μm, in a preservative free gel capsule, and a safety interlock. The safety interlock prevents inadvertent actuation of the device. Once Zingo™ is pressed against the skin, the interlock is released, allowing the device to discharge. The button is locked in the unlocked position as illustrated in Figure 5a.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients below the age of 3 years has not been established.

8.5 Geriatric Use
Use in patients 65 years of age or older should be carefully considered.

9 DRUG ABUSE AND DEPENDENCE
The safety of Zingo™ has been evaluated in 10 clinical trials, five in adults and five in pediatric patients. A total of 906 pediatric patients received active treatment, while 855 received placebo.

10 OVERDOSAGE
In adults, a single administration of Zingo™ in the plasma levels of lidocaine were below the limit of detection (5 ng/mL). Signs of central nervous system (CNS) toxicity may start at a plasma concentration of 2 mg/mL. CNS depression is thought to be at least additive. In the absence of massive topical overdose or oral ingestion, other etiologies for the clinical effects or overloading from other sources of lidocaine or other mechanisms (e.g., stoichiometry) should be considered. The management of overdose includes monitoring for signs of central nervous system toxicity, supportive care, and symptomatic treatment. Death is unlikely in the range of the treatment of acute overdose of lidocaine.

11 DESCRIPTION
Lidocaine is excreted into human milk; therefore, caution should be exercised when Zingo™ is used in nursing mothers.

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11 DESCRIPTION
Lidocaine hydrochloride monohydrate powder intradermal injection system contains 5.5 mg of sterile lidocaine hydrochloride monohydrate.

11 DESCRIPTION
The mechanism of the drug is a blockade of sodium channels, which results in the inhibition of impulse propagation through nerve fibers. The sodium channel blocker is effective on both peripheral and central nervous system. The sodium channel blocker is effective on both peripheral and central nervous system.
Zingo™ delivers lidocaine hydrochloride monohydrate into the dermis. Lidocaine is an amide-type local anesthetic agent that blocks sodium ion channels required for the conduction of neuronal impulses, resulting in local anesthesia.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Zingo™ delivers lidocaine hydrochloride monohydrate into the dermis. Lidocaine is an amide-type local anesthetic agent that blocks sodium ion channels required for the conduction of neuronal impulses, resulting in local anesthesia.

12.2 Pharmacodynamics
A single dose of Zingo™ in adults did not produce detectable plasma concentrations of lidocaine (0.2 ng/mL). Application of Zingo™ to broken or infected skin, or multiple Zingo™ applications, could result in increased local anesthetic concentrations at the site of administration. When lidocaine is administered topically to healthy volunteers, the steady-state volume of distribution is approximately 25 L/kg. At much higher plasma concentrations (5 to 10 mg/mL), the topical plasma binding of lidocaine is concentration dependent. Lidocaine is concentrated in the skin at a ratio of approximately 1000 ng/mL. Although the half-life of lidocaine in plasma may be at most 90 minutes, the half-life of lidocaine in the skin may be much longer in elderly patients (2.5 hours) than in younger patients (1.5 hours).

Use Zingo™ only on intact skin. Application of Zingo™ to broken or inflamed skin, or multiple Zingo™ applications, could result in increased local anesthetic concentrations at the site of administration.

12.2 Pharmacodynamics

Zingo™ delivers lidocaine hydrochloride monohydrate into the dermis. Lidocaine is an amide-type local anesthetic agent that blocks sodium ion channels required for the conduction of neuronal impulses, resulting in local anesthesia.

12.3 Pharmokinetics

Zingo™ provides local analgesia within 1–2 minutes of application. Analgesia diminishes within 30 minutes in most patients.

12.3 Pharmokinetics

The most common adverse reactions (≥5%) are skin reactions at the site of administration: erythema, petechiae, edema, and pruritus (6.1).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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 Reversion Mutation Assay, in the in vitro chromosomal aberration assay using Chinese hamster ovary cells, and the in vivo micronucleus assay in mice.

13.3 Impairment of Fertility

Impairment of fertility was not studied for lidocaine hydrochloride (USP).

14 CLINICAL STUDIES


HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Zingo™ safely and effectively. See full prescribing information for Zingo™.

Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection:

Initial use: 1948

---INDICATIONS AND USAGE---

Zingo™ is an anode local anesthetic indicated for use on intact skin to provide topical analgesia prior to venipuncture or peripheral intravenous cannulation in children 3–18 years of age (1).

Dosage and Administration

These highlights do not include all the information needed to use Zingo™ safely and effectively. See full prescribing information for Zingo™.

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