Mylan Lidocaine Patch 5%
A Generic Version of LIDODERM®
(lidocaine patch 5%)

Patient Brochure

Patch size 10 cm x 14 cm
(Each adhesive patch contains 140 mg of lidocaine, USP)

INDICATION AND IMPORTANT SAFETY INFORMATION

LIDOCAINE PATCH 5% is used to relieve the pain of post-herpetic neuralgia, also referred to as after-shingles pain. Apply only to intact skin with no blisters.

You should not use this product if you are sensitive to local anesthetics like lidocaine, or to any of the other ingredients in LIDOCAINE PATCH 5%.

Even a used LIDOCAINE PATCH 5% contains a large amount of lidocaine. A small child or a pet could suffer serious adverse effects from chewing or swallowing a new or used LIDOCAINE PATCH 5%. Store and dispose of patches out of the reach of children, pets, and others. Never reuse a patch.

Please see full Important Safety Information on pages 6–7 and accompanying full Prescribing Information.

*LIDODERM® is a registered trademark of Endo Pharmaceuticals, Inc.
How to apply the patch

1. Cut the pouch at the top and both sides along the dotted lines.

2. Peel open the pouch and remove the patch with the transparent release liner (clear plastic backing). Patches may be cut into smaller sizes with scissors before you remove the clear plastic backing. Safely discard the remaining unused pieces of cut patches where children and pets cannot get to them. Avoid contact of the patch or patch pieces with the eyes and wash hands immediately after handling the patch.

3. Remove the transparent release liner before application of patch to the skin. Apply immediately after removal from the pouch.

4. Apply up to a total of three (3) Lidocaine Patch 5% patches at one time to cover the most painful area, as directed by your healthcare provider. Patches can be left on for up to 12 hours, followed by 12 hours off. You may cut patches into smaller sizes with scissors before removing the release liner (clear plastic backing). Always follow your healthcare provider’s instructions for use of the patch.

Selected Important Safety Information

LIDOCAINE PATCH 5% should be worn for no more than 12 hours a day. Applying the patches for a longer time or using more than 3 patches could cause serious reactions.

During or immediately after using LIDOCAINE PATCH 5%, the skin around the patch may develop a change in color, colored spots, irritation, itching, flaking of the skin, rash, bruising, swelling, pimple-like raised skin, a cyst containing fluid, pain, burning, or abnormal sensation. These reactions are generally mild and go away on their own within a few minutes to hours. Other reactions may include dizziness, headache, and nausea. Tell your healthcare professional if you experience any of these symptoms while using LIDOCAINE PATCH 5%.

Note: Mylan recommends that the patch be held in place by applying gentle pressure for approximately 10-15 seconds.

Please see full Important Safety Information on pages 6–7 and accompanying full Prescribing Information.
FAQs

1. My Mylan Lidocaine Patch 5% doesn't look and feel the same as my previous lidocaine patches. Is this normal?

Mylan Lidocaine Patch 5% is thin, lightweight and pressure-sensitive and may feel different than LIDODERM® or other previous lidocaine patches. However, Mylan Lidocaine Patch 5% is FDA-approved as a therapeutic equivalent to LIDODERM®. This means that Mylan Lidocaine Patch 5% is expected to provide the same pain relief as LIDODERM® when used as directed.

2. What if the patch doesn’t stick?

Before applying the patch, the skin should be clean and completely dry. Apply the patch to intact skin without blisters. Because the patch adhesive is pressure-sensitive, Mylan suggests pressing gently on the patch, and holding it in place for about 10 to 15 seconds. Make sure the patch is fully adhered to the skin, especially around the edges. If desired, a hypo-allergenic dressing tape could be used along the edges.

3. Is it OK if the patch gets wet?

Mylan Lidocaine Patch 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

4. How quickly should I notice relief of my symptoms?

Because of differences in skin types, responses vary by individual. However, Mylan Lidocaine Patch 5% is FDA-approved as a therapeutic equivalent to LIDODERM®. This means that Mylan Lidocaine Patch 5% is expected to provide the same pain relief as LIDODERM® when used as directed.

5. Can I cut the patch?

Patches may be cut into smaller sizes with scissors before you remove the clear plastic backing as directed by your healthcare provider. Always follow your healthcare provider’s instructions for use of the patch.

6. After I cut a patch, can I save and use the remaining portion?

Patches should be applied immediately after being removed from the protective envelope. Safely discard used patches or pieces of cut patches where children and pets cannot get to them. Always follow your healthcare provider’s instructions for use of the patch.

7. How should I store the patch?

Store at 20° to 25°C (68° to 77°F). It is important to store and dispose of Mylan Lidocaine Patch 5% out of the reach of children, pets and others. Do not store patches outside the sealed envelope.

8. Are there any special instructions for throwing the patch away?

Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

9. If Mylan Lidocaine Patch 5% is equivalent to LIDODERM® (lidocaine patch 5%), why does your patch only contain 140 mg of lidocaine when LIDODERM® contains 700 mg of lidocaine?

Both LIDODERM® and Mylan Lidocaine Patch 5% are designed to deliver the same amount of medication during the time the patch is worn.

Mylan Lidocaine Patch 5% is approved by the FDA as a generic equivalent to LIDODERM®. The patches are made of different materials containing a different amount of medication but deliver the same dose and analgesic effect.

Please note that both patches will contain unused lidocaine in the patch after they are used. This is why you must safely discard all patches after they are used and they should not be reused.

Selected Important Safety Information

Even a used LIDOCAINE PATCH 5% contains a large amount of lidocaine. A small child or a pet could suffer serious adverse effects from chewing or swallowing a new or used LIDOCAINE PATCH 5%. Store and dispose of patches out of the reach of children, pets, and others. Never reuse a patch.

Fold used patches so that the adhesive side sticks to itself, and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

LIDOCAINE PATCH 5% should be worn for no more than 12 hours a day. Applying the patches for a longer time or using more than 3 patches could cause serious reactions.

Please see full Important Safety Information on pages 6–7 and accompanying full Prescribing Information.
INDICATION

LIDOCAINE PATCH 5% is used to relieve the pain of post-herpetic neuralgia, also referred to as after-shingles pain. Apply only to intact skin with no blisters.

IMPORTANT SAFETY INFORMATION

- You should not use this product if you are sensitive to local anesthetics like lidocaine, or to any of the other ingredients in LIDOCAINE PATCH 5%.

- Even a used LIDOCAINE PATCH 5% contains a large amount of lidocaine. A small child or a pet could suffer serious adverse effects from chewing or swallowing a new or used LIDOCAINE PATCH 5%. Store and dispose of patches out of the reach of children, pets, and others. Never reuse a patch.

- Fold used patches so that the adhesive side sticks to itself, and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

- LIDOCAINE PATCH 5% should be worn for no more than 12 hours a day. Applying the patches for a longer time or using more than 3 patches could cause serious reactions.

- Avoid the use of external heat sources, such as heating pads or electric blankets, as this has not been studied and may cause you to receive a higher dosage.

- Avoid contact of LIDOCAINE PATCH 5% with the eyes. If contact with the eye occurs, immediately wash the eye with water or saline and protect it until sensation returns.

- Be sure to tell your healthcare professional if you have liver disease, are pregnant or nursing, or are taking medication for irregular heartbeat. LIDOCAINE PATCH 5% should be used with caution in people with these conditions.

- Allergic reactions, though rare, can occur.

- During or immediately after using LIDOCAINE PATCH 5%, the skin around the patch may develop a change in color, colored spots, irritation, itching, flaking of the skin, rash, bruising, swelling, pimple-like raised skin, a cyst containing fluid, pain, burning, or abnormal sensation. These reactions are generally mild and go away on their own within a few minutes to hours. Other reactions may include dizziness, headache, and nausea. Tell your healthcare professional if you experience any of these symptoms while using LIDOCAINE PATCH 5%.

- LIDOCAINE PATCH 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

- Only your healthcare professional can determine if LIDOCAINE PATCH 5% is right for you. Always follow your healthcare professional's instructions when using LIDOCAINE PATCH 5%.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the accompanying LIDOCAINE PATCH 5% full Prescribing Information and discuss it with your healthcare professional.
Lidocaine Patch 5%

Prescribing Information

DESCRIPTION: Lidocaine patch 5% is comprised of an adhesive material containing 5% lidocaine, USP, which is applied to a pigmented polyethylene/polyester backing film printed with brown ink and covered with a silicone coated polyester film release liner. The release liner is removed prior to application to the skin. The size of the patch is 10 cm × 14 cm.

Lidocaine is chemically designated as 2-(diethylamino)-N-(2,6-dimethylphenyl)-acetamide, has an octanol: water partition ratio of 43 at pH 7.4, and has the following structure:

Each adhesive patch contains 140 mg of lidocaine, USP (50 mg per gram adhesive) in a polyisobutylene adhesive matrix.

CLINICAL PHARMACOLOGY: Pharmacodynamics: Lidocaine is an amide-type local anesthetic agent and is suggested to stabilize neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses.

The penetration of lidocaine into intact skin after application of lidocaine patch 5% is sufficient to produce an analgesic effect, but less than the amount necessary to produce a complete sensory block.

Pharmacokinetics: Absorption: The amount of lidocaine systemically absorbed from lidocaine patch 5% is directly related to both the duration of application and the surface area over which it is applied. In a pharmacokinetic study, three lidocaine patch 5% patches were applied over an area of 420 cm² of intact skin on the back of normal volunteers for 12 hours. Blood samples were withdrawn for determination of lidocaine concentration during the application and for 12 hours after removal of patches. The results are summarized in Table 1.

Table 1 Absorption of lidocaine from lidocaine patch 5%

<table>
<thead>
<tr>
<th>Lidocaine Patch 5%</th>
<th>Application Site</th>
<th>Area (cm²)</th>
<th>Dose (mg)</th>
<th>Cmax (mcg/mL)</th>
<th>Tmax (hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 patches Back</td>
<td>420</td>
<td>64 ± 32</td>
<td>0.13 ± 0.06</td>
<td>11 hr</td>
<td></td>
</tr>
</tbody>
</table>

When lidocaine patch 5% is used according to the recommended dosing instructions, only 11% ± 4% of the dose applied is expected to be absorbed. At least 82% (115 mg) of lidocaine will remain in a used patch. Mean peak blood concentration of lidocaine is about 0.13 mcg/mL (about 1/10 of the therapeutic concentration required to treat cardiac arrhythmias). Repeated application of three patches simultaneously for 12 hours (recommended maximum daily dose), once per day for 3 days, indicated that the lidocaine concentration does not increase with daily use. The mean plasma pharmacokinetic profile for the 15 healthy volunteers is shown in Figure 1.

Figure 1

Mean lidocaine blood concentrations after three consecutive daily applications of three lidocaine patch 5% patches simultaneously for 12 hours per day in healthy volunteers (n = 15).

Distribution: When lidocaine is administered intravenously to healthy volunteers, the volume of distribution is 0.7 to 2.7 L/kg (mean 1.5 ± 0.6 SD, n = 15). At concentrations produced by application of lidocaine patch 5%, lidocaine is approximately 70% bound to plasma proteins, primarily alpha-1-acid glycoprotein. At much higher plasma concentrations (1 to 4 mcg/mL of free base), the plasma protein binding of lidocaine is concentration dependent. Lidocaine crosses the placental and blood brain barriers, presumably by passive diffusion.

Metabolism: It is not known if lidocaine is metabolized in the skin. Lidocaine is metabolized rapidly by the liver to a number of metabolites, including monoethylglycinexylidide (MEGX) and glycinexylidide (GX), both of which have pharmacologic activity similar to, but less potent than that of lidocaine. A minor metabolite, 2,6-xylidine, has unknown pharmacologic activity but is carcinogenic in rats. The blood concentration of this metabolite is negligible following application of lidocaine patch 5%. Following intravenous administration, MEGX and GX concentrations in serum range from 11 to 36% and from 5 to 11% of lidocaine concentrations, respectively.

Excretion: Lidocaine and its metabolites are excreted by the kidneys. Less than 10% of lidocaine is excreted unchanged. The half-life of lidocaine elimination from the plasma following IV administration is 81 to 149 minutes (mean 107 ± 22 SD, n = 15). The systemic clearance is 0.33 to 0.90 L/min (mean 0.64 ± 0.18 SD, n = 15).

CLINICAL STUDIES: Single-dose treatment with lidocaine patch 5% was compared to treatment with vehicle patch (without lidocaine), and to no treatment (observation only) in a double-blind, crossover clinical trial with 35 post-herpetic neuralgia patients. Pain intensity and pain relief scores were evaluated periodically for 12 hours. Lidocaine patch 5% performed statistically better than vehicle patch in terms of pain intensity from 4 to 12 hours.

Multiple-dose, 2-week treatment with lidocaine patch 5% was compared to vehicle patch (without lidocaine) in a double-blind, crossover clinical trial of withdrawal-type design conducted in 32 patients, who were considered as responders to the open-label use of lidocaine patch 5% prior to the study. The constant type of pain was evaluated but not the pain induced by sensory stimuli (dysesthesia). Statistically significant differences favoring lidocaine patch 5% were observed in terms of time to exit from the trial (14 versus 3.8 days at p-value < 0.001), daily average pain relief, and patient’s preference of treatment. About half of the patients also took oral medication commonly used in the treatment of post-herpetic neuralgia. The extent of use of concomitant medication was similar in the two treatment groups.

INDICATION AND USAGE: Lidocaine patch 5% is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.

CONTRAINDICATIONS: Lidocaine patch 5% is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

WARNINGS: Accidental Exposure in Children: Even a used lidocaine patch 5% contains a large amount of lidocaine (at least 115 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing or ingesting a new or used lidocaine patch 5%, although the risk with this formulation has not been evaluated. It is important for patients to store and dispose of lidocaine patch 5% out of the reach of children, pets and others. (See HANDLING AND DISPOSAL)

Excessive Dosing: Excessive dosing by applying lidocaine patch 5% to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS: Systemic Reactions). Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 mcg/mL. The blood concentration of lidocaine is determined by the rate of systemic absorption and elimination. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine. With recommended dosing of lidocaine patch 5%, the average peak blood concentration is about 0.13 mcg/mL, but concentrations higher than 0.25 mcg/mL have been observed in some individuals.

PRECAUTIONS: General: Hepatic Disease: Patients with severe
hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally.

**Allergic Reactions:** Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine. However, lidocaine patch 5% should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

**Non-Intact Skin:** Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of lidocaine from increased absorption. Lidocaine patch 5% is only recommended for use on intact skin.

**External Heat Sources:** Placement of external heat sources, such as heating pads or electric blankets, over lidocaine patch 5% patch formulations must be considered.

**Eye Exposure:** The contact of lidocaine patch 5% with eyes, although not studied, should be avoided based on the findings of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

**Drug Interactions:** Antiarrhythmic Drugs: Lidocaine patch 5% should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

**Local Anesthetics:** When lidocaine patch 5% is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Carcinogenesis: A minor metabolite, 2,6-xylidine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of lidocaine patch 5%.

**Mutagenesis:** Lidocaine HCl is not mutagenic in Salmonella/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.

**Impairment of Fertility:** The effect of lidocaine patch 5% on fertility has not been studied.

**Pregnancy:** Teratogenic Effects: Pregnancy Category B. Lidocaine patch 5% has not been studied in pregnancy. Reproduction studies with lidocaine have been performed in rats at doses up to 30 mg/kg subcutaneously and have revealed no evidence of harm to the fetus due to lidocaine. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, lidocaine patch 5% should be used during pregnancy only if clearly needed.

**Labor and Delivery:** Lidocaine patch 5% has not been studied in labor and delivery. Lidocaine is not contraindicated in labor and delivery. Should lidocaine patch 5% be used concomitantly with other products containing lidocaine, total doses contributed by all formulations must be considered.

**Nursing Mothers:** Lidocaine patch 5% has not been studied in nursing mothers. Lidocaine is excreted in human milk, and the milk:plasma ratio of lidocaine is 0.4. Caution should be exercised when lidocaine patch 5% is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS:** Application Site Reactions: During or immediately after treatment with lidocaine patch 5%, the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

**Allergic Reactions:** Allergic and anaphylactoid reactions associated with lidocaine, although rare, can occur. They are characterized by angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock, and urticaria. If they occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

**Other Adverse Events:** Due to the nature and limitation of spontaneous reports in postmarketing surveillance, causality has not been established for additional reported adverse events including:

- Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoaesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

**Systemic (Dose Related) Reactions:** Systemic adverse reactions following use of lidocaine patch 5% are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY: Pharmacokinetics). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (light headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness.

**OVERDOSAGE:** Lidocaine overdose from cutaneous absorption is rare, but could occur. If there is any suspicion of lidocaine overdose (see ADVERSE REACTIONS: Systemic Reactions), drug blood concentration should be checked. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

In the absence of massive topical overdose or oral ingestion, evaluation of symptoms of toxicity should include consideration of other etiologies for the clinical effects, or overdosage from other sources of lidocaine or other local anesthetics.

The oral LD₅₀ of lidocaine HCl is 459 (346 to 773) mg/kg (as the salt) in non-fasted female rats and 214 (159 to 324) mg/kg (as the salt) in fasted female rats, which are equivalent to roughly 4000 mg and 2000 mg, respectively, in a 60 to 70 kg man based on the equivalent surface area dosage conversion factors between species.

**DOSEAGE AND ADMINISTRATION:** Apply lidocaine patch 5% to intact skin to cover the most painful area. Apply the prescribed number of patches (maximum of 3), only once for up to 12 hours within a 24 hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. (See HANDLING AND DISPOSAL) Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

If irritation or a burning sensation occurs during application, remove the patch(es) and do not reapply until the irritation subsides. When lidocaine patch 5% is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Lidocaine patch 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

**HANDLING AND DISPOSAL:** Hands should be washed after the handling of lidocaine patch 5%, and eye contact with lidocaine patch 5% should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. Lidocaine patch 5% should be kept out of the reach of children.

**HOW SUPPLIED:** Lidocaine patch 5% is available as the following:

Carton of 30 patches, packaged into individual child-resistant envelopes.

**NDC 0378-9055-93**

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]