

APPLICATION INSTRUCTIONS

See below for directions on applying your easy-to-use, peel-and-stick patch, as well as other important product information.

STEP 1:

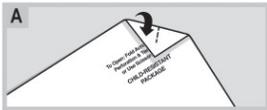
Check the skin where the patch will be worn



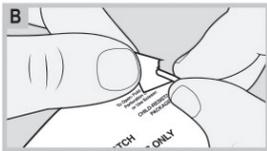
- Keep the patch in the unopened foil pouch until you are ready to put it on.
- Check the skin where your doctor or health care professional told you to wear it.
- Do not put the patch on skin that is cut, scratched or red (like a rash).
- Do not shave the area or you may hurt the skin.

STEP 2:

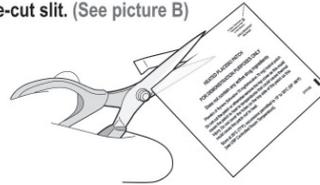
Open the foil pouch and remove the patch. Save the foil pouch.



- TO TEAR OPEN THE FOIL POUCH - fold the upper right corner toward you. (See picture A)
- Press the corner flat to form a small triangle.
- Tear the foil pouch in the middle of the fold along the pre-cut slit. (See picture B)

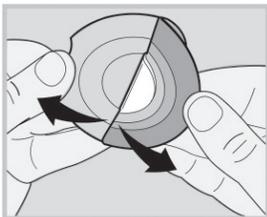


- TO CUT OPEN WITH SCISSORS - cut carefully along the edge of the package.
- SAVE THE FOIL POUCH.

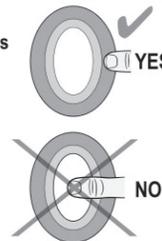


STEP 3:

Put the patch on your skin

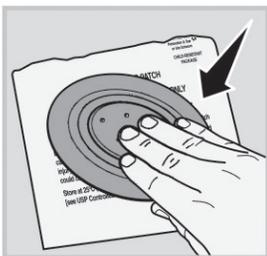


- DO NOT TOUCH THE MEDICINE IN THE MIDDLE - touch only the sticky edges of the patch. Never touch the center area.
- Peel the patch off of the hard plastic backing.
- Put the sticky side of the patch on your skin, where you were told to wear it. Press the edges to make sure the patch will stick to your skin.
- Wash your hands.

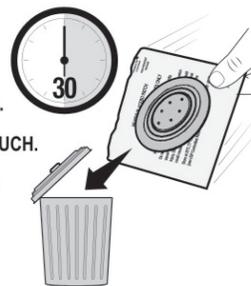


STEP 4:

IMPORTANT — How to remove and discard the patch



- Do not leave the patch on the skin for longer than 30 minutes.
- Carefully peel the patch off your skin, touching only the sticky edges of the patch - DO NOT TOUCH THE MEDICINE IN THE MIDDLE.
- PRESS THE STICKY SIDE OF THE USED PATCH ONTO THE FOIL POUCH.
- THROW FOIL POUCH WITH PATCH ATTACHED, AND HARD PLASTIC BACKING, IN THE GARBAGE so children and pets cannot reach it.
- Wash your hands.



While wearing the patch:

- Do not put the patch on your lips or near your eyes. If you get medicine from the patch in your eye, rinse it with water until the numbness goes away.
- Do not cut or tear the patch.
- Do not get water on the patch. Keep the patch dry. Do not cover the small holes on the outside of the patch. If you applied the patch to the back of your hand, wash your hands carefully.
- If your skin hurts or burns too much, you should take the patch off. It is normal for the skin to feel warm, but it should not burn.

After the patch is removed:

Be careful with your skin after the patch is removed. The skin that was covered by the patch stays numb and you won't be able to feel pain right away. Do not scratch or let this skin touch hot or cold things.

INDICATION

SYNERA[®] (lidocaine and tetracaine) Topical Patch is indicated for use on unbroken skin in children 3 years and up to help prevent the pain of needle sticks into superficial veins and some superficial skin procedures.

IMPORTANT SAFETY INFORMATION

SYNERA[®] is not to be used in patients with a known history of sensitivity to lidocaine, tetracaine, numbing medications of the amide or ester type, or any other component of the product and in patients with para-aminobenzoic acid (PABA) hypersensitivity. Keeping a patch on longer than recommended or applying multiple patches at the same time or one right after the other could result in absorption of sufficient amounts of drug to result in serious adverse effects. Patients should not use SYNERA[®] if they have a history of methemoglobinemia.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Used SYNERA[®] patches contain a large amount of lidocaine and tetracaine (at least 90% of the initial amount). Chewing or swallowing a new or used SYNERA[®] patch may result in serious adverse effects. Store and dispose of SYNERA[®] out of the reach of children and pets.

SYNERA[®] should be used with caution in patients who may be more sensitive to the general effects on the body of lidocaine and tetracaine, particularly those who are seriously ill or weakened by illness, and those with reduced liver function. Patients with severe liver disease or missing adequate blood plasma enzymes are at greater risk of developing toxic plasma concentrations.

Do not use on body passages such as inside the nose or mouth or on areas with unhealthy, broken skin.

Application to broken or inflamed skin may result in toxic blood concentrations of lidocaine and tetracaine.

Allergic or extreme sensitivity (skin rash, swelling or hives, narrowing of airways, and shock) to the active or inactive components of SYNERA[®] can occur and should be managed by a medical professional. Seek immediate emergency help if any of these occur.

Avoid contact of SYNERA[®] with the eyes due to potential irritation or abrasion. If contact occurs, immediately wash out the eye with water or saline, and protect it until sensation returns.

The application of more than two SYNERA[®] patches at the same time or one right after another to children is not recommended as it has not been fully studied. Safety and effectiveness of SYNERA[®] have been established in patients 3 years of age and older.

Lidocaine, one of the numbing medications in SYNERA[®], has been shown to prevent the growth of viruses and bacteria. The effect of SYNERA[®] on needle sticks into the skin for certain vaccines has not been determined.

The heating component contains iron powder, and the patch must be removed before some diagnostic procedures, including magnetic resonance imaging (MRI).

SYNERA[®] may lead to little or no feeling in the area of the skin where it is applied; therefore, patients should avoid trauma (rubbing, scratching, or exposure to heat or cold) before complete feeling returns.

SYNERA[®] should be used with caution in patients receiving certain heart medications and/or other local pain-preventing medications, because there may be additional toxic effects with lidocaine and tetracaine.

In clinical studies involving 1449 subjects treated with SYNERA[®], the most common local reactions were redness of the skin (71%), pale skin (12%) and swelling (12%); these reactions were generally mild and resolved on their own soon after patch removal. There were no treatment-related serious adverse events.¹

SYNERA[®] should be applied immediately after opening the pouch. Do not cut or remove the top cover of the patch as this could result in a burn injury.

If skin irritation or a burning sensation occurs during application, remove the patch and inform your child's doctor or nurse immediately.

Please see Full Prescribing Information including Instructions for Use before using SYNERA[®].

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.

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REFERENCE

1. SYNERA[®] Prescribing Information. Galen US Inc., Souderton, PA; March 2014.