

What is SYNERA[®]?

SYNERA[®] is a technological advance which can help prevent needle-stick pain in kids 3 years of age and older. SYNERA[®] combines two commonly used numbing medications (lidocaine and tetracaine) with warming technology in a simple-to-use peel-and-stick patch for certain procedures that require a needle stick.

The unique warming technology in SYNERA[®] has been proven to enhance the anesthetic effect providing a numbing depth of anesthesia of almost 7 mm at 30 minutes, increasing to greater than 8 mm even after patch removal, greater than has been shown in separate published studies with EMLA[®].⁴

What does SYNERA[®] look like?

SYNERA[®] looks like a large adhesive bandage. It is oval-shaped and has SYNERA[®], LIDOCAINE and TETRACAINE printed on it. There are also 6 tiny holes in the center of the patch where the warming mechanism is located.

How big is the SYNERA[®] patch?

The SYNERA[®] topical patch is oval-shaped and is approximately 3-1/4 inches wide and 2-3/8 inches tall.

How does SYNERA[®] work?

Once removed from the pouch and exposed to air, the SYNERA[®] patch starts to warm up. When placed on your child's skin, SYNERA[®] raises the skin temperature slightly to increase blood flow into the area and speeds up delivery of the numbing medications into the skin.¹ After 20-30 minutes, the area will be numb and the SYNERA[®] patch will be removed. The skin will be cleaned, and your child will be ready for the needle stick.

Does SYNERA[®] really work?

Yes. Studies have shown that SYNERA[®] is effective and safe to use for the prevention of needle-stick pain—even in children as young as 3 years of age.¹ In a study of children aged 3 to 17 years, 59% of patients reported no pain upon the needle stick compared to 20% for a patch containing no numbing medications.⁵ In the same study, investigators reported that 76% of children treated with SYNERA[®] experienced no pain compared to 20% for a patch containing no numbing medications.⁵

How does SYNERA[®] compare to other topical numbing creams like EMLA[®]?

SYNERA[®] works at least twice as fast and is more convenient to use than EMLA[®].^{1,3,6} In a study of adults, significantly more subjects reported no pain with SYNERA[®] after 20 and 30 minutes.⁶ At just 20 minutes, 90% of subjects reported no pain with SYNERA[®] vs 60% with EMLA[®], and at 30 minutes, 95% of subjects reported no pain with SYNERA[®] vs 65% with EMLA[®].⁶ SYNERA[®] is more convenient to use—it takes just 20-30 minutes to work vs at least 1 hour for EMLA[®].^{1,3} The quick and simple-to-use peel-and-stick SYNERA[®] patch also does not require the use of additional wraps to cover the site, making it great for active kids and their parents.

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.

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How long does it take SYNERA[®] to work?

Once placed on your child's skin, the area will be numb in just 20-30 minutes.¹

How is SYNERA[®] applied?

SYNERA[®] is simple to use. Once the SYNERA[®] pouch is opened and the patch is removed, it automatically begins to warm up. The backing is then removed from the patch, and it will be applied to your child's healthy, unbroken skin like an adhesive bandage. It will be placed directly over the area where the needle will be inserted.

Will SYNERA[®] hurt?

No. SYNERA[®] should not be much different from applying or removing an adhesive bandage. The warming is gradual and gentle. If at any time your child feels any irritation or burning, please tell the doctor or nurse immediately.

What happens once the SYNERA[®] patch is removed?

Once removed from your child's skin, the SYNERA[®] patch is no longer delivering additional numbing medications into the skin. Gradually the normal feeling will return but your child should avoid any trauma (rubbing, scratching, or exposure to heat or cold) before complete feeling returns to the area. Used SYNERA[®] patches contain a large amount of lidocaine and tetracaine. 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.

Will my child experience any side effects with SYNERA[®]?

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 went away on their own soon after patch removal. There were no serious adverse events as a result of treatment with SYNERA[®].

How do I get SYNERA[®] for my child?

SYNERA[®] is only available with a prescription. Ask your child's doctor or nurse about helping to prevent your child's needle-stick pain with SYNERA[®] before their needle-stick procedures.

Will SYNERA[®] be covered by insurance?

A special program has been set up by Galen called SNAP (SYNERA[®] NOW Access Program).

SNAP is designed to help answer questions about insurance coverage for SYNERA[®].

A pharmacy coordinator from SNAP can assist you with insurance questions specific to your plan and have SYNERA[®] shipped directly to you.

Call SNAP with any questions 1-844-GALENRX (1-844-425-3679).

Important Safety Information (continued)

Patients should not use SYNERA[®] if they have a history of methemoglobinemia.

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.

EMLA[®] is a registered trademark of Abraxis Bioscience, Inc.

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.

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

References

1. SYNERA[®] Prescribing Information. Galen US Inc., Souderton, PA; March 2014.
2. Masud S, Wasnich RD, Ruckle JL, et al. Contribution of a heating element to topical anesthesia patch efficacy prior to vascular access: results from two randomized, double-blind studies. *J Pain Symptom Manage.* 2010;40(4):510-519.
3. EMLA Cream 5% [package insert]. Lake Forest, IL: Akorn Inc; April 2012.
4. Wallace MS, Kopecky EA, Ma T, Brophy F, Campbell JC. Evaluation of the depth and duration of anesthesia from heated lidocaine/tetracaine (SYNERA[®]) patches compared with placebo patches applied to healthy adult volunteers. *Reg Anesth Pain Med.* 2010;35(6):507-513.
5. Sethna NF, Verghese ST, Hannallah RS, Solodiuk JC, Zurakowski D, Berde CB. A randomized controlled trial to evaluate S-Caine patch for reducing pain associated with vascular access in children. *Anesthesiology.* 2005;102(2):403-408.
6. Sawyer J, Febbraro S, Masud S, Ashburn MA, Campbell JC. Heated lidocaine/tetracaine patch (SYNERA[®], Rapydan) compared with lidocaine/prilocaine cream (EMLA) for topical anaesthesia before vascular access. *Br J Anaesth.* 2009;102(2):210-215.