



SYNERA® FACT SHEET

What is SYNERA?

[SYNERA is a peel-and-stick procedural topical anesthetic patch with a novel heating technology designed to enhance the delivery of the anesthetic. The anesthetic formulation is a eutectic mixture of equal parts lidocaine and tetracaine.]¹

The U.S. Food and Drug Administration (FDA) approved SYNERA in June 2005 for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures in both children three years and older and adults.

[SYNERA has an easy two-step, peel-and-stick application with a familiar, latex-free, adhesive bandage-like appearance.]²

[SYNERA has a quick onset of action and is effective in as little as 20 minutes.]¹

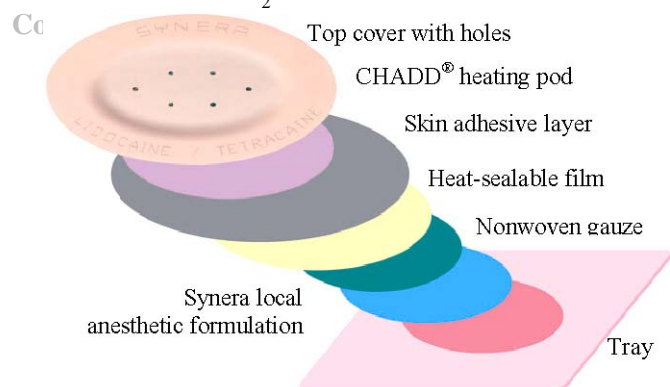
SYNERA is contraindicated in patients with a known history of sensitivity to lidocaine, tetracaine, or any other component of the product, and in those patients with para-aminobenzoic acid (PABA) sensitivity.



How Does SYNERA Work?

[SYNERA works through a novel technology called **Controlled Heat-Assisted Drug Delivery (CHADD®)**. The CHADD® heating pod technology gently warms the patch once it is removed from its packaging and each layer of the SYNERA patch is scientifically designed to facilitate the delivery of the anesthetics into the skin.]¹

[7 Layers of Technology in One



Keeping a patch on longer than recommended or applying multiple patches simultaneously or sequentially could result in systemic absorption sufficient to result in serious adverse events that are typical of drugs in this class.

Even a used SYNERA patch contains a large amount of lidocaine and tetracaine (at least 90% of the initial amount). Chewing or ingesting a new or used SYNERA patch may result in serious adverse events. Store and dispose out of the reach of children and pets.

Do not cut or remove the top layer of the patch as this could result in thermal injury.

What Have Clinical Trials of SYNERA Shown?

[SYNERA has been studied in 1,449 subjects in 28 clinical trials.]¹

[In clinical trials, SYNERA was effective in pediatric patients (3-17 years) and adult patients and demonstrated safety in infants as young as four months.]¹

[In a study of healthy adults receiving the SYNERA patch on one arm and EMLA[®] Cream (lidocaine 2.5%/prilocaine 2.5%) on the other arm, patients undergoing vascular access procedures reported less pain and distress with SYNERA than EMLA at times of less than 60 minutes, as measured by the Visual Analog Scale (VAS).]³

[In a study of pediatric patients undergoing venous access procedures, 68 percent of patients receiving SYNERA rated their pain at 10 or below on an Oucher[™] scale of one to 100 versus 20 percent of patients receiving an identical self-heating placebo.]²

In clinical studies, the most common local reactions were erythema (71%), blanching (12%), and edema (12%); these reactions were generally mild, resolving spontaneously soon after treatment.

For Safety Information and/or to learn more about the SYNERA patch, please visit <http://www.synera.com>.

Please see accompanying full prescribing information.

¹ Synera [package insert]. Chadds Ford, Pa; ZARS Pharma Inc; 2006.

² Sethna NF, Verghese ST, Hannallah RS, Solodiuk JC, Zurakowski D, Berde CB. *Anesthesiology*. 2005;102:403-408.

³ Sawyer J., Campbell J. *Anesthesiology* 2004;101:A1123.