

Applying SYNERA

Check the skin where the patch will be worn. **SYNERA** should only be applied to healthy, unbroken skin.

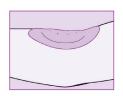


Open the foil pouch, remove the patch, and place the foil pouch aside.



Remove the backing and place the patch directly where the needle will be inserted. **Do NOT** touch the medicine in the middle.

When the SYNERA patch is placed on your skin, you will begin to feel gentle and gradual warming. The temperature of your skin will increase just slightly. The warming increases blood flow in that area to better deliver the numbing medications into your skin.



Wear for 20-30 minutes prior to your appointment. **Do NOT leave the patch on the skin for longer than 30 minutes.**



To discard the patch, adhere it to the foil pouch and dispose of it away from children and pets.

IMPORTANT SAFETY INFORMATION (Continued)

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 1,449 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.

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 doctor or nurse immediately.