



The FDA Safety Information and Adverse Event Reporting Program

Over-The-Counter Topical Muscle and Joint Pain Relievers: Drug Safety Communication - Rare Cases of Serious Burns

[Posted 09/13/2012]

美國FDA提醒，特定的非處方藥品(OTC)，如緩解輕度肌肉關節疼痛的皮膚外用藥品，會造成罕見之皮膚灼傷的案例，程度包含一到三級。使用皮膚外用藥品時，皮膚會有局部灼熱或輕涼感，這些產品不應造成疼痛或皮膚損傷，但是有罕見案例造成嚴重皮膚灼傷。

非處方(OTC)外用皮膚製劑用於緩解輕度肌肉關節疼痛，其成分為單方或複方，含薄荷油(menthol)，水楊酸甲酯(methyl salicylate)，或辣椒素(capsaicin)，市面上有各種品牌，也有不同劑型，如乳霜、乳液、軟膏、貼片。

使用非處方(OTC)外用皮膚製劑時，如果造成皮膚損傷，如疼痛、腫脹、起泡，應立即停用並就醫。醫療人員若建議患者使用非處方(OTC)外用皮膚製劑時，應告知如何適當使用該藥品、灼傷的風險性。

[Posted 09/13/2012]

AUDIENCE: Consumer, Health Professional

ISSUE: FDA is alerting the public that certain over-the-counter (OTC) products that are applied to the skin for the relief of mild muscle and joint pain have been reported to cause rare cases of serious skin injuries, ranging from first- to third-degree chemical burns, where the products were applied.

When applied to the skin, the products produce a local sensation of warmth or coolness. These products should not cause pain or skin damage, however, there have been rare cases of serious burns following their use. Some of the burns had serious complications requiring hospitalization

BACKGROUND: OTC topical muscle and joint pain relievers are used to temporarily relieve minor muscle and joint aches and pain. These OTC topical muscle and joint pain relievers are available as single- or combination-ingredient products that contain menthol, methyl salicylate, or capsaicin, and are marketed under various brand-names, such as, Bengay, Capzasin, Flexall, Icy Hot, and Mentholatum. The various formulations include creams, lotions, ointments, and patches.

RECOMMENDATION: Consumers using an OTC topical muscle and joint pain reliever who experience signs of skin injury where the product was applied, such as pain, swelling, or blistering of the skin, should stop using the product and seek medical attention immediately. When recommending OTC topical muscle and joint pain relievers to patients, healthcare professionals should counsel patients about how to use the products appropriately and inform them about the risk of serious burns.