



## Onfi (clobazam): Drug Safety Communication - Risk of Serious Skin Reactions

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FDA警告民眾，抗癲癇藥Onfi (clobazam)可能造成罕見而嚴重的皮膚反應，可能導致永久性傷害和死亡。FDA核准變更Onfi (clobazam)仿單和病患用藥指南，加上這些嚴重皮膚反應的敘述。

這些皮膚反應為Stevens-Johnson syndrome (SJS)和toxic epidermal necrolysis (TEN)，可能在Onfi治療期間的任何時間發生。但在首次治療的前八週，或是先前使用過Onfi並再度使用時，皮膚反應發生的可能性較大。FDA的蒐集案例中，所有SJS和TEN的患者均需住院，一位失明，一位死亡。

Onfi的藥物仿單已經加註嚴重皮膚反應的副作用。

### 背景

Onfidk是benzodiazepine 類藥物，與其他藥物並用可治療嚴重癲癇症狀，即Lennox-Gastaut Syndrome。

### 建議

病人應密切注意SJS / TEN的症狀，特別是前8週的治療期間，或是重新使用時。除非排除藥物引起的可能性，醫療人員若第一時間發現紅疹，應停用並考慮其他替代治療。

服用Onfi的病人若有紅疹、水泡、脫皮、口腔潰瘍、蕁麻疹等情形，應立即就醫治療。病人不應在尚未告知醫療人員之前就自行停藥，突然停止使用Onfi，可能會有戒斷問題，例如癲癇發作、幻覺、顫抖、緊張、胃部或肌肉痙攣。

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**AUDIENCE:** Neurology, Pharmacy, Dermatology

**ISSUE:** FDA is warning the public that the anti-seizure drug Onfi (clobazam) can cause rare but serious skin reactions that can result in permanent harm and death. FDA approved changes to the Onfi drug label and the patient Medication Guide to describe the risk of these serious skin reactions.

These skin reactions, called Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur at any time during Onfi treatment. However, the likelihood of skin reactions is greater during the first 8 weeks of treatment or when Onfi is stopped and then re-started. All cases of SJS and TEN in the FDA case series have resulted in hospitalization, one case resulted in blindness, and one case resulted in death.

The Onfi drug label has been revised to add information about the risk for serious skin reactions to the Warnings and Precautions section and to the Medication Guide.

**BACKGROUND:** Onfi is a benzodiazepine medication used in combination with other medicines to treat seizures associated with a severe form of epilepsy called Lennox-Gastaut Syndrome.

**RECOMMENDATION:** Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks of treatment or when re-introducing therapy. Health care professionals should discontinue use of Onfi and consider an alternate therapy at the first sign of rash, unless it is clearly not drug-related.

Patients taking Onfi should seek immediate medical treatment if they develop a rash, blistering or peeling of the skin, sores in the mouth, or hives. Patients should not stop taking Onfi without first talking to their health care professionals. Stopping Onfi suddenly can cause serious withdrawal problems, such as seizures that will not stop, hallucinations, shaking, nervousness, and stomach or muscle cramps.