



Practice sting 2024-05

Practice sting Esophageal complaints after taking flucloxacillin

This Practice Sting was developed in collaboration with pharmacovigilance centre [Lareb](#).

The Practice Sting is particularly interesting for pharmacists and healthcare professionals who administer medicines.

In the period 2007-2019, Lareb received [22 notifications](#) of esophageal damage after taking flucloxacillin capsules. In response to these notifications, the Dutch Medicines Evaluation Board asked manufacturers in 2020 to adjust the instructions for use in the package leaflet as follows: *Take your flucloxacillin hard capsule at least 1 hour before or 2 hours after a meal. To reduce the risk of pain in your esophagus (the tube that connects your mouth to your stomach), swallow the capsules with a large glass of water (250ml) and do not lie down immediately after taking your capsules.*

Even after adjusting the package leaflet, Lareb and 'Meldpunt Medicijnen' (Medicines Reporting Centre) still receive many notifications about esophageal complaints after taking flucloxacillin capsules. In the past three years more than 150 notifications were received.

Notifications

Examples of notifications are:

- "After taking the flucloxacillin capsule, I had an intense burning pain in my esophagus and noticed a dark discoloration of the stool."
- "Do not lie in bed immediately after taking the capsule. In my case, the capsule got stuck in the esophagus, causing a painful burning sensation in my chest. I still had problems with my esophagus for days afterwards, mainly when swallowing. According to the GP, this is a common problem, but the pharmacy did not mention this problem."

Analysis

Esophageal pain is a non-specific symptom that may indicate underlying diseases, such as reflux or esophagitis. The mechanism that causes this pain is still unclear. Activation of thermoreceptors (involved in sensation of hot and cold), mechanoreceptors (involved in dilation and contraction of muscles) or chemoreceptors (sensing acidity and hyperosmolarity of blood) may play a role in esophageal pain.

Since other medicines with the same capsule size cause complaints less often and there are notifications of irritation with flucloxacillin suspension, activation of the chemoreceptor is likely. It is suspected that taking the flucloxacillin capsule with too little water can lead to activation of this receptor.

The reason that Lareb and Meldpunt Medicijnen still receive many notifications of esophageal complaints after taking flucloxacillin capsules is probably that the patient or the person administering the medication does not (properly) read the instructions for use in the package leaflet and on the pharmacy label. The pharmacy label and the administration list also lack the recommendation that one should not lie down immediately after taking the flucloxacillin capsule.

Recommendations

For pharmacists

Realize that the patient does not read or follow the package leaflet and the text on the pharmacy label (properly). Therefore, provide a verbal explanation. Advise the patient to take the capsule 1 hour before or 2 hours after the meal while standing or sitting with a large glass of water and not to lie down for half an hour after taking it.

For healthcare professionals who administer medication

Read the administration instructions on the administration list carefully and follow them.

For organizations that fill the information in pharmacy information systems (AISs)

Ensure that the administration text of the flucloxacillin capsule in the AIS is supplemented with the information that the patient should not lie down for half an hour after taking it.