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Post-injection delirium sedation syndrome

Schizophrenia and related psychoses CHAPTER 1 Post-injection delirium sedation syndrome Although the precise mechanism of post-injection delirium sedation syndrome (PDSS) remains unclear, it is thought to occur when the pamoate salt of olanzapine is inadvertently exposed to a large volume of blood or plasma, such as through IV injection or a blood vessel injury.8,9 This exposure can cause the salt to dissolve more rapidly and release a large amount of olanzapine into the circulation.8 Olanzapine plasma levels may reach over 800mcg/L and confusion, delirium and somnolence result.10,11 Treatment is supportive and outcomes invariably good.9 The incidence of PDSS is less than 0.1% of injections and almost all reactions (86%) occur within 1 hour of injection (mean time is 30 minutes)12 and fully resolve within 72 hours.8,9,13 One study suggested an incidence of 0.044% of injections (less than 1 in 2,000) with 91% of reactions being apparent within 1 hour.14 There are very rare reports of events occurring after 3 hours, including one case where the reaction occurred 12 hours after the injection.15 In most countries, olanzapine LAI may only be given in healthcare facilities under supervision and patients need to be kept under observation for 3 hours after the injection is given. Given the tiny number of cases appearing only after 2 hours, a good case can be made for shortening the observation period to 2 hours (as in Australia, New Zealand16,17 and some other countries). Shorter monitoring periods were also employed during the COVID-19 pandemic.18 However, it is worth emphasising that PDSS may occur at any time and has no clear predictive risk factors,8 even after several uses in the same patient. That is to say, prior safe use of olanzapine LAI in an individual does not imply low risk of PDSS. The risk may be reduced in patients on 1-monthly injection intervals,8,19 presumably because they receive relatively fewer injections. In the EU and UK, the exact wording of the SPC4 is as follows: After each injection, patients should be observed in a healthcare facility by appropriately qualified personnel for at least 3 hours for signs and symptoms consistent with olanzapine overdose. Immediately prior to leaving the healthcare facility, it should be confirmed that the patient is alert, oriented, and absent of any signs and symptoms of overdose. If an overdose is suspected, close medical supervision and monitoring should continue until examination indicates that signs and symptoms have resolved. The 3-hour observation period should be extended as clinically appropriate for patients who exhibit any signs or symptoms consistent with olanzapine overdose. For the remainder of the day after injection, patients should be advised to be vigilant for signs and

symptoms of overdose secondary to post-injection adverse reactions, be able to obtain assistance if needed, and should not drive or operate machinery. This monitoring requirement has undoubtedly adversely affected the popularity of olanzapine LAI. Interestingly some patients continue treatment even after an episode of post-injection syndrome.20 As stated, no patient or medical factor has been identified which definitively predicts PDSS,10 except perhaps that those experiencing the syndrome are somewhat more likely to have previously had an injection site--related adverse effect.21 Male gender and higher doses have also been suggested to be risk factors for PDSS.12,14

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