

ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

An education program to the health care professionals (HCP) (doctors-nurses-pharmacists) shall address,

- 1) Description of post injection syndrome
 - Education about the 2 intramuscular formulations of olanzapine, including packaging differences
 - Description of reconstitution and proper administration technique
 - Recommendation for a 3-hour on-site observation period post injection
 - Recommendation that prior to giving the injection, the HCP should determine that the patient will not travel alone to their destination
 - Recommendation for informing patients that for the remainder of the day of the injection, they should not drive or operate machinery, should be vigilant for signs and symptoms of a post injection syndrome event, and should be able to obtain assistance if needed
 - Description of the most common symptoms reported with olanzapine overdose that represent the clinical manifestation in post injection syndrome events
 - Recommendation for appropriate monitoring until the event resolves if an event should occur
- 2) Recommendations for monitoring of patients for glucose, lipids, and weight.
 - Promote awareness of appropriate metabolic monitoring by distributing utilized published antipsychotic guidelines.

A patient card shall be distributed to all patients, including:

- Description of post injection syndrome
- Recommendation for a 3-hour on-site observation period post injection
- Recommendation that prior to giving the injection, the HCP should determine that the patient will not travel alone to their destination
- Recommendation for informing patients that for the remainder of the day of the injection, they should not drive or operate machinery, should be vigilant for signs and symptoms of a post injection syndrome event, and should be able to obtain assistance if needed
- Description of the most common symptoms reported with olanzapine overdose that represent the clinical manifestation in post injection syndrome events
- Recommendation for appropriate monitoring until the event resolves if an event should occur