



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2015
EMA/PRAC/118045/2015
Pharmacovigilance Risk Assessment Committee

PRAC recommendations on signals for update of the product information

Adopted at the 9-12 February 2015 PRAC

1. Amiodarone – Syndrome of inappropriate antidiuretic hormone secretion (SIADH) (EPITT no 18091)

Having considered the available evidence the PRAC has agreed that the MAHs of amiodarone for intravenous administration should submit a variation within 2 months, to amend the product information as described below (new text underlined). The package leaflets should be updated accordingly.

Summary of product characteristics (SmPC)

Section 4.8:

Endocrine disorders:

Very rare: Syndrome of inappropriate antidiuretic hormone secretion (SIADH)

Package leaflet

4. Possible side effects

Very rare (affects less than 1 in 10,000 people)

Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH).



2. Aripiprazole – Hyperprolactinaemia (EPITT no 18086)

Having considered the available evidence in EudraVigilance, the MAH's clinical trials and pharmacovigilance databases and the literature, the PRAC has agreed that the MAH of Abilify and Abilify Maintena should submit variations within 2 months, to amend the product information as described below (new text underlined). In addition, the MAH should describe the data on hyper- and hypoprolactinaemia in the SmPCs' sections 5.1. Following the variations of the marketing authorisations for these products, the MAH for any product with the same active substance should submit a respective variation application.

SmPC

Section 4.8 – Undesirable effects:

Tabulated list of adverse reactions:

Endocrine disorders

Frequency 'uncommon': Hyperprolactinaemia

Description of selected adverse reactions:

Hyperprolactinaemia

In clinical trials for the approved indication(s) and post-marketing, both increase and decrease in serum prolactin as compared to baseline was observed with aripiprazole (section 5.1).

Package leaflet

Section 4: Possible side effects

Uncommon side effects (may affect up to 1 in 100 people):

Increased blood levels of the hormone prolactin.