19 September 2013
EMA/764026/2013
Committee for Medicinal Products for Human Use (CHMP)

Fycompa

International non-proprietary name: perampanel

Procedure No. EMEA/H/C/002434/PSUV/0009

Period covered by the PSUR: 23 July 2012 – 22 January 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Fycompa, the scientific conclusions of PRAC are as follows:

Analysis of the data contained within this PSUR did not reveal any new safety concerns, new safety signals or adverse events not adequately reflected in the current perampanel SPC.

The PRAC considered that the overall risk/benefit of FYCOMPA remained favourable.

However, following a review of 6 events reported during this period with the code MedDRA SMQ of hostility/aggression, the PRAC agreed that amendments to the warning on aggression already present in section 4.4 of the SmPC were warranted as described below:

Aggression

Aggressive and hostile behaviour has been reported in patients receiving perampanel therapy. In perampanel-treated patients in clinical trials aggression, anger and irritability were reported more frequently at higher doses. Most of the reported events were either mild or moderate and patients recovered either spontaneously or with dose adjustment. However, thoughts of harming others, physical assault or threatening behaviour were observed in some patients (<1% in perampanel clinical studies). Patients and caregivers should be counselled to alert a health care professional immediately if significant changes in mood or patterns of behaviour are noted. The dosage of perampanel should be reduced if such symptoms occur and should be discontinued immediately if symptoms are severe.

~~*Cases of aggression have been reported and are dose related since they were more frequently reported with higher doses. Most of these events were either mild or moderate and recovered either spontaneously or with dose adjustment. However, in some cases, reports of aggression were severe which led to discontinuation of treatment. Therefore, the dose titration should be followed (see section 4.2) and a dose reduction should be considered in case of persistence of aggressive symptoms.*~~

These changes have been reflected in Section 2 of the PL as described below:

Fycompa may make you aggressive, angry or violent. It may also cause you to have unusual or extreme changes in behaviour or mood.

No new relevant information on efficacy and effectiveness in the authorised indication became available during the period covered by this PSUR.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Fycompa the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance perampanel is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.