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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 19-22 September 2011

Name of medicine	INN	Marketing authorisation holder	Scope
Revatio	sildenafil	Pfizer Limited	Type II variation following concern over the high doses of the medicine used in an ongoing paediatric study. CHMP Opinion recommending updating sections 4.2, 4.4 and 5.1 of the Summary of Product Characteristics (SmPC) to reinforce the current dosing recommendations.
Toviaz	fesoterodine	Pfizer Limited	Type II variation following the review of cases of angioedema. CHMP Opinion recommending to include a warning on angioedema in section 4.4 of the SmPC as it has been reported with fesoterodine and has occurred after the first dose in some cases. If angioedema occurs, fesoterodine should be discontinued and appropriate therapy should be promptly provided.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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Invega, Xeplion	paliperidone	Janssen-Cilag International NV	<p>Type II variation to update the SmPC and Package Leaflet (PL) regarding the use of antipsychotics during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns.</p> <p>CHMP opinion recommending to add neonatal drug withdrawal syndrome as listed adverse reaction and to update section 4.6 of the SmPC and section 2 of the PL in accordance with the PhVWP/CHMP class labelling recommended wording:</p> <p>SmPC: Neonates exposed to antipsychotics (including [NAME]) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder.</p> <p>PL: The following symptoms may occur in newborn babies, of mothers that have used [NAME] in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.</p>
Zyprexa, Zyprexa Velotab, Zypadhera	olanzapine	Eli Lilly Nederland B.V.	<p>Type II variation following PhVWP/CHMP conclusions of June 2011 regarding the use of antipsychotics during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns.</p> <p>CHMP opinion recommending to add neonatal drug withdrawal syndrome as listed adverse reaction and to update section 4.6 of the SmPC and section 2 of the PL in accordance with the PhVWP/CHMP class labelling recommended wording (see above).</p>

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Sycrest	asenapine	N.V. Organon	<p>Type II variation following PhVWP/CHMP conclusions of June 2011 regarding the use of antipsychotics during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns.</p> <p>CHMP opinion recommending to add neonatal drug withdrawal syndrome as listed adverse reaction and to update section 4.6 of the SmPC and section 2 of the PL in accordance with the PhVWP/CHMP class labelling recommended wording (see above).</p>