

To:  
Head of Paediatric Medicines  
European Medicines Agency  
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## Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): (3aR,4S,7aR)-octahydro-4-hydroxy-4-[(3-methylphenyl)ethynyl]-1H-indole-1-carboxylic acid methyl ester

Invented name:

Latest Decision number(s): 1) P/0107/2013 2) 3) 4)

Corresponding PIP number(s): 1) EMEA-001003-PIP01-10-M02 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:  
Treatment of fragile-X syndrome

- ☒ has been discontinued  
☐ has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): *(tick all that apply)*

- ☒ (possible) lack of efficacy in adults  
☒ (possible) lack of efficacy in children  
☐ (possible) unsatisfactory safety profile in adults  
☐ (possible) unsatisfactory safety profile in children  
☐ commercial reasons (please specify: )  
☐ manufacturing / quality problems  
☐ other regulatory action (please specify: ) *(e.g. suspension, revocation of M.A.)*  
☐ other reason (please specify: )

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

Name and signature of the PIP contact point: Peter Rock

Date: 20 May 2014

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