

Datum: 05.02.2018
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Unser Zeichen: PHV-10642700-A-180201
Ihr Zeichen:

PHV-issue: Risperidon

Sehr geehrte Damen und Herren,

Nach der Fertigstellung der Variations DE/H/1919/001-002/II/014, DE/H/3985/II/006/G, DE/H/1917/001-006/II/057 and DE/H/1918/001-006/II/053 kam das PRAC zu dem Schluss, dass folgende Informationen (siehe unten) noch nicht in allen Produktinformationen von Arzneimitteln, die den Wirkstoff Risperidon enthalten, abgebildet sind. (Siehe auch CMDh Press release vom 22.-24. Jänner 2018: <http://www.hma.eu/249.html>)

Auszug aus dem "Report from the CMDh meeting held on 22-24 January 2018"

Risperidone containing medicinal products

PRAC noted that information from previously finalised procedures DE/H/1919/001-002/II/014, DE/H/3985/II/006/G, DE/H/1917/001-006/II/057 and DE/H/1918/001-006/II/053 (please see below wording in bold italics) related to the risk of the occurrence of extrapyramidal symptoms when adjusting medications for patients receiving both, psychostimulants (e.g. methylphenidate) and risperidone is not reflected in the product information of all products. In accordance with Article 23 of Directive 2001/83/EC, the marketing authorisation holder(s) are reminded of the obligation to keep the product information up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26, and/or the CMDh webpage.

SmPC

Section 4.4 Special warnings and precautions for use

(...)

Tardive dyskinesia/extrapyramidal symptoms (TD/EPS)

Medicines with dopamine receptor antagonistic properties have been associated with the induction of tardive dyskinesia characterised by rhythmical involuntary movements, predominantly of the tongue and/or face. The onset of extrapyramidal symptoms is a risk factor for tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, the discontinuation of all antipsychotics should be considered.

Caution is warranted in patients receiving both, psychostimulants (e.g. methylphenidate) and risperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications. Gradual withdrawal of stimulant treatment is recommended (see section 4.5).

(...)

Section 4.5 Interaction with other medicinal products and other forms of interaction

Pharmacodynamic – related interactions

(...)

Psychostimulants

The combined use of psychostimulants (e.g. methylphenidate) with risperidone can lead to extrapyramidal symptoms upon change of either or both treatments (see section 4.4).

(...)

Package Leaflet

2. What you need to know before you take Risperdal

(...)

Other medicines and Risperdal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

(...)

- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)

(...)