

Ritalin (methylphenidate)

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information (SmPCs) of medicinal products containing the active substance methylphenidate are recommended:

Summary of product characteristics for all methylphenidate products:

- Section 4.1

The reference to DSM IV should be updated to DSM 5.

Summary of product characteristics for Ritalin, Equasym, Medikinet and methylphenidate (generic)

- Section 4.8

The adverse reaction(s) of **logorrhea** should be added under the SOC **psychiatric disorders** with a **frequency unknown**

Summary of product characteristics for Medikinet and methylphenidate (generic)

- Section 4.8

The adverse reaction(s) of **erectile dysfunction** should be added under the SOC **Reproductive system and breast disorders** with a **frequency unknown**

Package leaflet

These adverse events and frequency should also be reflected in section 4 of the patient leaflet in lay terms that are understood by the patient.

Logorrhea should be described as “excessive uncontrolled talking”

“Erectile dysfunction” is acceptable to be used as a term that would be understood by the patient.