

Part IC 3

Clinical Expert Report

Ritalin[®] (methylphenidate)

10 mg tablets

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hyperactivity, attention disorders and impulsiveness are the three essential components of the syndrome.

The latest version of the DSM classification (DSM-IV) has added new elements that make the diagnosis more restrictive. The disorders must be present in two or more situations (at home and at school). There must be a clinically significant alteration in social, scholastic or professional behaviour. The disorders must not appear during the evolution of development disturbances, schizophrenia or other psychotic disorders. Furthermore, they must not be associated with another mental disease (for example, mood disorders, anxiety disorders, dissociative disturbances or personality disturbances).

According to DSM-III-R, its differential diagnosis must consider excessive activity in relation to age, alterations associated with an inadequate, disorganised or chaotic environment, mental retardation, development disturbances and mood disorders.

The disease may be associated with behavioural disorders and hostility, anxiety disorders, motor tics or development disturbances (of language, personality) or neurological alterations of various origin (infective, toxic, traumatic) (Vallée, 1991).

DSM III (1980) identifies three characteristic types of evolution: the first is characterised by the persistence of the symptoms into adolescence (31% of the cases according to Gittelman) (Gittelman, 1985); in the second, the symptoms disappear at puberty; in the third, the hyperactivity disappears but the attention difficulties and impulsiveness persist into adolescence or adulthood (residual type).

The complications of the disease (Gittelman, 1985; Weiss, 1985) are severe and include scholastic failure (only 20% of the children have a normal education), behavioural alterations and, in 23% of the cases according to G. Weiss, the development of an antisocial personality in adulthood, with a more frequent abuse of alcohol and drugs than in the normal population. According to Gittelman, the persistence of ADHD is the greatest risk factor for the development of antisocial behaviour and drug abuse.

These complications considerably improve in children treated with methylphenidate (Klein, 1993), particular the deleterious effects on scholastic learning, but also the behavioural attitudes towards parents, teachers and schoolmates.

The important prognostic factors seem to be socio-economic status, intellectual level, the degree of acceptance by peers, the level of aggressiveness and the degree of hyperactivity.