

Requirements for Therapeutic Use Exemption for methylphenidate (Ritalin, Concerta) 2010

Should a child or patient have been diagnosed with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD), one of the treatment modalities is the use of medication.

The commonest medication used in South Africa for this condition is methylphenidate (Ritalin or Concerta). This agent is, according to the Prohibited List of the World Anti-Doping Agency (WADA), a prohibited substance in sport. The use of this would result in a "positive" doping test should doping control or testing take place in an athlete/player.

There are, however, exceptional circumstances where prohibited substances may be used for genuine and legal medical reasons. In such cases a Therapeutic Use Exemption (TUE) may be applied for and considered by the TUE Committee (TUEC) of the South African Institute for Drug Free Sport (SAIDS) (for National Level Athletes), or the relevant International Federation (for International level athletes). There are International Standards and Guidelines of the WADA that the SAIDS TUEC complies with in this regard.

In order for the SAIDS TUEC to evaluate and make decisions on a TUE application, the following requirements must be met. Should all the necessary documents not be completed, or all the relevant documents not submitted or compliance not adhered to; all TUE applications will be returned without a decision, and the athlete /player runs the risk of being tested "positive" if doping control takes place.

Thus, the following are required for TUE applications for the use of methylphenidate#:

1. A full and detailed *medical report*, where;
 - a. the report is not older than 6 months
 - b. the medical practitioner completing the report is either a:
 - i. Paediatrician
 - ii. (Paediatric) psychiatrist or
 - iii. (Paediatric) neurologist.
 1. Reports from other practitioners and health care providers will not be accepted (see point (e) in reference to psychologists)
 - c. The diagnosis is explicitly stated and;
 - i. Uses DSM IV criteria
 - ii. Indicates the onset of symptoms of the condition
 - iii. States the date of clinical diagnosis
 - iv. Names the person who first made the diagnosis
 - d. The management is stated, including;
 - i. Medication trade name
 - ii. Active ingredient name
 - iii. Dosage
 - iv. Frequency of dosage
 - v. Expected duration of treatment, if known
 - vi. Other management strategies e.g. behavioral or psychotherapy

- e. Additional reports, if available, may include: Educational Psychologists' evaluations; Teacher's Conner's Tests; and/or blood tests, scans and other special investigations that may have been conducted to exclude other pathologies. Please note these are not essential, but may assist the TUEC in making an appropriate decision.
2. Follow up medical reports, if available, since the onset of treatment
3. A completed TUE application form (please note *not* an abbreviated therapeutic use exemption [ATUE] form, but Standard TUE form). These are available from the SAIDS office, the website, the WADA website and sports federations.
4. **In cases of re-application**, in addition to a fully completed TUE form, a detailed and updated medical report needs to be submitted on at least an *annual* basis by the relevant specialist, and it is recommended that regular assessments are done in the interim. Details of these assessments must be included in the annual report.
5. Any changes in medication during the period of a granted TUE will require a renewed application for TUE, should the new drug be listed on the WADA Prohibited list.

All the relevant information should be submitted to the SAIDS office, as soon as available, and if with respect to competition, within 21 days before the competition. Faxed applications will be accepted, but must be followed by original documentation sent to the SAIDS office.

We appreciate and thank you for your understanding and cooperation in assisting us in complying with the International Standards and the World Anti Doping Agency. This allows our athletes with medical conditions to enjoy fair participation in sport.

From: The Therapeutic Use Exemption Committee of the South African Institute for Drug Free Sport.

References:

1. The World Anti-Doping Code, **THE 2007 PROHIBITED LIST INTERNATIONAL STANDARD, January 2010.**
2. The World Anti-Doping Code, **INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS, January 2010.**
3. The World Anti-Doping Program, **THERAPEUTIC USE EXEMPTIONS GUIDELINES, January 2010**

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Checklist for TUE applications for methylphenidate

1. Standard TUE form completed ☐
2. Valid specialist medical report ☐
3. Other reports if available ☐ not needed ☐
4. Faxed to SAIDS on _____
5. Sent to SAIDS on _____