Banned substances in sports supplements

Consumer Information Sheet

The Health Protection Service (HPS) is aware that sports supplements labelled as containing banned substances are being sold in the ACT primarily through retail supplement stores. Banned substances include selective androgen receptor modulators (SARMs), stenabolic, ibutamoren, cardarine, tadalafil, oxedrine, melatonin, phenibut, clomifene, l-dopa and DHEA.

Most of these substances are associated with significant health and safety concerns and their long-term effects on the human body are unknown. Some substances are prescription medicines that without appropriate medical management and monitoring, pose significant risks to the individuals who take them. Some substances are prohibited substances that are associated with high risk of harm to individuals who take them and have no therapeutic purpose.

This information sheet provides further details on these substances. If you are taking a supplement which is labelled as containing a banned substance and that has not been prescribed by your doctor, you should stop taking it immediately and report the name of the product and place of purchase to the Pharmaceutical Services Section of the HPS on (02) 6205 0998. If you have concerns about your health, please see your General Practitioner.

Selective Androgen Receptor Modulators (SARMs)

SARMs are a group of compounds which act in a similar way to anabolic steroids and cause tissue (bone and muscle) growth. Unlike anabolic steroids, SARMs are less likely to cause unfavourable side effects such as the development of male gender characteristics in females, and the development of baldness, breast tissue and testicular shrinkage in males.

SARMs are associated with serious safety concerns including liver toxicity and the potential to increase the risk of heart attack and stroke.[1] The long-term effects of SARMs on the human body are unknown.

SARMs are a Schedule 4 (prescription only) medicine in Australia. It is illegal for supplements containing SARMs to be supplied by supplement stores. It is also illegal for consumers to possess these products without a prescription. Some products labelled as containing SARMs include the disclaimer “for research purposes only” on their packaging. This does not

[1] US Food and Drug Administration. FDA In Brief: FDA warns against using SARMs in body-building products. Oct 2017. Available from: https://www.fda.gov/newsevents/newsroom/fdainbrief/ucm583021.htm

legitimise their use. At present, SARMS have no known therapeutic purpose and there are no registered products containing SARMS available in Australia for medical use.

Below is a list of substances which are commonly known as SARMs:

- Enobosarm (also known as Ostarine, GTx-024, MK-2866 and S-22)
- Ligandrol (also known as VK5211, LGD-4033)
- YK11
- RAD140 (also known as Testolone)
- Andarine (also known as Acetamidoxolutamide, Androxolutamide, GTx-007, S-4, S4)

Stenabolic

Supplements containing stenabolic and its related compounds may be marketed as sports performance enhancers, anti-ageing or fat-reducing products.

These is no human safety data for stenabolic or its related compounds. Potential safety concerns include an increased risk of cancer, heart attack and stroke. Stenabolic may also have an effect on sleep, metabolism and mental health problems.[2]

Stenabolic and its related compounds are Schedule 4 (prescription only) medicines in Australia. It is illegal for supplements containing stenabolic (and related compounds) to be supplied by supplement stores. It is also illegal for consumers to possess these products without a prescription. At present, stenabolic has no known therapeutic purpose and there are no registered products containing stenabolic available in Australia for medical use.

Stenabolic is also known as SR9009. Compounds related to stenabolic are known as SR9011, GSK2945, GSK0999, GSK5072 and GSK2667.

Ibutamoren

Ibutamoren stimulates the release of growth hormone. However its theoretical benefits of increased bone and muscle mass have not been established in clinical trials. Supplements containing ibutamoren may be marketed as anti-ageing or performance-enhancing.

[2] Therapeutic Goods Administration. Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, November 2017. 5 Feb 2018. Available from: https://www.tga.gov.au/book-page/13-stenabolic-sr9009

The long-term safety of ibutamoren has not been established. Its use may increase the risk of heart failure.[3]

Ibutamoren is a Schedule 4 (prescription only) medicine in Australia. It is illegal for supplements containing ibutamoren to be supplied by supplement stores. It is also illegal for consumers to possess these products without a prescription. At present, there are no registered products containing ibutamoren available in Australia for medical use.

Ibutamoren is also known as MK-0677, MK-677 and Nutrobal.

Cardarine

Cardarine is a metabolic activator which was primarily developed to treat obesity, diabetes, and heart health problems. Cardarine may reverse metabolic abnormalities in obese and pre-diabetic individuals by changing the body's metabolism to burn fat for energy instead of muscle or carbohydrates.[4] Supplements containing cardarine may be marketed as performance-enhancing products.

Cardarine is associated with the risk of cancer. The clinical development of this substance was abandoned for safety reasons when it was demonstrated to cause a range of cancers in animals.[4] Cardarine's long-term effects on the human body are unknown.

Cardarine is a Schedule 10 substance in Australia which means that it is of such danger to health to warrant prohibition of sale, supply and use.

Cardarine is also known as Endurobol, GSK-516, GW1516, GW501516, GW501 and 2-[2-methyl-4-[[4-methyl-2-[4-(trifluoromethyl)phenyl]-1,3-thiazol-5-yl]methylsulfanyl]phenoxy]acetic acid (IUPAC).

Tadalafil

Tadalafil is a Schedule 4 (prescription only) medicine in Australia. It is used to treat erectile dysfunction and a type of high blood pressure that affects blood vessels in the lungs and the heart. Supplements containing tadalafil may be marketed as sexual enhancers.

[3] Therapeutic Goods Administration. Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, November 2017. 5 Feb 2018. Available from: https://www.tga.gov.au/book-page/14-ibutamoren

[4] Therapeutic Goods Administration. Scheduling delegates' interim decisions and invitations for further comment: ACCS/ACMS, November 2017. 5 Feb 2018. Available from: https://www.tga.gov.au/book-page/12-cardarine

Serious side effects of tadalafil include vision loss, hearing loss, seizures (fits), heart attack, and a persistent and painful erection. People with heart or blood vessel problems or who are taking certain medications should not take tadalafil due to the risk of severely low blood pressure and heart attack.

As with all prescription medicines, tadalafil should not be used without medical supervision.

Tadalafil may be included in a supplement's ingredient list as "(6R-trans)-6-(1,3-benzodioxol-5-yl)- 2,3,6,7,12,12a-hexahydro-2-methyl-pyrazino [1',2':1,6] pyrido[3,4-b]indole-1,4-dione".

Oxedrine

Oxedrine is found in the herb *Citrus aurantium* (also known as bitter orange). Products containing oxedrine may be marketed as energy supplements, appetite suppressants and weight loss products.[5] When taken in combination with caffeine and other stimulants, oxedrine may have serious effects on the heart and blood vessels such as raised heart rate, increased blood pressure, stroke and heart attack.[5]

Oxedrine is a Schedule 4 (prescription only) medicine for internal use except in preparations labelled with a recommended daily dose of 30mg or less. It is illegal for supplements labelled with a recommended daily dose of more than 30mg to be sold by retail supplement stores.

Oxedrine is also known as synephrine.

Melatonin

Melatonin is a naturally occurring hormone produced by the pineal gland in the brain. It helps to bring on sleep by its involvement in the body's sleep cycle. Supplements containing melatonin may be marketed to treat sleep disorders.

The melatonin in supplements may interact with medications and substances taken by an individual. Underlying sleep conditions may not be diagnosed or managed appropriately. Evidence of the long-term effects of melatonin treatment on the human body is lacking.[6]

[5] Therapeutic Goods Administration. Caffeine and oxedrine containing products. Oct 2013. Available from: https://www.tga.gov.au/monitoring-communication/caffeine-and-oxedrine-containing-products

[6] Therapeutic Goods Administration. Scheduling delegate's final decisions, March 2017. 23 Mar 2017. Available from: https://www.tga.gov.au/book-page/32-melatonin-0

Melatonin is a Schedule 4 (prescription only) medicine in Australia. It is illegal for supplements containing melatonin to be sold in retail supplement stores.

Phenibut

Phenibut has anti-anxiety and sedative effects. Supplements containing phenibut may be marketed to relieve anxiety and depression, improve sleep and enhance cognition (thinking).[7]

Risks of phenibut use include toxicity and overdose potentially requiring hospitalisation and intensive care unit (ICU) admission. People who take phenibut may develop dependence and experience withdrawal symptoms such as hallucinations, psychosis, seizures (fits), agitation, tremor, insomnia (difficulty sleeping), abdominal pain and vomiting. The use of supplements containing phenibut may mean that underlying sleep or mental health conditions are not diagnosed or managed appropriately.[7]

Phenibut is a Schedule 9 (prohibited) substance in Australia. The sale, distribution, use, manufacture and possession of Phenibut is prohibited except in certain circumstances such as approved medical or scientific research.

Phenibut is also known as beta-phenyl-gamma-aminobutyric acid (beta-phenyl-GABA).

Clomifene

Clomifene is a prescription only (Schedule 4) medicine used to treat female infertility. Clomifene works by inhibiting the effects of estrogen in the body. For this reason, clomifene is also associated with abuse and misuse to counteract the estrogenic effects of anabolic steroids in men, such as over-growth of breasts (gynecomastia).

As with all prescription medicines, clomifene should not be used without medical supervision. Serious side effects reported in females following infertility treatment include vision changes and rarely ‘ovarian hyperstimulation syndrome’ which can be life-threatening. In males, long term safety has not been determined and clomifene has been associated with an increased risk of heart disease, stroke and liver damage. Clomifene is unsafe for people who have liver disease, hormone-sensitive tumours, and in women with ovarian cysts, abnormal uterine (womb) bleeding or who are pregnant.

Clomifene is also known as clomiphene and Clomid.

[7] Therapeutic Goods Administration. Scheduling delegate’s final decisions, October 2017. 31 Oct 2017. Available from: https://www.tga.gov.au/book-page/33-phenibut

L-dopa

Levodopa is a prescription only medicine (Schedule 4) which is used in combination with other medications to treat Parkinson's disease (a disorder that affects movement).

As with all prescription medicines, l-dopa should not be used without medical supervision. Serious side effects of l-dopa include uncontrollable movements of the face or limbs, a sudden drop in blood pressure when standing causing dizziness, irregular beating of the heart, drowsiness and hallucinations. Other side effects include severe or persistent nausea or vomiting and unusual changes in mood.

People who have angle-closure glaucoma, a history of melanoma or who have suspicious undiagnosed skin lesions should not take l-dopa. Conditions such as heart disease, irregular heart rhythms, peptic ulcer disease (a condition that affects the stomach lining) and psychiatric disorders can be aggravated by l-dopa. L-dopa can interact with a number of medications.

L-dopa is also known as levodopa.

DHEA

DHEA can cause higher than normal levels of female and male hormones in the body. It is not known whether DHEA is safe for long-term use. It may increase the risk of breast cancer, prostate cancer, heart disease, diabetes and stroke. Other side effects include liver disease, an abnormal heart rhythm, acne, and unusual mood changes.

People with abnormal heart rhythms, blood clotting disorders, liver disease, diabetes, cholesterol problems, depression and mood disorders and women who are pregnant or breastfeeding should not take DHEA. DHEA may interact with other medications.

DHEA is a Schedule 4 (prescription only) medicine. It is illegal for supplements containing DHEA to be supplied by supplement stores. It is also illegal for consumers to possess these products without a prescription. At present, there are no registered products containing DHEA available in Australia for medical use.

DHEA is also known as dehydroepiandrosterone or prasterone.

Accessibility

If you have difficulty reading a standard printed document and would like an alternative format, please phone 13 22 81.

If English is not your first language and you need the Translating and Interpreting Service (TIS), please call 13 14 50.

For further accessibility information, visit: www.health.act.gov.au/accessibility

www.health.act.gov.au | Phone: 132281 | Publication No HPS-00-1097

Australian Capital Territory, Canberra September 2018