Classification of octodrine

Information about a New Chemical Entity for the Medicines Classification Committee

Medsafe

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OCTODRINE (SYNONYMS INCLUDE 1,5-DIMETHYLHEXYLAMINE, DMHA AND 2-AMINO-6-METHYLHEPTANE)

Octodrine is an α-adrenergic agonist originally developed as a decongestant in the 1950s. It has resurfaced as an ingredient in sports supplements. It is a central nervous stimulant that increases the uptake of dopamine and noradrenaline, used as a pre-work out stimulant/fat burner. Effects include enhanced euphoria and alertness, and increased pain threshold.

There is limited research on the therapeutic benefits and harms associated with the use of octodrine. However, the potential side effects of this stimulant are wide and significant reported adverse events for dimethylbutylamine (DMBA) and 1,3-dimethylamylamine (DMAA) include cardiac, nervous system and psychiatric disorders.

NZ scheduling

Octodrine is currently unscheduled in NZ and has not previously been considered by the Medicines Classification Committee. Octodrine is not scheduled as a controlled drug under the Misuse of Drugs Act 1975. Octodrine is considered a New Chemical Entity and there are no approved medicines containing octodrine.

Relationship to other similar substances

Octodrine is similar in structure to DMBA and DMAA. These substances are promoted as pre-workout stimulants and for weight loss.

DMAA

Structurally similar to octodrine, DMAA was brought to the Medicines Classification Committee in November 2015 after being considered by the Expert Advisory Committee on Drugs and after being categorised as a medicine by Medsafe. The Expert Advisory Committee on Drugs acknowledged the potential of DMAA to cause harm and agreed that the substance required regulation. However, the Expert Advisory Committee on Drugs considered that DMAA did not meet enough of the criteria or reach the appropriate harm threshold to be scheduled as a controlled drug.

The Medicines Classification Committee recommended that DMAA should be classified as a prescription medicine, except when present as an unmodified, naturally occurring substance. DMAA has been banned by regulatory agencies in Australia, the US, the UK, the Netherlands and Brazil owing to its links to negative health events (strokes, heart failure and sudden death).

Categorisation

While commonly found in sports and dietary supplements overseas, it appears that most of the octodrine being manufactured for supply is synthetic. Products containing octodrine does not meet any of the requirements to be defined as a dietary supplement. Some products claim that octodrine comes naturally from plants and have been labelled as *Kigelia Africana* extract, but there is no clear evidence that octodrine can be found in these plants.

In both scientific literature and social media, octodrine (and DMBA and DMAA) has been positioned alongside Performance and Image-Enhancing Drugs (PIEDs) and nootropics (medicines that improve cognitive and executive function, memory and creativity). Racetams, a class of nootropics, have been recently classified as prescription medicines.

Medsafe has received advice that octodrine is a medicine as it is only added to products for a therapeutic effect, despite any absence of therapeutic purpose claims for the finished product. There

does not seem to be any other reason for octodrine to be added to the product other than for a therapeutic effect.

Import and sale in New Zealand
There have been a number of importations of octodrine over the past 5 years, including three recent importations of octodrine in commercial quantities. There appears to be a number of New Zealand websites that are advertising products containing octodrine for sale.

Other jurisdictions
Australia - In October 2017 the TGA included entries for "*DMBA and other aliphatic alkylamines with stimulant properties including DMHA"*, into Schedule 10 of the Poisons Standard.

USA - The FDA website includes warnings regarding DMAA, DMBA, and β-Methylphenethylamine (BMPEA) in dietary supplements. None of these substances have been determined to meet its statutory definition of a dietary ingredient.

Canada - DHMA is known as "octodrine and its salts" and is listed as prohibited on the Health Canada Cosmetic Ingredient list.

World Anti-Doping Agency (WADA) - octodrine is a prohibited substance in sports competitions under class S6 of the Prohibited List.

Ministry for Primary Industries (MPI) - There is considerable uncertainty over the safety of this compound as an ingredient added into food. A recent systematic review[1] identified significant data gaps in the pharmacology and safety of DMHA that would be important to address considering its structural similarity to known psychoactive substance. A number of adverse effects were reported from users, including mood swings, tremor, concentration deficiency, over-stimulation, energy crashes, anxiety, high blood pressure, dyspnoea, rapid heartbeat and heartburn. MPI are supportive of the recommendation to classify DMHA (octodrine) as a prescription medicine.

Recommendation
That octodrine should be classified as a prescription medicine.

[1] Catalani V, Prilutskaya M, Al-Imam A, et al. Octodrine: New Questions and Challenges in Sport Supplements. *Brain Sci*. 2018;8(2):34. Published 2018 Feb 20. doi:10.3390/brainsci8020034