

Summary Safety Review – Propofol-containing products – Assessing the potential risk of prolonged erection of the penis (priapism)

Product: Propofol-containing products

Potential Safety Issue: Prolonged erection of the penis (priapism)

Key Messages

- **Propofol-containing products are sedative/anesthetic drugs used by health care professionals during surgeries, or other medical procedures, in children and adults.**
- **Health Canada reviewed the risk of prolonged and painful erection not caused by sexual stimulation (priapism) with propofol-containing products because of a reported Canadian case.**
- **Health Canada’s review concluded that there may be a link between propofol-containing products and the risk of priapism.**
- **Health Canada will notify the manufacturers of propofol-containing products to update the Canadian product safety information to inform Canadians and health care professionals about this potential safety issue.**

Overview

A safety review was initiated by Health Canada to evaluate the available information regarding the potential risk of priapism with the use of propofol-containing products. These products are used to make a patient relaxed, calm or sleepy (sedation) or unconscious (anesthesia) during surgery or medical procedures.

Priapism is a prolonged, and usually painful, erection of the penis not caused by sexual stimulation. It is a rare, but potentially serious, medical condition. Failure to treat this condition promptly may result in permanent disability, such as the inability to get and keep an erection firm enough for sex (erectile dysfunction).

Health Canada’s review was triggered by a Canadian report of priapism in a patient that was sedated with a propofol-containing product for a medical procedure.

Use in Canada

- Propofol-containing products are prescription drugs which are authorized for sale in Canada and used by health care professionals to make a patient (adult or child) relaxed, calm or sleepy (sedation) or unconscious (anesthesia) during surgery or medical procedures.
- Propofol-containing products have been marketed in Canada since 1993 under the brand name Diprivan. Generic versions of propofol are also available. Propofol is available as a 10 mg/mL solution for injection.

Safety Review Findings

- At the time of the review, Health Canada had received 1 unique Canadian report^a of priapism related to the use of propofol-containing products. A review of this report found a possible link between propofol-containing products and priapism.
- This safety review also looked at 10 international published reports. The link between propofol-containing products and priapism was likely in 2 reports and possible in 7 reports. In 1 report, the priapism was found unlikely to be caused by propofol-containing products.
- In the majority of the reports (9/11), priapism happened between 5 minutes to 2 hours after propofol was administered.
- Most patients (10/11) recovered after treatment of the priapism with only 1 reporting long-term disability (ongoing erectile dysfunction).

Conclusions and Actions

- Health Canada's review found that there may be a link between propofol-containing products and the risk of priapism.
- Health Canada has already approved the addition of the risk of priapism to the Canadian product information for Diprivan 1%. Health Canada will notify the manufacturers of other propofol-containing products to update the Canadian product safety information to inform Canadians and health care professionals about this potential safety issue.
- Health Canada will continue to monitor safety information involving propofol-containing products, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action if and when any new health risks are identified.

Additional Information

The analysis that contributed to this safety review included scientific and medical literature, Canadian and international information, and what is known about the use of these products both in Canada and internationally.

For additional information about the safety review, [contact the Marketed Health Products Directorate](#).

If manufacturers or industry associations require more information at this time, they are encouraged to contact the Therapeutic Products Directorate (hc.tpdgeneral-general@dpt.sc@canada.ca).

- a. Canadian reports can be accessed through the [Canada Vigilance Online Database](#)