

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrPrecedex[®]

Dexmedetomidine Hydrochloride for Injection

Dexmedetomidine Hydrochloride Injection

Read this carefully before you start taking **Precedex[®]** and each time you receive an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Precedex[®]**.

What is Precedex[®] used for?

Precedex[®] is used in adults to keep you calm (sedated):

- when you arrive at the intensive care unit (ICU) and have a breathing tube after you have had surgery under a general anesthesia
- when you are having certain surgical procedures under a local anesthesia or nerve block
- when you receive a breathing tube while you are awake

How does Precedex[®] work?

Precedex[®] works by activating a part of the brain which helps keep you calm.

What are the ingredients in Precedex[®]?

Medicinal ingredients: dexmedetomidine hydrochloride

Non-medicinal ingredients: sodium chloride and water for injection. Precedex[®] is preservative-free and contains no additives or other chemicals.

Precedex[®] comes in the following dosage forms:

Solution: 4 mcg / mL, 100 mcg / mL

Do not use Precedex[®] if:

- you are allergic to dexmedetomidine hydrochloride or to any non-medicinal ingredient in Precedex[®] (see **What are the ingredients in Precedex[®]?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Precedex[®]. Talk about any health conditions or problems you may have, including if you:

- have heart problems, including chronic high blood pressure
- have diabetes mellitus
- have liver problems
- have severe kidney problems
- are taking any other medicines
- have had a condition called malignant hyperthermia (a very high body temperature) after receiving Precedex[®] or another similar medication to calm you in the ICU, during surgery or other medical procedure
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
- are older than 65 years of age

- are pregnant or think you might be pregnant
- are breastfeeding

Other warnings you should know about:

An increased mortality risk has been seen for patients 65 years of age and younger being administered this medicine. This was especially in patients with a more severe disease condition, who were admitted to the intensive care unit for reasons other than after surgery. The healthcare professional will decide if this medicine is still suitable for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Precedex[®]:

- anesthetic drugs, used during surgery such as: sevoflurane, isoflurane, propofol, alfentanil, and midazolam
- neuromuscular blockers, used to relax you if you need a breathing tube such as rocuronium, cisatracurium
- heart medications

How to take Precedex[®]:

- **Precedex[®] will be given to you by a healthcare professional skilled in the management of patients in the ICU or operating room setting.**
- Your healthcare professional will monitor your blood pressure, heart rate and oxygen levels while you are receiving Precedex[®], and for as long as required, after you have stopped receiving Precedex[®].
- After you have received Precedex[®] it is important that you do not try to change position or get out of bed without assistance.

Usual dose:

Your healthcare professional will decide what the appropriate dose is for your specific case. You will get a starting dose first, then regular doses, specific for your body weight and the procedure you are undergoing. Your healthcare professional will decide what the appropriate dose is for your specific case.

Overdose:

If you think you, or a person you are caring for, have taken too much Precedex[®] contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Precedex[®]?

These are not all the possible side effects you may have when taking Precedex[®]. If you experience any side effects not listed here, tell your healthcare professional.

Tell your healthcare professional if you have any of the following side effects within 48 hours after receiving Precedex[®]:

- dry mouth
- nausea, vomiting
- diarrhea
- constipation

- nervousness, agitation
- headaches
- weakness
- confusion
- excessive sweating
- weight loss
- salt cravings
- dizziness or light-headedness
- low blood pressure
- slower than normal heart beat

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypotension (low blood pressure): dizziness, fainting, light-headedness			√
Hypertension (high blood pressure): headaches, vision disorders, nausea and vomiting			√
Hyperglycemia (high blood sugar): frequent urination, thirst, hunger			√
Hypokalemia (low potassium blood level): irregular heartbeats, muscle weakness and generally feeling unwell			√
Bradycardia : slow heartbeat			√
Tachycardia : fast heartbeat			√
Hypoxia : blueish colouration to the skin, confusion, fast heartbeat, shortness of breath, sweating			√
RARE			
Anaemia (low levels of red blood cells): fatigue, loss of energy, weakness, shortness of breath		√	
Breathing problems			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Precedex[®] is stored between 15 to 30°C.
Keep out of reach and sight of children.

If you want more information about Precedex[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://health-products.canada.ca/dpd-bdpp/>; the manufacturer's website www.pfizer.ca or by calling 1-800-463-6001.

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