

# Dexmedetomidine Medsurge

Dexmedetomidine hydrochloride

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Dexmedetomidine Medsurge?

Dexmedetomidine Medsurge contains the active ingredient Dexmedetomidine (as hydrochloride).

Dexmedetomidine is a relatively selective alpha2-adrenoreceptor agonist with a broad range of pharmacologic properties.

#### ICU Sedation

Dexmedetomidine Medsurge concentrated injection can be used for sedation of initially intubated patients during treatment in an intensive care setting. The use of Dexmedetomidine hydrochloride by continuous infusion in these patients should not exceed 24 hours.

#### Procedural Sedation

Dexmedetomidine Medsurge concentrated injection can be used for sedation of non-intubated patients prior to and/or during surgical and other procedures.

For more information, see Section [1. Why am I using Dexmedetomidine Medsurge?](#) in the full CMI.

### 2. What should I know before I use Dexmedetomidine Medsurge?

Do not use if you have ever had an allergic reaction to Dexmedetomidine Hydrochloride or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Dexmedetomidine Medsurge?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Dexmedetomidine Medsurge and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Dexmedetomidine Medsurge?

- Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your weight. The dose will be adjusted to keep you at the right depth of sleep or sedation.
- Dexmedetomidine Medsurge concentrated solution is given by a slow injection (drip) into a vein. It will usually be given to you by a doctor or nurse.

More instructions can be found in Section [4. How do I use Dexmedetomidine Medsurge?](#) in the full CMI.

### 5. What should I know while using Dexmedetomidine Medsurge?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.</li><li>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>It may affect other medicines used during surgery.</li><li>If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not take Dexmedetomidine concentrated injection to treat any other complaints unless your doctor tells you to.</li><li>Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>This medicine may cause dizziness, light-headedness, tiredness, drowsiness, and therefore affect alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Ask your doctor when you can return to work involving driving or operating machinery or heavy equipment.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store below 25°C. Store in the original container.</li><li>Use as soon as practicable after dilution to reduce microbiological hazard. If storage is necessary, hold at 2-8°C for not more than 24 hours</li><li>Product is for single use in one patient only. Discard any residue.</li><li>Keep out of reach of children</li></ul>

For more information, see Section [5. What should I know while using Dexmedetomidine Medsurge?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dexmedetomidine Medsurge.

This medicine helps most people with sedation, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Dexmedetomidine Medsurge

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Dexmedetomidine Medsurge. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dexmedetomidine Medsurge.**

**Where to find information in this leaflet:**

1. [Why am I using Dexmedetomidine Medsurge?](#)
2. [What should I know before I use Dexmedetomidine Medsurge?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Dexmedetomidine Medsurge?](#)
5. [What should I know while using Dexmedetomidine Medsurge?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using Dexmedetomidine Medsurge?

Dexmedetomidine Medsurge contains the active ingredient Dexmedetomidine Hydrochloride.

Dexmedetomidine is a relatively selective alpha<sub>2</sub>-adrenoreceptor agonist with a broad range of pharmacologic properties.

### ICU Sedation

Dexmedetomidine Medsurge concentrated injection can be used for sedation of initially intubated patients during treatment in an intensive care setting. The use of Dexmedetomidine hydrochloride by continuous infusion in these patients should not exceed 24 hours.

### Procedural Sedation

Dexmedetomidine Medsurge concentrated injection can be used for sedation of non-intubated patients prior to and/or during surgical and other procedures.

The sedative actions of dexmedetomidine are believed to be mediated primarily by post-synaptic alpha<sub>2</sub>-adrenoreceptors, which in turn act on inhibitory pertussis-toxin-sensitive G protein, thereby increasing conductance through potassium channels. The site of the sedative effects of dexmedetomidine has been attributed to the locus coeruleus. The analgesic actions are believed to be mediated by a similar mechanism of action at the brain and spinal cord level.

## 2. What should I know before I use Dexmedetomidine Medsurge?

### Warnings

**Do not use Dexmedetomidine Medsurge if:**

- you are allergic to Dexmedetomidine Hydrochloride or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction may include:

shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin

**Check with your doctor if you:**

**Have or have had any of the following medical conditions:**

- heart problems
- high or low blood pressure
- diabetes
- kidney or liver problems
- Elderly patients greater than 65 years old may be more prone to the blood pressure lowering effects of Dexmedetomidine Medsurge.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. For additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### Some medicines may interfere with Dexmedetomidine Medsurge and affect how it works.

Anaesthetics/Sedatives/Hypnotics/Opioids:

Co-administration of dexmedetomidine is likely to lead to an enhancement of effects with anaesthetics, sedatives, hypnotics, and opioids.

Specific studies have confirmed these effects with sevoflurane, isoflurane, propofol, alfentanil, and midazolam. No pharmacokinetic interactions between dexmedetomidine and isoflurane, propofol, alfentanil, and midazolam were demonstrated. However, due to pharmacodynamic effects, when co-administered with dexmedetomidine, a reduction in dosage with these agents may be required.

**Medicines that may increase the effect of**

**Dexmedetomidine Medsurge include:**

- Sevoflurane,
- Isoflurane,
- Propofol,
- Alfentanil,
- Midazolam

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dexmedetomidine Medsurge.**

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## 4. How do I use Dexmedetomidine Medsurge?

### How much to take / use

Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your weight. The dose will be adjusted to keep you at the right depth of sleep or sedation.

Dexmedetomidine Medsurge is given by a slow injection (drip) into a vein.

Dexmedetomidine Medsurge should only be given by a doctor or nurse.

### If you use too much Dexmedetomidine Medsurge

As Dexmedetomidine Medsurge is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include extreme drowsiness, confusion, dizziness, weakness or becoming unconscious.

If you think that you have used too much Dexmedetomidine Medsurge, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using Dexmedetomidine Medsurge?

### Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

### Things you should not do

Do not take Dexmedetomidine Medsurge to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dexmedetomidine Medsurge affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness, and therefore affect alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Ask your doctor when you can return to work involving driving or operating machinery or heavy equipment.

### Looking after your medicine

- Store below 25°C. Store in the original container.
- Use as soon as practicable after dilution to reduce microbiological hazard. If storage is necessary, hold at 2-8°C for not more than 24 hours.
- Product is intended for single use in one patient only. Discard any residue.
- Keep out of reach of children

Follow the instructions in the carton on how to take care of your medicine properly.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• dizziness</li><li>• light-headedness</li><li>• nausea and/or vomiting</li><li>• high temperature</li><li>• dry mouth</li><li>• constipation or diarrhoea</li><li>• feelings of agitation, confusion or tiredness</li><li>• fluid retention or swelling in the arms or legs</li><li>• changes in your blood sugar levels</li><li>• increased sweating</li><li>• changes to your vision</li><li>• reduced or increased urine output or feeling thirsty</li></ul>	<p>If you are over 65 years of age you may have an increased chance of getting side effects. Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• changes in heart rate including slowing or quickening of heart beat</li><li>• shortness of breath, rapid breathing or breathing difficulties</li></ul>	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

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<ul style="list-style-type: none"><li>• pressure, tightness or pain in your</li><li>• chest or arms that may spread to your neck, jaw or back</li><li>• unusual bruising</li><li>• overheating of your body that you can't control by normal cooling methods</li><li>• excessive thirst, extreme fatigue, lack of energy, confusion, muscle twitching or spasms, restlessness, seizures</li></ul>	<b>your nearest hospital if you notice any of these serious side effects.</b>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Dexmedetomidine Medsurge contains

<b>Active ingredient (main ingredient)</b>	Dexmedetomidine (100 microgram/mL) contains 118 microgram/mL of dexmedetomidine hydrochloride (equivalent to 100 microgram/mL dexmedetomidine base)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Water for injections
<b>Potential allergens</b>	This medicine does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

**The solution contains no additives, antimicrobial preservatives or chemical stabilisers.**

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Dexmedetomidine Medsurge looks like

Dexmedetomidine Medsurge concentrated injection solution for intravenous infusion (100 microgram/mL) is a clear, colourless or yellowish solution. It is available in 2 mL glass ampoules and 4 mL and 10 mL glass vials.

#### **Dexmedetomidine Medsurge 200 micrograms /2 mL**

concentrated injection is supplied as a sterile solution in clear glass ampoules each containing 200 micrograms of

dexmedetomidine available in 5 x 2 mL, 10 x 2 mL or 25 x 2 mL packs (AUST R 352312).

#### **Dexmedetomidine Medsurge 400 micrograms/4 mL**

concentrated injection is supplied as a sterile solution in clear glass vials each containing 400 micrograms of dexmedetomidine available in 1 x 4mL, 4 x 4 mL or 5 x 4 mL packs (AUST R 352310).

#### **Dexmedetomidine Medsurge 1000 micrograms/10 mL**

concentrated injection is supplied as a sterile solution in clear glass vials each containing 1000 micrograms of dexmedetomidine, available in 1 x 10 mL, 4 x 10 mL or 5 x 10 mL packs (AUST R 352311).

Not all presentations and pack sizes are marketed.

### Who distributes Dexmedetomidine Medsurge

Medsurge Pharma Pty Ltd  
Unit 1&2, 6-7 Gilda Court  
Mulgrave, Victoria 3170

### Marketed and Distributed by Medsurge Healthcare.

Telephone: 1300 788 261

Website: [www.medsurgehc.com](http://www.medsurgehc.com)

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