

# Dexmedetomidine-AFT

## 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-AFT?

Dexmedetomidine-AFT contains the active ingredient dexmedetomidine hydrochloride. Dexmedetomidine-AFT can be used as a sedative (calming agent) if adults need to be calm or sleepy in the Intensive Care Unit whilst they are being ventilated (on a breathing machine). It may be given as an infusion up to 24 hours.

Dexmedetomidine-AFT can be given to adults prior to an operation if they are not on a ventilator (breathing machine) if it is required for the procedure or surgery that they be sleepy and calm.

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

### 2. What should I know before I use Dexmedetomidine-AFT?

Do not use if you have ever had an allergic reaction to Dexmedetomidine-AFT 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-AFT?](#) in the full CMI.

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

Some medicines may interfere with Dexmedetomidine-AFT 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-AFT?

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.

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

### 5. What should I know while using Dexmedetomidine-AFT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Dexmedetomidine-AFT</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-AFT to treat any other complaints unless your doctor tells you to.</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.</li></ul>

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

### 6. Are there any side effects?

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.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. However, some side effects may need medical attention and they may include:

- changes in heart rate including slowing or quickening of heartbeat
- shortness of breath, rapid breathing or breathing difficulties

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-AFT

**Active ingredient(s):** *Dexmedetomidine (dex-med-e-toh-med-een) hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Dexmedetomidine-AFT. **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-AFT.**

### Where to find information in this leaflet:

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

## 1. Why am I using Dexmedetomidine-AFT?

**Dexmedetomidine-AFT contains the active ingredient dexmedetomidine hydrochloride.** Dexmedetomidine-AFT be used as a sedative (calming agent) if adults need to be calm or sleepy in the Intensive Care Unit whilst they are being ventilated (on a breathing machine). It may be given as an infusion up to 24 hours.

Dexmedetomidine-AFT can be given to adults prior to an operation if they are not on a ventilator (breathing machine) if it is required for the procedure or surgery that they be sleepy and calm.

This medicine belongs to a group of medicines called alpha-2-receptor agonists.

This medicine works by its actions on brain chemicals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Dexmedetomidine-AFT is available only with a doctor's prescription.

## 2. What should I know before I use Dexmedetomidine-AFT?

### Warnings

#### Do not use Dexmedetomidine-AFT if:

- you are allergic to dexmedetomidine hydrochloride, or any of the ingredients listed at the end of this leaflet. 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
- Always check the ingredients to make sure you can use this medicine.
- Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.
- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- If it has expired or is damaged, return it to your pharmacist for disposal.
- If you are not sure whether you should start taking this medicine, talk to your doctor.

#### Check with your doctor if you:

- have any other medical conditions listed below:
  - heart problems
  - high or low blood pressure
  - diabetes
  - kidney or liver problems
- take any medicines for any other condition
- Elderly patients greater than 65 years old may be more prone to the blood pressure lowering effects of Dexmedetomidine-AFT.
- 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. See 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.

The active ingredient in Dexmedetomidine-AFT may affect your developing baby if you take it during pregnancy. It also passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

### 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 and Dexmedetomidine-AFT may interfere with each other. These include:

- medicines used to produce calmness or to help you sleep, such as sevoflurane, isoflurane, propofol, alfentanil and midazolam
- strong pain relievers

These medicines may be affected by Dexmedetomidine-AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information medicines to be careful with or avoid while taking this medicine.

**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-AFT.**

### 4. How do I use Dexmedetomidine-AFT

#### 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.

#### How Dexmedetomidine-AFT is given

Dexmedetomidine-AFT is given by a slow injection (drip) into a vein. Dexmedetomidine-AFT should only be given by a doctor or nurse.

#### If you use too much Dexmedetomidine-AFT

As Dexmedetomidine-AFT 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-AFT, 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-AFT

#### 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-AFT 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-AFT 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.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

#### Looking after your medicine

Dexmedetomidine-AFT will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30 °C.

## 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
<b>Gastrointestinal-related:</b> <ul style="list-style-type: none"><li>nausea and/or vomiting</li><li>constipation or diarrhoea</li><li>dry mouth</li></ul> <b>Eye-related</b> <ul style="list-style-type: none"><li>changes to your vision</li></ul> <b>Nervous system-related</b> <ul style="list-style-type: none"><li>dizziness</li><li>light-headedness</li><li>feelings of agitation, confusion or tiredness</li></ul> <b>Other</b> <ul style="list-style-type: none"><li>fluid retention or swelling in the arms or legs</li><li>changes in your blood sugar levels</li><li>increased sweating</li><li>high temperature</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Heart-related</b> <ul style="list-style-type: none"><li>changes in heart rate including slowing or quickening of heart beat</li><li>pressure, tightness or pain in your chest or arms that may spread to your neck, jaw or back</li></ul> <b>Breathing-related</b> <ul style="list-style-type: none"><li>shortness of breath, rapid breathing or breathing difficulties</li></ul> <b>Other</b> <ul style="list-style-type: none"><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,</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

confusion, muscle twitching or spasms, restlessness, seizures	
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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-AFT contains

<b>Active ingredient (main ingredient)</b>	Dexmedetomidine hydrochloride
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride, Hydrochloric acid or Sodium hydroxide, Water for injections

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

### What Dexmedetomidine-AFT looks like

Dexmedetomidine-AFT is a clear, colourless solution, free from visible particles and fibers. It is available in 2 mL glass ampoules (Aust R 396293).

### Who distributes Dexmedetomidine-AFT

AFT Pharmaceuticals Pty Ltd

113 Wicks Road North Ryde

NSW 2113 AUSTRALIA

Phone: 1800 AFTPHARM (1800 238 74276)

Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)

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