

## 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.

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### 1. Why am I using IBILEX?

IBILEX contains the active ingredient cefalexin monohydrate. IBILEX is used to treat infections caused by bacteria in different parts of the body, including infections of the respiratory tract (throat, tonsils, chest and lungs), nose (sinusitis), ears (otitis media), skin and soft tissue, kidneys and bladder (urinary tract). For more information, see Section [1. Why am I using IBILEX?](#) in the full CMI.

### 2. What should I know before I use IBILEX?

Do not use if you have ever had an allergic reaction to cefalexin monohydrate, penicillin, other cephalosporins, 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 IBILEX?](#) in the full CMI.

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

Some medicines may interfere with IBILEX 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 IBILEX?**

- Follow all directions give to you by your doctor or pharmacist.
- Your doctor will tell you how much and how often you should take IBILEX.

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

### **5. What should I know while using IBILEX?**

<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 IBILEX.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor if the symptoms of your infection do not improve within a few days or if they become worse.</li> <li>• Tell your doctor if you become pregnant while taking IBILEX.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or change the dosage unless your doctor tells you to.</li> <li>• Do not take IBILEX 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>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• IBILEX may cause dizziness or drowsiness in some people.</li> <li>• Be careful driving or operating machinery until you know how IBILEX affects you.</li> <li>• Children should be careful when riding</li> </ul>

	bicycles or climbing trees.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• IBILEX capsules: store below 30°C.</li> <li>• IBILEX suspension: store between 2-8°C. Do not freeze. Shake well before use and discard after 14 days.</li> </ul>

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

## 6. Are there any side effects?

Common side effects include: sore or white mouth or tongue, sore and itchy vagina and/or discharge, diarrhoea, nausea, vomiting, dizziness, unusual tiredness/ weakness, abdominal pain, headache. Serious side effects include severe body rash, swelling of face, lips, mouth, tongue or throat, fever, swelling of the joints, yellowing of the skin or eyes, joint pain, confusion and hallucinations, seizure potential, bleeding or bruising more easily than normal, severe stomach cramps or pain, severe, watery or bloody diarrhoea. 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

# IBILEX<sup>®</sup>

**Active ingredient:** *cefalexin monohydrate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using IBILEX. **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 IBILEX.**

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

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

## 1. Why am I using IBILEX?

**IBILEX contains the active ingredient cefalexin monohydrate.** IBILEX is an antibiotic that belongs to a group of medicines called cephalosporins. These medicines work by killing the bacteria that are causing your infection.

**IBILEX is used to treat infections caused by bacteria in different parts of the body, including infections of the:**

- **respiratory tract (throat, tonsils, chest and lungs)**
- **nose (sinusitis)**
- **ears (otitis media)**
- **skin and soft tissue**
- **kidneys and bladder (urinary tract).**

**Ask your doctor or pharmacist if you have any questions about why IBILEX has been prescribed for you.**

Your doctor may have prescribed IBILEX for another reason.

IBILEX will not work against infections caused by viruses, such as colds or flu.

IBILEX is available only with a doctor's prescription.

There is no evidence that IBILEX is addictive.

## **2. What should I know before I use IBILEX?**

### **Warnings**

**Do not use IBILEX if:**

- **you are allergic to cefalexin monohydrate, penicillin, other cephalosporins, or any of the ingredients listed at the end of this leaflet.**

You may have an increased chance of being allergic to IBILEX if you are allergic to penicillins.

- 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.
- **the expiry date printed on the pack or bottle has passed.**

If you take this medicine after the expiry date, it may not work as well.
- the package is torn or show signs of tampering, or if the capsules or mixture do not look quite right.

### **Check with your doctor if you:**

- are allergic to any other medicines or any foods, preservatives or dyes
- have any other medical conditions, especially the following:
  - liver problems
  - kidney problems
  - bowel problems.

Your doctor may want to take special care if you have any of these conditions.

- take any medicines for any other condition.

**If you have not told your doctor about any of the above, tell them before you start using IBILEX.**

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.

Your doctor will discuss the risks and benefits of taking IBILEX.

## **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 be affected by IBILEX, or may affect how well it works. These include:

- probenecid, a medicine commonly used to treat gout
- metformin, a medicine used to treat diabetes.

Your doctor can tell you what to do if you are taking this medicine.



**Talk to your doctor about the need for additional contraception while taking IBILEX.**

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with IBILEX.

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

## **4. How do I take IBILEX?**

### **How much to take**

**Follow all directions given to you by your doctor or pharmacist.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack or bottle, ask your doctor or pharmacist.**

#### **Adults:**

- Your doctor will tell you how much IBILEX you need to take each day and when to take it.
- This will depend on the type of infection you have. The dose varied from patient to patient.

#### **Children:**

- The dose for children will depend on the child's age, weight and the type of infection. Your doctor and

pharmacist will tell you how much IBILEX your child should take.

## **When to take IBILEX**

- IBILEX can be taken with or without food.
- **Take IBILEX at about the same time each day, spaced evenly apart.**
- This will allow IBILEX to have its best effect and also help you remember when to take it.

## **How to take IBILEX**

### **Capsules:**

- Swallow whole with a glass of water.

### **Suspension:**

- Shake the bottle well then accurately measure the correct dose. Always use a metric measure.

## **How long to take IBILEX for**

- Keep taking IBILEX until you finish the pack or bottle, or for as long as your doctor recommends.

**Do not stop taking IBILEX, even if you feel better, unless advised by your doctor.**

Your infection may not clear completely if you stop taking your medicine too soon.

## **If you forget to use IBILEX**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

## **If you use too much IBILEX**

**If you think that you have used too much IBILEX, you may need urgent medical attention.**

**You should immediately:**

- **phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.**

If you have taken too much IBILEX, you may feel sick in the stomach, experience diarrhoea, blood in the urine, or have unusually increased reflexes, convulsions or hallucinations.

## **5. What should I know while using IBILEX?**

### **Things you should do**

- **If your symptoms do not improve within a few days, or if they become worse, tell your doctor.**
- **If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking IBILEX.**

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without checking with your doctor.

- **If you become pregnant while taking IBILEX, tell your doctor.**
- **Before starting any new medicine, tell your doctor or pharmacist that you are taking IBILEX.**
- **Tell all the doctors, dentists and pharmacists who are treating you that you are taking IBILEX, especially if you are about to be started on any new medicines.**
- **If you have to have any blood or urine tests, tell your doctor that you are taking IBILEX.**

IBILEX may affect the results of some tests.

- **If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.**

IBILEX may affect the results of some of these tests.

- **Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using IBILEX.

## **Things you should not do**

- **Do not stop taking IBILEX or lower the dose because you are feeling better, unless advised by your doctor.**

If you do not complete the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

- **Do not use IBILEX to treat any other conditions unless your doctor tells you to.**
- **Do not give IBILEX to anyone else, even if they have the same condition as you.**

## **Things to be careful of**

- **If you get a sore, white mouth or tongue while taking or soon after stopping IBILEX, tell your**

**doctor. Also tell your doctor if you get vaginal itching or discharge.**

This may mean you have a fungal infection called thrush. Sometimes, the use of IBILEX allows fungi to grow and the above symptoms to occur. IBILEX does not work against fungi.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how IBILEX affects you.**

IBILEX generally does not cause any problems with your ability to drive a car or operate machinery. However, IBILEX may rarely cause dizziness, tiredness or fatigue in some people. If this occurs, do not drive, operate machinery or do anything else that may be dangerous.

Children should be careful when riding bicycles or climbing trees.

## **Looking after your medicine**

- **Keep IBILEX where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- **Keep your capsules in the pack until it is time to take them.**

If you take your capsules out of the pack, they may not keep as well.

- **Keep your capsules in a cool dry place where the temperature stays below 30°C.**

- **Keep IBILEX suspension in the refrigerator but not in the freezer, and keep the bottle tightly closed. Do not use any mixture that is left in the bottle after 14 days.**
- **Do not store IBILEX or any other medicine in the bathroom or near a sink.**
- **Do not leave IBILEX in the car or on window sills.**  
Heat and dampness can destroy some medicines.

## **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?**

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

IBILEX treats infections in most people and is usually well tolerated, but it may have unwanted side effects in some people. These side effects are very rare.

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>● sore or white mouth or tongue (oral thrush)</li><li>● sore and itchy vagina and/or discharge (another form of thrush)</li><li>● diarrhoea</li><li>● nausea</li><li>● vomiting</li><li>● dizziness</li><li>● unusual tiredness/ weakness</li><li>● abdominal pain</li><li>● headache.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● fever</li><li>● swelling of the joints</li><li>● yellowing of the skin or eyes</li><li>● joint pain</li><li>● confusion and hallucinations</li></ul>	<p><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></p>



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● seizure</li> <li>● bleeding or bruising more easily than normal.</li> <li>● encephalopathy (such as reduced ability to think clearly or concentrate, memory loss, drowsiness, seizures, muscle twitches and personality change)</li> <li>● myoclonus (sudden, brief involuntary muscle twitching or jerking)</li> <li>● symptoms of an allergic reaction including: <ul style="list-style-type: none"> <li>○ rash, itching or hives on the skin</li> <li>○ swelling of the face, lips, tongue or other parts of the body</li> <li>○ shortness of breath, wheezing or trouble breathing.</li> </ul> </li> </ul>	

**Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with IBILEX:**

- severe stomach cramps or pain

- severe, watery or bloody diarrhoea
- fever, in combination with one of the above.

**Do not take any diarrhoea medicine without first checking with your doctor.**

You may have a serious condition affecting your bowel requiring urgent medical attention.

**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 IBILEX contains

### Capsules:

<b>Active ingredient (main ingredient)</b>	cefaalexin monohydrate (equivalent to 250 mg or 500 mg of cefalexin)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Avicel RC 591 (ARTG PI No: 2530)</li><li>• dimeticone 350</li><li>• magnesium stearate</li><li>• gelatin</li><li>• patent blue V</li><li>• quinoline yellow</li><li>• titanium dioxide</li></ul>

### Suspension:

<b>Active ingredient (main ingredient)</b>	cefaalexin monohydrate (125 mg/5 mL or 250 mg/5 mL)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium lauryl sulfate</li><li>• allura red AC</li><li>• methylcellulose</li><li>• dimeticone 350</li><li>• xanthan gum</li><li>• pregelatinised maize starch</li></ul>

	<ul style="list-style-type: none"> <li>• sucrose</li> <li>• tutti frutti 51880 TP0551 (ARTG PI No: 1775)</li> </ul>
<b>Potential allergens</b>	Contains sugars.

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

## **What IBILEX looks like**

IBILEX is available as capsules or suspension.

### **Capsule:**

The capsules come in two strengths:

- IBILEX 250 - green and white capsule (AUST R 73524).
- IBILEX 500 - dark green and light green capsule (AUST R 73525).

Each pack contains 20 capsules.

### **Suspension:**

The suspensions come in two strengths:

- IBILEX 125 - A white free-flowing powder before reconstitution and a red, fruity bubble gum flavoured suspension after reconstitution (AUST R 92972).
- IBILEX 250 - A white free-flowing powder before reconstitution and a red, fruity bubble gum flavoured suspension after reconstitution (AUST R 92973).

Each bottle contains 100 mL when reconstituted with water.

## **Who distributes IBILEX**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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IBILEX® is a Viatris company trade mark

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