

# Ibilex

contains the active ingredient cephalexin (as monohydrate)

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Ibilex.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Ibilex against the benefits expected for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

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### What Ibilex is used for

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Ibilex is used to treat infections in different parts of the body caused by bacteria. Ibilex can be used to treat infections of the:

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

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

Your doctor may have prescribed Ibilex for another reason.

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 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.

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### Before you take Ibilex

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#### **When you must not take it**

**Do not take Ibilex if you are allergic to:**

- \* cephalexin or any other cephalosporin antibiotic
- \* any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching; shortness of breath; swelling of the face, lips, tongue or other parts of the body.

**Do not take Ibilex if you have had a serious allergic reaction to penicillin.**

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

**Do not take Ibilex if 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.

**Do not take Ibilex if the packaging shows signs of tampering or the capsules or mixture do not look quite right.**

#### **Before you start to take it**

**Tell your doctor if you have had any type of allergic reaction to penicillin antibiotics.**

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

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.**

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

**Tell your doctor if you have, or have had, any 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.

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

## ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a 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.

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## **How to take Ibilex**

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

They may differ from the information contained in this leaflet.

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

### ***How much to take***

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.

#### **Adults**

The usual adult dose is 250 mg every 6 hours.

#### **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.

## ***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.**

## ***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 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 take 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 take too much Ibilex (overdose)***

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Ibilex. 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, or have convulsions or hallucinations.

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## **While you are taking Ibilex**

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### ***Things you must 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.**

**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.

## **Things you must 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.

**Be careful driving or operating machinery 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.

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## **Side effects**

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**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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

## **While you are taking Ibilex**

**Tell your doctor if you notice any of the following and they worry you:**

- \* oral thrush (white, furry sore tongue and mouth)
- \* vaginal thrush (sore and itchy vagina, vaginal discharge)
- \* diarrhoea
- \* nausea, stomach pain, vomiting
- \* dizziness, tiredness.

The above list includes the milder side effects of Ibilex. They are usually short-lived.

**Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- \* watery and severe diarrhoea, which may also be bloody
- \* fever
- \* severe body rash
- \* itching
- \* swelling of the face, lips, tongue or other parts of the body
- \* shortness of breath
- \* swelling or pain of the joints
- \* yellowing of the eyes or skin (jaundice).

The above list includes serious side effects which may require medical attention.

## **After you have finished taking Ibilex**

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

- \* watery and severe diarrhoea, which may also be bloody
- \* severe stomach cramps.

**Tell your doctor if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## **After taking Ibilex**

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### **Storage**

**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 degrees 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.

## Disposal

If your doctor tells you to stop taking Ibilex, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

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## Product description

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### What it looks like

Ibilex is available as capsules or suspensions.

### CAPSULES

The capsules come in two strengths:

- \* Ibilex 250 - green and white capsule, marked GP 1
- \* Ibilex 500 - dark green and light green capsule, marked GP 2.

Each pack contains 20 capsules.

### SUSPENSIONS

The suspensions come in two strengths. There are two formulations of each strength available at present. These are identified by the AUST R number on the bottle.

#### New formulation:

- \* Ibilex 125 - red, fruity bubblegum flavoured liquid; AUST R 92972
- \* Ibilex 250 - red, fruity bubblegum flavoured liquid; AUST R 92973.

#### Old formulation:

- \* Ibilex 125 - pink, fruity bubblegum flavoured liquid; AUST R 59241
- \* Ibilex 250 - orange, fruity bubblegum flavoured liquid; AUST R 57464.

Each bottle contains 100 mL.

**Ask your pharmacist if you are not sure which Ibilex suspension you have.**

## Ingredients

The active ingredient in Ibilex capsules and suspensions is cephalexin (as monohydrate).

- \* each Ibilex 250 capsule contains 250 mg of cephalexin (as monohydrate)
- \* each Ibilex 500 capsule contains 500 mg of cephalexin (as monohydrate)
- \* each 5 mL of Ibilex 125 suspension contains 125 mg of cephalexin (as monohydrate)
- each 5 mL of Ibilex 250 suspension contains 250 mg of cephalexin (as monohydrate).

### CAPSULES

The capsules also contain the following inactive ingredients:

- \* microcrystalline cellulose
- \* carmellose sodium
- \* dimethicone 350
- \* magnesium stearate
- \* gelatin
- \* patent blue V CI42051 (E131)
- \* quinoline yellow CI47005 (E104)
- \* titanium dioxide CI77891 (E171)
- \* Edible Black Ink.

### SUSPENSIONS

The new formulation Ibilex suspensions contain the following inactive ingredients:

- \* sodium lauryl sulfate
- \* allura red AC CI16035 (E129)
- \* methylcellulose 15
- \* dimethicone 350
- \* xanthan gum
- \* pregelatinised maize starch
- \* sucrose
- \* Imitation Guarana Flavour 51880TP.

The old formulation Ibilex suspensions contain the following inactive ingredients:

- \* sucrose
- \* Imitation Guarana Flavour 51880TP
- \* erythrosine CI45430 (E127) (Ibilex 125 only)
- \* sunset yellow FCF CI15985 (E110) (Ibilex 250 only).

Ibilex capsules and suspensions do not contain gluten, lactose or tartrazine.

## Supplier

Ibilex is supplied by:

### Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

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

### Medical Information

Phone: 1800 028 365

Australian registration numbers:

#### Capsules

Ibilex 250 - AUST R 73524

Ibilex 500 - AUST R 73525

#### Suspensions

Ibilex 125 - AUST R 92972 or 59241

Ibilex 250 - AUST R 92973 or 57464

The new formulation of Ibilex suspensions identified by AUST R 92972 and 92973 are replacing the old formulation suspensions identified by AUST R 59241 and 57464, respectively.

This leaflet was prepared on 7 April 2004.