

# Sandoz® Ibuprofen Plus Codeine Tablets

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using Sandoz Ibuprofen Plus Codeine?

Sandoz Ibuprofen Plus Codeine contains the active ingredient ibuprofen and codeine phosphate. Sandoz Ibuprofen Plus Codeine is used to provide temporary relief of acute moderate pain and inflammation.

For more information, see Section [1. Why am I using Sandoz Ibuprofen Plus Codeine?](#) in the full CMI.

### 2. What should I know before I use Sandoz Ibuprofen Plus Codeine?

Do not use if you have ever had an allergic reaction to Sandoz Ibuprofen Plus Codeine 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.** You may develop addiction, dependence and tolerance.

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

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

Some medicines may interfere with Sandoz Ibuprofen Plus Codeine 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 Sandoz Ibuprofen Plus Codeine?

- The usual dose of Sandoz Ibuprofen Plus Codeine is 2 tablets then, if necessary 1 or 2 tablets every 4 to 6 hours.

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

### 5. What should I know while using Sandoz Ibuprofen Plus Codeine?

<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 Sandoz Ibuprofen Plus Codeine.</li><li>• Talk to your doctor about pain control if Sandoz Ibuprofen Plus Codeine is not helping.</li><li>• Tell your doctor if you become pregnant while taking Sandoz Ibuprofen Plus Codeine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take more than 6 tablets in 24 hours.</li><li>• Do not give Sandoz Ibuprofen Plus Codeine to children under the age of 12 years.</li><li>• Do not take Sandoz Ibuprofen Plus Codeine for more than three days at a time.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Sandoz Ibuprofen Plus Codeine affects you.</li><li>• Sandoz Ibuprofen Plus Codeine may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not drink alcohol while taking Sandoz Ibuprofen Plus Codeine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 30°C.</li><li>• Store in a cool dry place away from moisture, heat or sunlight.</li></ul>

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

### 6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following side effects; asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash, fainting. These may be the sign of an allergic reaction.

Speak to your doctor if you have any of the following common side effects and they worry you; nausea or vomiting, constipation, or dizziness, light-headedness, drowsiness.

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.

**WARNING:****Limitations of use**

Sandoz Ibuprofen Plus Codeine should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

**Hazardous and harmful use**

Sandoz Ibuprofen Plus Codeine poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

**Life threatening respiratory depression**

Sandoz Ibuprofen Plus Codeine can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time, but the risk is higher when first starting Sandoz Ibuprofen Plus Codeine and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

**Use of other medicines while taking Sandoz Ibuprofen Plus Codeine**

**Using Sandoz Ibuprofen Plus Codeine with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis oil and alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death.** Your doctor will minimise the dose and duration of use and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Sandoz Ibuprofen Plus Codeine.

# Sandoz<sup>®</sup> Ibuprofen Plus Codeine

**Active ingredient(s):** *Ibuprofen 200 mg and Codeine phosphate hemihydrate 12.8 mg*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Sandoz Ibuprofen Plus Codeine. **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 Sandoz Ibuprofen Plus Codeine.**

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

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

## 1. Why am I using Sandoz Ibuprofen Plus Codeine?

**Sandoz Ibuprofen Plus Codeine contains the active ingredient ibuprofen and codeine phosphate.** Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and/or inflammation (swelling, redness, soreness) and fever. Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

**Sandoz Ibuprofen Plus Codeine is used to provide temporary relief of acute moderate pain and inflammation in patients over the age of 12 years.**

After taking codeine, the body changes codeine into the active morphine by a special liver enzyme. However, about 8% of people may experience less pain relief compared to others, as their bodies do not change codeine to morphine as well as others.

## 2. What should I know before I use Sandoz Ibuprofen Plus Codeine?

### Warnings

Do not give Sandoz Ibuprofen Plus Codeine to children under the age of 12 years.

**Do not use Sandoz Ibuprofen Plus Codeine if:**

- you are allergic to ibuprofen, codeine, other opioids, or any medicine containing ibuprofen, aspirin or other NSAIDs or any of the ingredients listed at the end of this leaflet.  
Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if you are taking any of these medicines, ask your pharmacist.  
Always check the ingredients to make sure you can use this medicine.
- Symptoms of an allergic reaction to these medicines may include:
  - asthma, wheezing or shortness of breath.
  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.

- hives, itching or skin rash.
- fainting.
- If you are allergic to aspirin or NSAIDs and take Sandoz Ibuprofen Plus Codeine these symptoms may be severe.
- you are in the last three months of pregnancy or are breast-feeding.
- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea
- you have peptic ulcer (i.e. stomach or duodenal ulcer) or have had one before.
- you are using other NSAIDs
- you have chronic constipation or shallow breathing, or severe diarrhoea.
- You consume regular and heavy amounts of alcohol.
- You are a CYP2D6 ultra-rapid metaboliser.
- If you have severe liver impairment
- If you have heart or kidney problems
- If you are currently taking a Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with a MAOI.

Do not take Sandoz Ibuprofen Plus Codeine if the packaging is torn or shows signs of tampering.

Do not take Sandoz Ibuprofen Plus Codeine if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give Sandoz Ibuprofen Plus Codeine to children under 12 years or to those aged 12 -18 years in whom respiratory function may be compromised.

### Check with your doctor if you:

- have any other medical conditions:
  - difficulty breathing, wheezing, chronic cough, allergies, asthma or other breathing conditions
  - a history of drug dependence, including alcohol dependence
  - skin rash (dermatitis)
  - skin irritation
  - a history of stomach ulcer.
  - liver disease.
  - kidney disease.
  - heart problems/failure, including swelling of ankles or feet.
  - thyroid problems or low blood pressure.
  - a head injury or intracranial pressure.
  - prostatic problems.
  - stomach problems or recent stomach surgery.

Tell your doctor if you take sedatives (medicines used to help you relax or sleep).

Tell your doctor if you have allergies to:

- any other medicines including aspirin, or other NSAID medicines.
- any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start taking Sandoz Ibuprofen Plus Codeine.

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.

Sandoz Ibuprofen Plus Codeine is not recommended during the last 3 months of pregnancy. Your doctor will decide if you should take Sandoz Ibuprofen Plus Codeine during the first 6 months of pregnancy.

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

Sandoz Ibuprofen Plus Codeine should not be taken while breastfeeding.

### Addiction

You can become addicted to Sandoz Ibuprofen Plus Codeine even if you take it exactly as prescribed. Sandoz Ibuprofen Plus Codeine may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

### Dependence

As with all other opioid containing products, your body may become used to you taking Sandoz Ibuprofen Plus Codeine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Sandoz Ibuprofen Plus Codeine suddenly, so it is important to take it exactly as directed by your doctor.

### Tolerance

Tolerance to Sandoz Ibuprofen Plus Codeine may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

## 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 Sandoz Ibuprofen Plus Codeine and affect how it works.**

These include:

- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives.
- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to prevent blood clots.
- medicines that are used to treat high blood pressure including diuretics (fluid tablets)
- methotrexate.
- zidovudine.
- lithium
- mifeprisone, quinolone antibiotics
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease.
- medicines used to treat diarrhoea (e.g. kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting
- medicines that affect serotonin levels (serotonergic medicines)
- selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines such as ciclosporin, tacrolimus, prednisone, prednisolone and cortisone which reduce the activity of your immune system
- probenecid-medicines used to treat gout
- phenytoin – medicine used to treat epilepsy
- other opioid pain killers.

These medicines may be affected by Sandoz Ibuprofen Plus Codeine or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

## **4. How do I use Sandoz Ibuprofen Plus Codeine?**

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

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

### **How much to take and when to take it**

- The usual dose of Sandoz Ibuprofen Plus Codeine is 2 tablets then, if necessary 1 or 2 tablets every 4 to 6 hours. **Do not take more than six tablets in 24 hours.**

- Follow the instructions provided and use Sandoz Ibuprofen Plus Codeine until your doctor tells you to stop.

### **How to take it**

- Take Sandoz Ibuprofen Plus Codeine by mouth with fluid. It may also be taken with or immediately after food.

### **How long to take it**

- You should not take Sandoz Ibuprofen Plus Codeine for more than three days at a time.

**If your symptoms persist, worsen or new symptoms develop, talk to your doctor.**

**Talk to your doctor about pain control if Sandoz Ibuprofen Plus Codeine is not helping.**

Depending on your body's individual ability to break down codeine, you may be getting reduced benefit or experience signs of overdose even when you take Sandoz Ibuprofen Plus Codeine as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

### **If you use too much Sandoz Ibuprofen Plus Codeine**

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately and call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Sandoz Ibuprofen Plus Codeine that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or upset stomach, vomiting and/or gastric irritation
- Convulsions, fits or unconsciousness
- Excitability
- Blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes.

If you think that you have used too much Sandoz Ibuprofen Plus Codeine, 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.**

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

## 5. What should I know while using Sandoz Ibuprofen Plus Codeine?

### Things you should do

- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Sandoz Ibuprofen Plus Codeine.
- Remind any doctor, dentist or pharmacist you visit that you are using Sandoz Ibuprofen Plus Codeine.
- If you are going to have surgery, tell your doctor you are taking Sandoz Ibuprofen Plus Codeine.
- Talk to doctor if your symptoms do not improve. Your doctor will assess your condition and decide if you should continue to take the medicine.

### Call your doctor straight away if you:

- Become pregnant while taking Sandoz Ibuprofen Plus Codeine.

Remind any doctor, dentist or pharmacist you visit that you are using Sandoz Ibuprofen Plus Codeine.

### Things you should not do

- Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.
- Do not give Sandoz Ibuprofen Plus Codeine to anyone else, even if they have the same condition as you.
- Do not use Sandoz Ibuprofen Plus Codeine to treat any other complaints unless your doctor tells you to.
- Do not take more than the recommended dose unless your doctor tells you to.
- Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Sandoz Ibuprofen Plus Codeine affects you.**

Sandoz Ibuprofen Plus Codeine may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, light-headedness and/or drowsiness may be worse.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Using Sandoz Ibuprofen Plus Codeine with alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death.

### Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety

- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Sandoz Ibuprofen Plus Codeine given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

### Looking after your medicine

- Keep the tablets in the original pack until it is time to take the dose. If you take them out they will not keep well.

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

Store it in a cool dry place where the temperature stays below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

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

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
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"><li>• stomach upset including nausea (feeling sick), vomiting</li><li>• heartburn, indigestion</li><li>• constipation</li><li>• diarrhoea, pain in the stomach</li><li>• loss of appetite</li></ul> <p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"><li>• sleeplessness, nightmares</li><li>• change in mood e.g. depression, restlessness, irritability</li><li>• sore or dry mouth or tongue</li><li>• dizziness, light-headedness, drowsiness</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• headache</li> <li>• hearing disturbance</li> </ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"> <li>• shallow breathing</li> <li>• cough suppression</li> <li>• central sleep apnoea</li> </ul>	
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<p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>• bleeding or bruising more easily than normal, reddish or purplish blotches under the skin</li> <li>• signs of anaemia, such as tiredness, being short of breath, and looking pale</li> </ul> <p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"> <li>• unusual or extreme mood swings</li> <li>• dizziness, light-headedness</li> <li>• severe dizziness, spinning sensation</li> <li>• severe or persistent headache</li> <li>• difficulty hearing, deafness</li> <li>• tingling or numbness of the hands or feet</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>• eye problems such as blurred vision, sore red eyes, itching</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• severe pain or tenderness in the stomach</li> <li>• vomiting blood or material that looks like coffee grounds.</li> <li>• bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• shallow breathing or shortness of breath</li> <li>• flushing of the face</li> <li>• swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.</li> <li>• asthma, wheezing, shortness of breath, pain or tightness in the chest</li> <li>• symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>• fast heart beat</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• yellowing of the skin and eyes, also called jaundice</li> <li>• sudden or severe itching, skin rash, hives, skin peeling</li> </ul> <p><b>Urinary related:</b></p> <ul style="list-style-type: none"> <li>• a change in the colour of urine passed, blood in the urine</li> <li>• a change in the amount or frequency of urine passed, burning feeling when passing urine</li> <li>• unusual weight gain, swelling of ankles or legs</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>• signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers</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>

**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 Sandoz Ibuprofen Plus Codeine contains

<b>Active ingredient (main ingredient)</b>	Ibuprofen and Codeine phosphate hemihydrate
<b>Other ingredients (inactive ingredients)</b>	microcrystalline cellulose pregelatinised maize starch croscarmellose sodium colloidal anhydrous silica Opadry complete film coating system OY-58900 white
<b>Potential allergens</b>	Sandoz Ibuprofen Plus Codeine does not contain gluten or preservatives.

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

### **What Sandoz Ibuprofen Plus Codeine looks like**

Sandoz Ibuprofen Plus Codeine is white to off white coloured, caplet shaped film coated tablets plain on both sides (AUST R 211512).

Sandoz Ibuprofen Plus Codeine tablets are available in Australia in blister packs of 10 and 30 tablets.

*\*not all presentations may be marketed*

### **Who distributes Sandoz Ibuprofen Plus Codeine**

Sandoz Pty Ltd

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54 Waterloo Road

Macquarie Park NSW 2113

Australia

Tel: 1800 726 369

This leaflet was revised in March 2023.