

# Sandoz Ibuprofen Plus Codeine

*Ibuprofen 200mg and Codeine phosphate 12.8mg Tablets*

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## Consumer Medicine Information

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### What is in this Leaflet?

This leaflet answers some common questions about Sandoz Ibuprofen Plus Codeine tablets. 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 or pharmacist has weighed the risks of you taking Sandoz Ibuprofen Plus Codeine tablets against the benefits this medicine is expected to have for you.

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

**Keep this leaflet with the medicine.** You may need to read it again.

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### What Sandoz Ibuprofen Plus Codeine is used for

Sandoz Ibuprofen Plus Codeine tablets contain two active ingredients:

**Ibuprofen and Codeine phosphate.** Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, 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 tablets relieve inflammation and strong pain associated with migraine headache, tension headache, headache, period pain, dental pain, back pain, neuralgia, rheumatic pain, arthritic pain and muscular pain.

Sandoz Ibuprofen Plus Codeine tablets are not recommended for use in children under the age of 12 years.

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### Before You Take Sandoz Ibuprofen Plus Codeine

*When you must not take it*

**Do not take Sandoz Ibuprofen Plus Codeine tablets if you have an allergy to:**

- **Ibuprofen, codeine or other opioid analgesics such as morphine or pethidine, or any of the ingredients of Sandoz Ibuprofen Plus Codeine tablets, listed at the end of this leaflet**
- **Aspirin**
- **any other NSAID medicine.**

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips, or tongue; this may affect swallowing or breathing
- hives, itching or skin rash
- fainting.

**If you are allergic to Aspirin or NSAID group of medicines and take Sandoz Ibuprofen Plus Codeine tablets, these symptoms may be severe.**

**Do not take Sandoz Ibuprofen Plus Codeine if you are also taking any other medicines that contain one or more NSAID medicine, whether prescribed by your doctor or obtained without prescription.**

Several medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if the medicines you are taking contain these ingredients, ask your pharmacist.

**Do not take Sandoz Ibuprofen Plus Codeine tablets during the last 3 months of pregnancy.**

Unless advised by a medical doctor, do not take Sandoz Ibuprofen Plus Codeine tablets during pregnancy. NSAIDs should not be taken during pregnancy.

**Do not take Sandoz Ibuprofen Plus Codeine:**

- if you are vomiting blood or material that looks like coffee grounds
- if you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- if you have a stomach ulcer
- if you have chronic constipation or shallow breathing, or severe diarrhoea
- if you consume heavy amounts of alcohol regularly
- if the packaging is torn or shows signs of tampering

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## How to Take Sandoz Ibuprofen Plus Codeine

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### *How much to take*

The usual dose of Sandoz Ibuprofen Plus Codeine for adults and children over 12 years of age is 2 tablets followed by, if necessary 1 or 2 tablets every 4 hours.

### **Do not take more than 6 tablets in 24 hours.**

Sandoz Ibuprofen Plus Codeine is not recommended for children under 12 years of age. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

### *How to take it*

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

### *How long to take it*

You should not take Sandoz Ibuprofen Plus Codeine for more than a few days.

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

### *If you take too much (overdose)*

If you take too much of this medicine you may experience nausea or upset stomach, vomiting and gastric irritation, drowsiness, dizziness or very slow, laboured breathing. You may also experience blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes. Excitability, convulsions and unconsciousness may be experienced in rare cases.

If you think you have taken too many Sandoz Ibuprofen Plus Codeine tablets, talk to your pharmacist or doctor, or contact the Poisons Information Centre on Tel 13 11 26.

- if the expiry date (EXP) printed on the pack has passed; it may not work as well
- if you are not sure whether you should start taking Sandoz Ibuprofen Plus Codeine, contact your pharmacist or doctor.

### *Before you start to take it*

#### **Tell your pharmacist or doctor:**

- if you are pregnant or intend to become pregnant. Sandoz Ibuprofen Plus Codeine is not recommended for use during pregnancy. Your doctor will decide if you should take Sandoz Ibuprofen Plus Codeine tablets.
- if you are breast-feeding or plan to breast-feed. Sandoz Ibuprofen Plus Codeine is not recommended while you are breast-feeding. If there is a need to consider Sandoz Ibuprofen Plus Codeine tablets while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it
- if you have any medical conditions, especially the following:
  - a history of stomach ulcer
  - liver disease
  - kidney disease
  - heart failure
  - swelling of ankles or feet
  - asthma, or have suffered in the past from asthma.
  - thyroid problems or low blood pressure
  - a head injury or intercranial pressure
  - prostate problems
  - stomach problems or recent stomach surgery.
- aspirin, salicylates or other NSAID medicines
- warfarin or other medicines used to stop blood clots or thin the blood
- medicines that are used to treat high blood pressure eg diuretics (fluid tablets) or heart problems
- methotrexate a medicine used to treat arthritis and some types of cancer
- zidovudine a medicine used to treat HIV infection
- lithium and other medicines used to treat depression or anxiety eg MAOIs (even if taken within the last 14 days)
- medicines used to relieve stomach cramps or spasms
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide)
- metoclopramide, a medicine used to treat nausea and vomiting
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines used to treat diabetes
- medicines used to treat Parkinson's disease
- medicines used to prevent travel sickness
- other opioids to treat pain or suppress cough.

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 or pharmacist will advise you. Your pharmacist and doctor have more information on medicines to avoid or be careful with while taking Sandoz Ibuprofen Plus Codeine tablets.

### *Taking other medicines*

**Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with each other. These include:**

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## While You Are Using Sandoz Ibuprofen Plus Codeine

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### *Things you must do*

- If you become pregnant while taking Sandoz Ibuprofen Plus Codeine tablets stop taking and talk to your doctor.
- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Sandoz Ibuprofen Plus Codeine tablets.
- Tell all of the doctors, dentists and pharmacists that are treating you that you are taking Sandoz Ibuprofen Plus Codeine tablets.
- If you are going to have surgery, tell your doctor you are taking Sandoz Ibuprofen Plus Codeine tablets.
- Talk to your doctor or pharmacist if your symptoms do not improve.

### *Things you must not do*

- Do not give Sandoz Ibuprofen Plus Codeine tablets to anyone else, even if they have the same condition as you
- Do not use Sandoz Ibuprofen Plus Codeine tablets to treat any other complaints
- Do not take Sandoz Ibuprofen Plus Codeine tablets with any other product containing ibuprofen and or codeine/other opioid unless your doctor tells you
- Do not take for more than a few days at a time unless your doctor tells you to.

### *Things to be careful of*

- Be careful driving or operating machinery until you know how Sandoz Ibuprofen Plus Codeine tablets affects you.

- Sandoz Ibuprofen Plus Codeine tablets 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 or drowsiness may be worse.
- Products containing codeine should not be taken for prolonged periods; Codeine may be habit forming.

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## Side Effects

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Check with your pharmacist or doctor as soon as possible if you have any problems while taking Sandoz Ibuprofen Plus Codeine, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Sandoz Ibuprofen Plus Codeine can cause some side effects in some people. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention. Ask your pharmacist or doctor to answer any questions you may have.

### **Tell your pharmacist or doctor if you notice any of the following symptoms that worry you:**

- stomach upset including nausea (feeling sick), vomiting
- heartburn, indigestion
- diarrhoea, pain in the stomach
- dizziness, light-headedness, drowsiness
- constipation
- cough suppression
- headache
- hearing disturbance.

These are the more common side effects of Sandoz Ibuprofen Plus Codeine and are usually mild and short lived.

### **If any of the following happen, stop taking Sandoz Ibuprofen Plus Codeine and tell your doctor immediately or go to casualty at your nearest hospital:**

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath, pain or tightness in the chest
- sudden or severe itching, skin rash, hives, skin peeling
- easy bruising
- shallow breathing
- fluid retention.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare. Some people may get other side effects while taking Sandoz Ibuprofen Plus Codeine tablets. Tell your doctor or pharmacist if you notice anything else that worries you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After Using Sandoz Ibuprofen Plus Codeine

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### *Storage*

**Keep the tablets in the pack until it is time to take the dose.**

If you take them out they will not keep well.

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

**Do not store Sandoz Ibuprofen Plus Codeine or any other medicine in the bathroom or near a sink.**

**Do not leave the tablets in the car or on windowsills. Heat and dampness can destroy some medicines.**

**Keep the tablets where children cannot reach them.**

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

### *Disposal*

When you stop taking Sandoz Ibuprofen Plus Codeine or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

### *More Information*

If you have any further questions or if you are not sure about anything relating to the use of Sandoz Ibuprofen Plus Codeine tablets, your doctor or pharmacist can best assist you.

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## Product Description

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### *What it looks like?*

Sandoz Ibuprofen Plus Codeine is white to off-white capsule-shaped, biconvex, film-coated tablet.

### *Ingredients*

Sandoz Ibuprofen Plus Codeine tablets contains 200mg ibuprofen and 12.8mg codeine phosphate as the active ingredients.

The other ingredients in Sandoz Ibuprofen Plus Codeine tablets are:

- Starch - pregelatinised maize
- Cellulose microcrystalline
- Croscarmellose sodium
- Silica colloidal anhydrous
- Water purified
- Opadry white colouring.

Sandoz Ibuprofen Plus Codeine does not contain gluten or preservatives.

### *Presentation:*

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

### *Supplier*

#### **Sandoz Pty Ltd**

ABN 60 075 449 553  
Level 2, 19 Harris Street  
Pymont NSW 2009  
Australia  
Tel: 1800 634 500

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- 200mg/12.8mg Tablets:  
AUST R 211512