

# Sandoz Ibuprofen Plus Codeine

Ibuprofen 200mg and Codeine phosphate 12.8mg Tablets

## Consumer Medicine Information

### 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 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.

### What Sandoz Ibuprofen Plus Codeine is used for

Sandoz Ibuprofen Plus Codeine tablets contain two active ingredients:

#### **Ibuprofen and Codeine phosphate hemihydrate.**

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 provides 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.

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

Ask your doctor if you have any questions about this medicine.

Your doctor may have given it for another reason.

### Before You Take Sandoz Ibuprofen Plus Codeine

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

**Do not take Sandoz Ibuprofen Plus Codeine tablets if**

**1. you have an allergy to:**

- **Ibuprofen, codeine or other opioids, or any of the ingredients of Sandoz Ibuprofen Plus Codeine tablets, listed at the end of this leaflet**
- **any medicine containing aspirin, ibuprofen or other NSAIDs.**

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID. If you are not sure if you are taking any of these medicines, ask your pharmacist.

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.**

2. **you are in the last three months of pregnancy or are breastfeeding Sandoz Ibuprofen Plus Codeine should not be taken during pregnancy except during the first 6 months of pregnancy. All NSAIDs should not be taken during the last three months of pregnancy.**
3. **you are vomiting blood or material that looks like coffee grounds**
4. **you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea**
5. **you have peptic ulcer (ie. Stomach or duodenal ulcer), or have had one before**
6. **you are using other NSAIDs**
7. **you have chronic constipation or shallow breathing, or severe diarrhoea**
8. **you consume regular and heavy amounts of alcohol**
9. **you are a CYP2D6 ultra-rapid metaboliser**

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.

If you are not sure whether you should start taking Sandoz Ibuprofen Plus Codeine, contact your doctor.

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.

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

**Tell your pharmacist or doctor if:**

1. you have allergies to any other medicines including aspirin, or other NSAID medicines
2. you are pregnant or intend to become pregnant  
Sandoz Ibuprofen Plus Codeine is not recommended during the last 3 months of pregnancy. Your doctor should decide if you should take Sandoz Ibuprofen Plus Codeine during the first 6 months of pregnancy.
3. you are breast-feeding or plan to breast-feed  
Sandoz Ibuprofen Plus Codeine should not be taken while breastfeeding except on your doctor's advice.  
Codeine passes into the breast milk. If there is a need to consider Sandoz Ibuprofen Plus Codeine while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it.
4. you have or have had any of the following 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 intercranial pressure
- prostatic problems
- stomach problems or recent stomach surgery.

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

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

#### *Taking other medicines*

**Tell your 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 Sandoz Ibuprofen Plus Codeine. 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 stop blood clots or thin the blood
- medicines that are used to treat high blood pressure eg diuretics (fluid tablets)
- methotrexate
- zidovudine
- lithium
- mifepristone, quinolone antibiotics
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide)
- metoclopramide, a medicine used to treat nausea and vomiting
- 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 cyclosporin, tacrolimus, prednisolone and cortisone, which reduce the activity of your immune system
- Probenecid - medicine used to treat gout
- Phenytoin - medicine used to treat epilepsy
- other opioids 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.

Your doctor has more information on medicines to avoid or be careful with while taking Sandoz Ibuprofen Plus Codeine tablets.

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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 to 6 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 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.

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

Immediately telephone your doctor or Poisons Information Centre (in Australia 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Sandoz Ibuprofen Plus Codeine. Do this even if there are no signs of discomfort or poisoning.

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.

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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 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.
- Your doctor will assess your condition and decide if you should continue to take the medicine

### *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 more than the recommended dose unless your doctor tells you
- Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

### *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.
- 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.

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## Side Effects

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Check with your 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 doctor to answer any questions you may have.

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

- stomach upset including nausea (feeling sick), vomiting
- heartburn, indigestion
- loss of appetite
- sleeplessness, nightmares
- change in mood for example depression, restlessness, irritability
- diarrhoea, pain in the stomach
- dizziness, light-headedness, drowsiness
- constipation
- shallow breathing
- cough suppression
- headache
- hearing disturbance.

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

### **Tell your doctor as soon as possible if you notice any of the following:**

- shallow breathing or shortness of breath
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat
- severe pain or tenderness in the stomach

- eye problems such as blurred vision, sore red eyes, itching
- severe dizziness, spinning sensations
- severe or persistent headache
- tingling or numbness of hands or feet
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia such as tiredness, being short of breath, and looking pale
- a change in the colour of urine passed, blood in urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles and legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

The above side effect may be serious and may require urgent medical attention.

Serious side effects are rare for low doses of this medicine and when used for a short period of time.

### **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

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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:

- pregelatinised maize starch
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- Opadry complete film coating system OY-58900 white

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  
54 Waterloo Road  
Macquarie Park NSW 2113  
Australia  
Tel: 1800 726 369

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### *Australian Register Number:*

200mg/12.8mg Tablets: AUST R 211512