

# TRUST IBUPROFEN PLUS CODEINE

*Ibuprofen 200mg and Codeine phosphate hemihydrate 12.8mg*

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## Consumer Medicine Information

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### What is in this Leaflet?

This leaflet answers some common questions about Trust Ibuprofen Plus Codeine. 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 Trust Ibuprofen Plus Codeine 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 Trust Ibuprofen Plus Codeine is used for

Trust 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.

Trust Ibuprofen Plus Codeine tablets are indicated for temporary

relief of acute, moderate pain and inflammation.

Do not use Trust Ibuprofen Plus Codeine in children under the age of 12 years.

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### Before You Take Trust Ibuprofen Plus Codeine

*When you must not take it*

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

- **Ibuprofen, codeine or other opioid analgesics such as morphine or pethidine, or any of the ingredients of Trust Ibuprofen Plus Codeine, listed at the end of this leaflet.**
- **Aspirin;**
- **any other NSAID or anti-inflammatory medicines.**

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 Trust Ibuprofen Plus Codeine tablets, these symptoms may be severe.**

**Do not take Trust Ibuprofen Plus Codeine tablets 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 doctor.

**Do not take Trust Ibuprofen Plus Codeine during the last 3 months of pregnancy including the last few days before expected birth.**

**Do not take Trust Ibuprofen Plus Codeine during labour, especially if the baby is premature.**

This medicine may produce withdrawal effects in the newborn baby.

Unless advised by a medical doctor, do not take Trust Ibuprofen Plus Codeine tablets during the first 6 months of pregnancy.

**Do not use Trust Ibuprofen Plus Codeine tablets if you are breastfeeding or planning to breastfeed.**

This medicine passes into breastmilk and may affect the baby.

**Do not take Trust 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 you are an Ultra-rapid metaboliser of CYP2D6
- if you are aged below 18 years of age and have had your tonsils or adenoids removed
- to treat sleep apnoea
- if the packaging is torn or shows signs of tampering
- 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 Trust Ibuprofen Plus Codeine, contact your doctor.

### *Before you start to take Trust Ibuprofen Plus Codeine*

#### **Tell your doctor:**

- if you are pregnant or intend to become pregnant. Trust Ibuprofen Plus Codeine is not recommended for use during the first 6 months of pregnancy. Your doctor will decide if you should take Trust Ibuprofen Plus Codeine tablets. **Do not take Trust Ibuprofen Plus Codeine tablets at all during the last 3 months of pregnancy.**
- if you are breast-feeding or plan to breast-feed. Trust Ibuprofen Plus Codeine is not recommended while you are breast-feeding.
- If you are aged 65 years or over. Unless your doctor tells you to, you should not use
- Trust Ibuprofen Plus Codeine tablets.
- 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

### *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 each other. These include:**

- 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 including heart failure,
- methotrexate a medicine used to treat arthritis and some type of cancers,
- 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 heartbeat,

- 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 Trust Ibuprofen Plus Codeine tablets 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 Trust Ibuprofen Plus Codeine tablets.

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## How to Take Trust Ibuprofen Plus Codeine tablets

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### *How much to take*

The usual dose of Trust Ibuprofen Plus Codeine tablets 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.** Trust 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 Trust Ibuprofen Plus Codeine tablets by mouth with fluid. It may also be taken before, or after food.

### *How long to take it*

Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use

can be harmful and increase the risk of heart attack, stroke or liver damage.

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

### *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 Trust Ibuprofen Plus Codeine tablets, talk to your pharmacist or doctor, or contact the Poisons Information Centre (in Australia Tel 13 11 26 and in New Zealand 0800-764 766) for advice.

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## While You Are Using Trust Ibuprofen Plus Codeine

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### *Things you must do*

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

### *Things you must not do*

- Do not give Trust Ibuprofen Plus Codeine tablets to anyone else, even if they have the same condition as you
- Do not use Trust Ibuprofen Plus Codeine tablets to treat any other complaints
- Do not take Trust 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 3 days at a time unless your doctor tells you to. Do not exceed the recommended dose. Excessive use of ibuprofen 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 Trust Ibuprofen Plus Codeine tablets affects you.
- Trust 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 doctor as soon as possible if you have any problems while taking Trust Ibuprofen Plus Codeine tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Trust Ibuprofen Plus Codeine tablets can cause some side effects in rare

cases. 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,
- diarrhoea, pain in the stomach,
- dizziness, light-headedness, drowsiness,
- constipation,
- cough suppression,
- headache,
- hearing disturbance
- nervousness
- fatigue

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

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

- get sunburnt more quickly than usual
- unusual or extreme mood swings
- flushing of the face
- fast heart beat

The above list includes serious side effects that may require 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 Trust 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 Trust Ibuprofen Plus Codeine tablets. Tell your doctor 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 Trust 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 Trust Ibuprofen Plus Codeine tablets 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 is a good place to store medicines.

### *Disposal*

When you stop taking Trust 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 Trust 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?*

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

### *Ingredients*

Trust Ibuprofen Plus Codeine contains 200mg Ibuprofen and 12.8mg Codeine phosphate hemihydrate as the active ingredients.

The other ingredients in Trust Ibuprofen Plus Codeine are:

- starch – pregelatinised maize
- cellulose microcrystalline
- croscarmellose sodium
- silica colloidal anhydrous
- water purified
- opadry white colouring

Trust Ibuprofen Plus Codeine tablets do not contain gluten, lactose or preservatives.

### **Presentation:**

Trust Ibuprofen Plus Codeine tablets are available in Australia in blister packs of 10, 12, 15, 18, 20, 24, and 30 tablets.

### **Distributor:**

Pharmacor Pty Ltd  
Suite 501, 7 Oaks Ave  
DEE WHY NSW 2099  
AUST R 175264

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