BRUFEN® PLUS 200/12.8

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 BRUFEN PLUS 200/12.8?

BRUFEN PLUS 200/12.8 contains the active ingredients ibuprofen and codeine phosphate hemihydrate. BRUFEN PLUS 200/12.8 is used to provide temporary relief of acute to moderate pain and inflammation in patients over the age of 12 years.
For more information, see Section 1. Why am I using BRUFEN PLUS 200/12.8? in the full CMI.

2. What should I know before I use BRUFEN PLUS 200/12.8?

Do not use if you have ever had an allergic reaction to BRUFEN PLUS 200/12.8 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 addition, dependence and tolerance. For more information, see Section 2. What should I know before I use BRUFEN PLUS 200/12.8? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BRUFEN PLUS 200/12.8 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 BRUFEN PLUS 200/12.8?

The usual dose of BRUFEN PLUS 200/12.8 is 2 tablets followed by, if necessary, 1 or 2 tablets every 4 hours. More instructions can be found in Section 4. How do I use BRUFEN PLUS 200/12.8? in the full CMI.

5. What should I know while using BRUFEN PLUS 200/12.8?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using BRUFEN PLUS 200/12.8.

	• If your symptoms do not improve after a few days, talk to your doctor. • If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.
Things you should not do	• Do not take more than 6 tablets in 24 hours. • BRUFEN PLUS 200/12.8 is not recommended for use in children under the age of 12 years. • You should not take BRUFEN PLUS 200/12.8 for more than three days at a time.
Driving or using machines	• Be careful driving or operating machinery until you know how BRUFEN PLUS 200/12.8 affects you. • BRUFEN PLUS 200/12.8 may cause dizziness, light-headedness or drowsiness in some people. If you have any of these symptoms,

	do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	• You must not drink alcohol while taking BRUFEN PLUS 200/12.8.
Looking after your medicine	• Store below 30°C • Store in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using BRUFEN PLUS 200/12.8? in the full CMI.

6. Are there any side effects?

Contact your doctor immediately or go to the Emergency Department at your nearest hospital if any of the following happen: asthma, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin, fainting. These may be the sign of an allergic reaction. **Tell your doctor or pharmacist if you notice any of the following 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

BRUFEN PLUS 200/12.8 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

BRUFEN PLUS 200/12.8 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

BRUFEN PLUS 200/12.8 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 during use, but the risk is higher when first starting BRUFEN PLUS 200/12.8 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 Using BRUFEN PLUS 200/12.8

Using BRUFEN PLUS 200/12.8 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 and alcohol may result in severe drowsiness, decreased awareness, breathing

problems, 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 BRUFEN PLUS 200/12.8.

BRUFEN® PLUS 200/12.8

Active ingredient(s): *ibuprofen and codeine phosphate hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BRUFEN PLUS 200/12.8. **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 BRUFEN PLUS 200/12.8.**

Where to find information in this leaflet:

1. Why am I using BRUFEN PLUS 200/12.8?

BRUFEN PLUS 200/12.8 contains the 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 (e.g. swelling, redness, soreness) and fever. Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

BRUFEN PLUS 200/12.8 is used to provide temporary relief of acute to moderate pain and inflammation in patients over the age of 12 years.

Once taken, your body processes the codeine into its active form, morphine, in the liver. In about 8% of people, they may experience less pain relief compared to others as their body doesn't convert codeine to morphine very well.

2. What should I know before I use BRUFEN PLUS 200/12.8?

Warnings

Do not give BRUFEN PLUS 200/12.8 to children under the age of 12 years.

Do not use BRUFEN PLUS 200/12.8 if:

- you are allergic to ibuprofen, codeine phosphate hemihydrate, other opioid analgesics or any medicine including aspirin, other NSAID or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - asthma, shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
  - fainting

  Always check the ingredients to make sure you can use this medicine.
- **you are also taking other medicines that contain one or more NSAID medicine, whether prescribed by your doctor or obtained without prescription.**

  Many 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 any of these medicines , ask your doctor or pharmacist.
- **you are in the last three months of pregnancy.**
- **you are breastfeeding or planning to breastfeed.**
- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea

- you have a stomach or duodenal ulcer or have had one in the past
- you have or have had a history of ulcerative colitis or Crohn's disease
- you have chronic constipation or severe diarrhoea
- you have shallow breathing
- you consume large amounts of alcohol regularly
- you have severe heart, liver or kidney failure
- you are an ultra-rapid CYP2D6 metaboliser
- you are currently taking a Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with a MAOI.
- you are aged between 12 and 18 years of age and have compromised respiratory function including having had your tonsils or adenoids removed.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have or have had 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) and skin irritation
  - a history of stomach ulcer
  - stomach problems or recent gastrointestinal surgery

- 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
- prostate problems
- a tendency for convulsions, fits
- a recent head injury

- 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, foods, preservatives or dyes.
- Tell your doctor if you are over 65 years of age.

If you have not told your doctor about any of the above, tell them before you start taking BRUFEN PLUS 200/12.8.

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.

Unless advised by your doctor, do not take BRUFEN PLUS 200/12.8 during the first 6 months of pregnancy. Your doctor will decide if you should take BRUFEN PLUS 200/12.8 during the first 6 months.

BRUFEN PLUS 200/12.8 is should not be taken during the last three months of pregnancy.

BRUFEN PLUS 200/12.8 given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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

BRUFEN PLUS 200/12.8 should not be taken while breastfeeding except on your doctor's advice. Codeine passes into the breast milk.

Addiction

You can become addicted to BRUFEN PLUS 200/12.8 even if you take it exactly as prescribed. BRUFEN PLUS 200/12.8 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 BRUFEN PLUS 200/12.8. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking BRUFEN PLUS

200/12.8 suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to BRUFEN PLUS 200/12.8 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 BRUFEN PLUS 200/12.8 and affect how it works.

These include:

- medicines used to help you relax, sleep or relieve anxiety, such as benzodiazepines, barbiturates and sedatives
- gabapentinoids (gabapentin, pregabalin)
- aspirin, salicylates or other NSAID medicines
- aminoglycoside antibiotics, medicines used to treat bacterial infections
- atropine
- warfarin, clopidogrel, ticlopidine or other medicines used to stop blood clots or thin the blood

- medicines that are used to treat high blood pressure, e.g. ACE inhibitors, diuretics (fluid tablets) or heart problems including heart failure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- zidovudine, a medicine used to treat HIV infection
- mifepristone
- quinolone, a medicine used to treat bacterial infections
- medicines used to relieve stomach cramps or spasms
- medicines used to treat diarrhoea (e.g. kaolin, pectin, loperamide)
- medicines used to prevent travel sickness, such as hydroxyzine
- 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 depression such as moclobemide
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- lithium and other medicines used to treat depression or anxiety, e.g. MAOIs (even if taken within the last 14 days)
- medicines such as prednisone, prednisolone, cortisone, ciclosporin and tacrolimus which reduce the activity of your immune system
- quinidine, a medicine used to treat abnormal or irregular heartbeat

- medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- phenytoin, a medicine used to treat epilepsy
- medicines used to treat Parkinson's disease
- other opioids to treat pain or suppress cough
- colestyramine, a medicine used to treat high cholesterol
- cimetidine, a medicine used to reduce stomach acid production
- herbal medicines such as ginkgo biloba
- mexiletine, a medicine used to treat abnormal heart beat
- naloxone, a medicine used in the treatment of an opioid overdose

These medicines may be affected by BRUFEN PLUS 200/12.8 or may affect how well it works. You may different amounts of your medicines, or you may need different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BRUFEN PLUS 200/12.8.

4. How do I use BRUFEN PLUS 200/12.8?

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

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

How much to take

- The usual dose of BRUFEN PLUS 200/12.8 is 2 tablets followed by, if necessary, 1 or 2 tablets every 4 hours.
- **Do not take more than 6 tablets in 24 hours.**
- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.
- Follow the instructions provided and use BRUFEN PLUS 200/12.8 until your doctor tells you to stop.

How to take BRUFEN PLUS 200/12.8

- Swallow the tablets whole with a glass of water. It can be taken with food or on an empty stomach.

How long to take BRUFEN PLUS 200/12.8

- You should not take BRUFEN PLUS 200/12.8 for more than three days at a time unless instructed to by your doctor.
- If your symptoms persist, worsen or new symptoms develop, talk to your doctor.

If you use too much BRUFEN PLUS 200/12.8

If you or someone else take too much (overdose), and experience one or more of the symptoms below, immediately 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 has accidentally taken BRUFEN PLUS 200/12.8 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 or fits
- excitability
- blurred vision, ringing in the ears or rapid uncontrollable movements of the eyes.

If you think that you or someone else have used too much BRUFEN PLUS 200/12.8, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take BRUFEN PLUS 200/12.8 as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

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 BRUFEN PLUS 200/12.8?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BRUFEN PLUS 200/12.8.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.**
- **If your symptoms do not improve after a few days, talk to your doctor.** Your doctor will assess your condition and decide if you should continue to take BRUFEN PLUS 200/12.8.

Call your doctor straight away if you:

- become pregnant while taking this medicine and stop taking it immediately.

Remind any doctor, dentist or pharmacist who treat you that you are using BRUFEN PLUS 200/12.8.

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 your medicine to anyone else, even if they have the same condition as you.
- Do not take BRUFEN PLUS 200/12.8 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 BRUFEN PLUS 200/12.8 affects you.

BRUFEN PLUS 200/12.8 may cause dizziness, light-headedness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. If you drink

alcohol, dizziness, light- headedness and/or drowsiness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

Using BRUFEN PLUS 200/12.8 with alcohol may result in severe dizziness, light-headedness or drowsiness, decreased awareness, breathing difficulties, coma and death.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop taking 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

Products containing codeine should not be used for prolonged periods; codeine may be habit forming.

Brufen Plus 200/12.8 given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

Store it in a cool dry place 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • stomach upset including nausea (feeling sick), vomiting • heartburn, indigestion • constipation • diarrhoea, pain in the stomach • loss of appetite **Head and neurology related**: • sleeplessness, nightmares	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• changes in mood, for example depression, restlessness, irritability • sore or dry mouth or tongue • dizziness, light-headedness, drowsiness • headache • hearing disturbance • central sleep apnoea **Respiratory related**: • shallow breathing • cough suppression **Skin related:** • a rash that always appears in the exact same spot on your skin (fixed eruption)	

Serious side effects

Serious side effects	What to do
Gastrointestinal related: • severe pain or tenderness in the stomach	**Call your doctor straight away, or go straight to the Emergency Department at your**

Serious side effects	What to do
• vomiting blood or material that looks like coffee grounds • bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea **Allergy related**: • shallow breathing or shortness of breath • flushing of the face • 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 • symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than usual **Heart related**: • fast heart beat	**nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Skin related: • yellowing of the skin and eyes, known as jaundice • sudden or severe itching, skin rash, hives, skin peeling **Urinary related**: • a change in the colour of your urine, blood in the urine • a change in the amount or frequency of urine passed, burning feeling when passing urine • fluid retention • unusual weight gain, swelling of ankles or legs **Infection related**: • signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers **Bleeding related**: • bleeding or bruising more easily than normal,	**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.**

Serious side effects	What to do
reddish or purplish blotches under the skin • signs of anaemia, such as tiredness, being short of breath and looking pale **Head and neurology related**: • unusual or extreme mood swings • dizziness, light-headedness • severe dizziness, spinning sensation • severe or persistent headache • difficulty hearing, deafness • tingling or numbness of the hands or feet **Eyes related**: • eye problems such as blurred vision, sore red eyes, itching **Pregnancy related**: • low amniotic fluid in the womb during pregnancy	

Serious side effects	What to do
• newborns with impaired kidney function	

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. 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 BRUFEN PLUS 200/12.8 contains

Active ingredient **(main ingredient)**	**Ibuprofen and codeine phosphate hemihydrate**

Other ingredients **(inactive ingredients)**	• pregelatinised maize starch • microcrystalline cellulose • croscarmellose sodium • colloidal anhydrous silica • Opadry complete film coating system OY-58900 White (ID 3446)

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

What BRUFEN PLUS 200/12.8 looks like

BRUFEN PLUS 200/12.8 are white to off-white capsule-shaped, biconvex, film-coated tablets (AUST R 298439).

BRUFEN PLUS 200/12.8 are available in blister packs containing 30 tablets.

Who distributes BRUFEN PLUS 200/12.8

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in March 2025.

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