BRUFEN® PLUS 200/12.8

ibuprofen and codeine phosphate hemihydrate

Consumer Medicine Information

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.

What is in this leaflet

This leaflet answers some common questions about BRUFEN PLUS 200/12.8. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BRUFEN PLUS 200/12.8 against the benefits they expect it will have for you.

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

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

What BRUFEN PLUS 200/12.8 is used for

BRUFEN PLUS 200/12.8 contains 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 (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 provides 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.

BRUFEN PLUS 200/12.8 is not recommended for use in children under the age of 12 years.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take BRUFEN PLUS 200/12.8

When you must not take it

Do not take BRUFEN PLUS 200/12.8 if you have an allergy to:

- any medicine containing ibuprofen or codeine phosphate hemihydrate
- any other similar medicines to ibuprofen including aspirin and other NSAID medicines
- any other similar medicines to codeine such as other opioid analgesics including morphine or pethidine

- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- 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

Do not take BRUFEN PLUS 200/12.8 if you are also taking 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 BRUFEN PLUS 200/12.8 if you are in the last three months of pregnancy.
Unless advised by your doctor, do not take BRUFEN PLUS 200/12.8 during the first 6 months of pregnancy.

Do not take BRUFEN PLUS 200/12.8 if you are breastfeeding or planning to breastfeed.
The active ingredients in BRUFEN PLUS 200/12.8 pass into breast milk and there is a possibility that your baby may be affected.

Do not take BRUFEN PLUS 200/12.8 if you:

- are vomiting blood or material that looks like coffee grounds
- are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- have a stomach or duodenal ulcer or have had one in the past
- have or have had a history of ulcerative colitis or Crohn's disease
- have chronic constipation or severe diarrhoea
- have shallow breathing
- consume large amounts of alcohol regularly
- have severe heart, liver or kidney failure
- are an ultra-rapid CYP2D6 metaboliser
- 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if 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) 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 are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

BRUFEN PLUS 200/12.8 is not recommended during the last three months of pregnancy. Your doctor will decide if you should take BRUFEN PLUS 200/12.8 during the first six months.

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

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

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BRUFEN PLUS 200/12.8 may interfere with each other. These include:

- medicines used to help you relax, sleep or relieve anxiety, such as benzodiazepines, barbiturates and sedatives
- 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
- selective serotonin reuptake inhibitors (SSRIs) and monoamine oxide 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.

How to take 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.

How to take it

Swallow the tablets whole with a glass of water.

It can be taken with food or on an empty stomach.

How long to take it

You should not take BRUFEN PLUS 200/12.8 for more than three days unless instructed to by your doctor.

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

If you take too much (overdose)

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 PLUS200/12.8 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 vomiting
- convulsions or fits

If you think you or someone else may have taken too much BRUFEN PLUS 200/12.8, 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.

Depending on your body’s individual ability to break down codeine, you may experience signs of overdose even when you take BRUFEN PLUS200/12.8 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.

While you are using BRUFEN PLUS 200/12.8

Things you must 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 you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.

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.

Things you must not do

Do not take BRUFEN PLUS 200/12.8 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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.

Things to be careful of

Be careful driving or operating machinery until you know how BRUFEN PLUS 200/12.8 affects you.
This medicine 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 or drowsiness may be worse.

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 PLUS200/12.8. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking BRUFEN PLUS200/12.8 suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance
Tolerance to BRUFEN PLUS200/12.8 may develop, which means that the effect of the medicine may decrease. If this happens, more maybe needed to maintain the same effect.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BRUFEN PLUS 200/12.8.

This medicine helps most people with pain and inflammation, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting
- heartburn, indigestion
- loss of appetite
- sleeplessness, nightmares
- changes in mood, for example depression, restlessness, irritability
- sore or dry mouth or tongue
- 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 BRUFEN PLUS 200/12.8 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 sensation
- severe or persistent headache
- tingling or numbness of the 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 your urine, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- yellowing of the skin and eyes, known as jaundice
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than usual

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 BRUFEN PLUS 200/12.8 and tell your doctor immediately or go to Accident and Emergency 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

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

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

Other side effects not listed above may also occur in some people.

After using BRUFEN PLUS 200/12.8

Storage

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.

Do not store BRUFEN PLUS 200/12.8 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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.

Product description

What it looks like

BRUFEN PLUS 200/12.8 are white to off-white capsule shaped, biconvex, film-coated tablets.

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

Ingredients

BRUFEN PLUS 200/12.8 contains 200 mg ibuprofen and 12.8 mg codeine phosphate hemihydrate as the active ingredients.

The tablets also contain:

- pregelatinised maize starch
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- Opadry film coating system OY-58900 white (ARTG PI No: 3446)

Supplier

BRUFEN PLUS 200/12.8 is distributed in Australia by:

Viatris Pty Ltd
Level 1, 30 The Bond

30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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