Contrave® 8/90

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.

1. Why am I using Contrave?

Contrave contains the active ingredients naltrexone hydrochloride and bupropion hydrochloride. Contrave is used in obese or overweight adults to manage weight together with a reduced calorie diet and physical exercise.

For more information, see Section 1. Why am I taking Contrave? in the full CMI.

2. What should I know before I use Contrave?

Do not use if you have ever had an allergic reaction to Contrave or any of the ingredients listed at the end of the CMI.

Do not take Contrave if you are pregnant or plan to become pregnant. Talk to your doctor if you have any other medical conditions, take any other medicines or are breastfeeding or intend to breastfeed.

For more information, see Section 2. What should I know before I take Contrave? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Contrave 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 take Contrave?

Carefully follow all directions given by your doctor or other healthcare professionals and never change the dose yourself.

- The starting dose is one tablet once a day in the morning. The dose is gradually increased over a four-week period.
- Swallow the tablet whole with a glass of water. **Do not cut, chew or crush the tablets**.

More instructions can be found in Section 4. How do I use Contrave? in the full CMI.

5. What should I know while using Contrave?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Contrave. • Reduce the energy content of your diet and exercise regularly.
Things you should not do	• Do not take any other medicines while taking Contrave without first telling your doctor. • Do not change your dose without first checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Contrave affects you.
Drinking alcohol	• Avoid or minimise drinking alcohol when taking Contrave.
Looking after your medicine	• Store in a cool dry place where the temperature stays below 25°C and keep out of reach of children. • Do not freeze.

For more information, see Section 5. What should I know while using Contrave? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details).
Common side effects include nausea or vomiting, dizziness, dry mouth, constipation and headache.
Serious side effects include seizures, allergic reactions and mental disturbances like suicidal thoughts, irritability, anxiety or agitation and some skin reactions.

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.

Contrave® 8/90

Active ingredients: *Naltrexone hydrochloride & Bupropion hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Contrave. **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 Contrave.**

Where to find information in this leaflet:

1. Why am I taking Contrave?
2. What should I know before I take Contrave?
3. What if I am using other medicines?
4. How do I take Contrave?
5. What should I know while using Contrave?
6. Are there any side effects?
7. Product details

1. Why am I taking Contrave?

Contrave contains two active ingredients - naltrexone hydrochloride and bupropion hydrochloride. Contrave works on areas on the brain involved in the control of food intake and energy use.

Contrave is used in obese or overweight adults to manage weight together with a reduced calorie diet and physical exercise.

- Your doctor will review your treatment after 16 weeks, and you should only continue using Contrave if you have lost at least 5% of your initial body weight. Your doctor may also recommend stopping treatment if you have not maintained the loss of at least 5% of your initial body weight after 1 year of treatment or if there are concerns about increased blood pressure, or other concerns with the safety or tolerability of this medicine.
- Contrave will only assist in reducing body weight if it is used in conjunction with a reduction in calorie intake and/or an increase in physical activity.

2. What should I know before I take Contrave?

Warnings

Do not use Contrave if you:

- are allergic to naltrexone hydrochloride, bupropion hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have high blood pressure that is not controlled with medicines.
- have ever had a seizure.
- have a brain tumour.
- are usually a heavy drinker and have just suddenly stopped drinking a lot of alcohol or are going to stop while you are taking this medicine.
- have recently stopped taking sedatives (sleeping tablets) or medicines to treat anxiety or epilepsy or you plan to stop them while you are taking this medicine.
- are taking any other medicines containing naltrexone hydrochloride or bupropion hydrochloride.
- have an eating disorder or had one in the past, such as bulimia or anorexia nervosa.
- are regularly using opioids or taking opioids for the treatment of dependence (for example methadone or buprenorphine), or you are going through acute withdrawal (cold turkey). You must have stopped taking any opioid medicines at least 7-10 days before starting Contrave. If you require treatment with opioids (for example during surgery) while taking Contrave, you should stop taking Contrave at least 3 days before starting the treatment with opioids or a surgical procedure. Naltrexone contained in Contrave blocks the effects of opioids for several days after you stop taking Contrave.
- have or have had a bipolar disorder (extreme mood swings).
- are taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken them in the last 14 days.
- have severe liver disease.
- have end-stage kidney disease.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- feel depressed, contemplate suicide, have a history of attempting suicide, experience panic attacks or any other mental health problems.
- are aged 65 years or older. Contrave has not been adequately studied in older people to know if they will respond to Contrave in the same way as younger adults.
- have high blood pressure.
- have heart disease.
- have liver or kidney problems.
- have mood disorders including depression or mania.
- are galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.
- have a condition called Brugada syndrome (a rare hereditary syndrome that affects the heart rhythm) or if cardiac arrest or sudden death occurred in your family.
- take any medicines for any other condition.
- are taking medicines for treating depression or opioids which may cause serious life-threatening reactions, such as serotonin syndrome and seizure.
- are at risk of having a seizure. Contrave may cause seizures (fits) in some people. Seizures are more likely while taking Contrave if you:

- have had a serious head injury, head trauma or stroke.
- regularly drink a lot of alcohol.
- regularly use medicines to help you to sleep (sedatives).
- are dependent on or addicted to cocaine or other stimulating products.
- have diabetes for which you use insulin or tablets.
- have a brain or spinal tumour or infection.
- have severe liver disease.
- have low blood sugar or salt levels.
- have hypoxia, a condition where oxygen levels in your tissues are low.
- are taking medicines, such as for treating depression, that may increase the chance of having a fit.

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

Do not use Contrave if you are pregnant or intend to become pregnant. Weight loss offers no potential benefit to a pregnant woman and may result in harming your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Contrave passes into human milk and is not recommended during breastfeeding.

Use in Children

Contrave is not recommended for use in children less than 18 years because it has not been adequately studied in these patients.

3. What if I am using 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 increase your chance of having a seizure when taking Contrave. These medicines need to be used very carefully. Examples include:

- antidepressants
- antipsychotics
- asthma medicines such as theophylline and systemic corticosteroids
- antimalarials
- tramadol
- sedating antihistamines
- quinolone antibiotics
- insulin or oral diabetic medicines
- sedatives, such as benzodiazepines.

Some medicines may interfere with Contrave and affect how it works.

These include:

- Medicines for depression known as monoamine oxidase inhibitors, even if you have stopped taking them now, but have taken them within the last 14 days. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.
- opioid painkillers e.g., codeine, morphine, methadone.
- some medicines for example to treat cough and cold (such as mixtures containing dextromethorphan or codeine).
- medicines used to treat high blood pressure such as metoprolol.
- medicines used to treat irregular heart rhythm such as propafenone or flecainide.
- medicines for Parkinson's disease such as levodopa or amantadine.
- ticlopidine or clopidogrel, mainly used in the treatment of heart disease or stroke.
- medicines used in the treatment of HIV infection and AIDS, such as efavirenz and ritonavir.
- medicines for depression or other mental health conditions that affect serotonin levels, such as amitriptyline, desipramine, venlafaxine, imipramine, paroxetine, fluoxetine, citalopram, escitalopram, risperidone, haloperidol, thioridazine and opioids.
- digoxin, used to treat certain heart problems.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Contrave.

4. How do I take Contrave?

How much to take

- The starting dose is one tablet once a day in the morning. The dose will be gradually increased as follows:
- Week 1: One tablet once a day in the morning
- Week 2: One tablet twice a day, one in the morning and one in the evening
- Week 3: Three tablets every day, two in the morning and one in the evening
- Week 4 and onward: Two tablets twice a day, two in the morning and two in the evening.

  The maximum recommended daily dose of Contrave is two tablets taken twice a day.

  If you have liver or kidney problems, you may need a lower dose of Contrave.

  Swallow the tablet whole with a glass of water. **Do not cut, chew or crush the tablets.**

- Follow the instructions provided and use Contrave until your doctor tells you to stop.

When to take Contrave

- Contrave should be taken with food.
- Continue using Contrave as long as your doctor recommends it.
- Some people do not respond to Contrave. Treatment should not be continued for more than 16 weeks if

you have not lost more than 5% of your initial body weight.

If you forget to take Contrave

Contrave should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much Contrave

If you think that you have taken too much Contrave, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand**), 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.

- If you take too much Contrave you may experience some of the following symptoms: seizure, hallucinations, loss of consciousness, increased heart rate or irregular heartbeat, fever, muscle stiffness and/or pain, low blood pressure and breathing difficulties.

5. What should I know while using Contrave?

Things you should do

- remind any doctor, dentist or pharmacist you visit that you are using Contrave.
- reduce the energy content of your diet by at least 500 kcal (2092 kJ). A review of your diet by a dietician is recommended.
- review your treatment with your doctor after 16 weeks to monitor your weight-loss.
- tell your doctor before you undergo a blood or any other laboratory tests. Contrave may interfere with laboratory tests.
- keep enough medicine to last weekends and holidays.

Call your doctor straight away if you:

- have depression and it gets worse or you any have thoughts about suicide or doing harm to yourself.

  All thoughts or talk about suicide are serious, including:

- thoughts or talk about death or suicide
- thoughts or talk about self-harm
- an increase in aggressive behaviour, irritability or agitation.
- become pregnant while taking this medicine.
- experience hypersensitivity reactions. Serious skin reactions, including Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with bupropion-containing products, including Contrave. Stop using Contrave and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 6 - side effects.

Things you should not do

- Do not take any other medicines while taking Contrave without first telling your doctor.
- Do not take this medicine for a longer time than your doctor has prescribed.
- Do not change your dose without first checking with your doctor.
- Do not give this medicine to anyone else, even if their condition seems similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Contrave affects you.

Contrave may cause dizziness in some people and therefore may affect alertness.

Drinking alcohol

Avoid or minimise drinking alcohol when taking Contrave. Tell your doctor if you drink alcohol.

Excessive use of alcohol may increase your chance of having a seizure.

Looking after your medicine

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

Store Contrave below 25°C 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.

Do not freeze.

Keep it where young children cannot reach it.

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.

Less serious side effects

Less serious side effects	What to do
The most commonly reported side effects are: • nausea or vomiting • dizziness • dry mouth • constipation • headache **Changes in behaviour:** • mood swings • difficulty sleeping or abnormal dreams • feeling spacey or jittery • forgetfulness or difficulty concentrating • weakness or lack of energy • tremor • sexual function problems such as delayed ejaculation or difficulty getting an erection. **Stomach or bowel problems:** • diarrhoea • loss of appetite • stomach pain or cramps • burping • sudden need to urinate. **Changes in your senses:** • taste disorders • ringing in the ears • feeling thirsty • excessive sweating • hot flushes • chills • watery eyes. • tingling or numbness of the hands or feet **Other effects:** • toothache or jaw pain • joint or muscle pain • chest pain • hair loss • irregular menstrual periods • vaginal dryness • fast or irregular heartbeat • feeling faint when standing up from sitting or lying down • muscle stiffness • feeling agitated • lack of coordination • unstable blood pressure.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• **Seizures:** If you have a seizure, tell your doctor when you have recovered. Do not take any more Contrave tablets until you have spoken to your doctor. Symptoms of a seizure include: • convulsions • usually loss of consciousness. Someone who has had a seizure may be confused afterwards and may not remember what has happened. You can reduce the chance of having a seizure by giving your doctor all the information they need before taking Contrave and carefully following your doctor's directions while taking Contrave. **Allergic Reactions:** • wheezing • swelling of the lips, mouth or eyelids • difficulty breathing • hayfever • hives (itchy skin rash). **Mental disturbances:** • suicidal thoughts • suicide attempts • feeling hostile • irritability, anxiety, panic attacks or agitation. **Serious skin reactions:** • Acute generalised exanthematous pustulosis (AGEP) - a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment. • Erythema multiforme - Erythema multiforme is a severe condition of the skin that may affect the mouth and other parts of the body, with red, often itchy spots starting on the limbs. • Stevens Johnson Syndrome (SJS)/ toxic epidermal necrolysis (TEN) - rare skin condition with severe skin blisters, bleeding in the lips, eyes, mouth, nose and genitals. These serious skin	**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
rashes can be preceded by fever and flu-like symptoms. • Drug reaction with eosinophilia and systemic symptoms (DRESS) - widespread rash, high body temperature and enlarged lymph nodes **Other effects:** • bleeding from the rectum • skin or the whites of your eyes turning yellow	

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 in Australia, or Medsafe at www.medsafe.govt.nz/safety/report-a-problem.asp in New Zealand.

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 Contrave contains

Active ingredients (main ingredients)	Naltrexone hydrochloride and bupropion hydrochloride
Other ingredients (inactive ingredients)	• Cysteine hydrochloride monohydrate • Microcrystalline cellulose • Hyprolose • Magnesium stearate • Lactose • Lactose monohydrate • Crospovidone • Indigo carmine aluminium lake • Hypromellose • Disodium edetate • Silicon dioxide • OPADRY II complete film coating system 85F90663 BLUE.
Potential allergens	Contain sugars as lactose.

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

What Contrave looks like

Contrave is a blue, biconvex, round tablet with "NB-890" on one side.

It is available in blisters in pack sizes of 28 (starter pack) and 112 tablets. (AUST R 288372).

Who distributes Contrave

Australia:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood, NSW 2067

Telephone (toll free): 1800 630 056

New Zealand:

iNova Pharmaceuticals (New Zealand) Limited

C/- Simpson Grierson,

Private Bag 92518,

88 Shortland Street

AUCKLAND 1141

Telephone (toll free): 0508 375 394

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