

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems in Australia or www.medsafe.govt.nz/safety/report-a-problem.asp in New Zealand.

CONTRAVE[®] 8/90

Naltrexone hydrochloride & Bupropion hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CONTRAVE tablets. It does not contain all the available information about CONTRAVE tablets. It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CONTRAVE against the benefits he or she expects it will have.

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 CONTRAVE is used for

The name of your medicine is CONTRAVE.

It contains 2 active ingredients - bupropion hydrochloride and naltrexone hydrochloride.

It is used in obese or overweight adults to manage weight together with a reduced calorie diet and physical exercise. This medicine works on areas on the brain involved in the control of food intake and energy use.

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.

Ask your doctor if you have any questions about why CONTRAVE has been prescribed for you.

If you have any concerns, discuss them with your doctor.

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

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.

Before you take CONTRAVE

When you must not take it

Do not take CONTRAVE if you are allergic to bupropion, naltrexone or 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 CONTRAVE if you:

- 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 bupropion or naltrexone
 - have an eating disorder or had one in the past, such as bulimia or anorexia nervosa
 - are regularly using opioids or opiate agonists (for example methadone), or you are going through acute withdrawal (cold turkey)
 - 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.
- Do not take CONTRAVE if you are pregnant or currently planning to become pregnant.**

Do not take CONTRAVE after the expiry date (EXP) 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 CONTRAVE, talk to your doctor.

Before you start to take it

Tell your doctor if:

You are allergic to any other medicines or any foods, dyes or preservatives.

You feel depressed, contemplate suicide, have a history of attempting suicide or any other mental health problems.

You 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.

You are at risk of having a seizure.

CONTRAVE may cause fits (seizures) in some people. Fits 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 that may increase the chance of having a fit.

Tell your doctor if you have or have had any other medical conditions, including:

- high blood pressure
- heart disease
- liver or kidney problems
- mood disorders including depression or mania
- galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

CONTRAVE contains lactose.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor will discuss the risks and benefits of taking CONTRAVE if you are pregnant, planning a pregnancy or breastfeeding.

If you have not told your doctor about any of the above, tell them before you take any CONTRAVE.

Taking other medicines

Tell your doctor 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 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. 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
- 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 and thioridazine
- digoxin, used to treat certain heart problems.

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking CONTRAVE.

Tell your doctor if you are taking CONTRAVE tablets before you undergo any laboratory test.

CONTRAVE may interfere with laboratory tests.

How to take CONTRAVE

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.

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

Your doctor will tell you how many tablets you need to take each day. This may depend on whether you have any other illnesses and whether or not you are taking any other medicines.

The starting dose is usually 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.

Do not change your dose unless your doctor tells you to.

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

How to take it

Swallow the tablet whole with a glass of water.

Take your tablet with food.

Do not cut, chew or crush CONTRAVE tablets.

How long to take it

Continue taking 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 it

Skip the missed dose and take your next dose at the next usual time.

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

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: telephone 13 11 26; New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CONTRAVE. Do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol which has been taken. You may need urgent medical attention.

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.

While you are using CONTRAVE

Reduce the energy content of your diet by at least 500 kcal (2092 kJ), a review by a dietician is recommended.

Things you must do

Take CONTRAVE exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking CONTRAVE.

Tell your doctor immediately 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.

Avoid or minimise drinking alcohol when taking CONTRAVE.

If you drink a lot of alcohol or suddenly stop drinking you may increase your chance of having a seizure.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking CONTRAVE.

Always discuss with your doctor any problems or difficulties you have during or after taking CONTRAVE.

Keep enough CONTRAVE to last weekends and holidays.

Things you must not do

Do not take any other medicines while you are taking CONTRAVE without first telling your doctor.

Do not drive or operate machinery until you know how CONTRAVE affects you.

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

Make sure you know how you react to CONTRAVE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Do not take CONTRAVE for a longer time than your doctor has prescribed.

Do not change your dose without first checking with your doctor.

Do not stop taking CONTRAVE or lower the dose, without first checking with your doctor.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms or condition seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CONTRAVE.

CONTRAVE helps some overweight or obese adults with weight management, but it often causes unwanted side effects. These side effects are most common in the first few weeks of starting treatment.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment 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.

Ask your doctor or pharmacist any questions you may have.

The most commonly reported side effects are:

- nausea or vomiting
- dizziness
- dry mouth
- constipation
- headache

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

Changes in your behaviour such as:

- 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 such as:

- diarrhoea
- loss of appetite
- stomach pain or cramps
- burping
- sudden need to urinate

Changes in your senses such as:

- taste disorders
- ringing in the ears
- feeling thirsty
- excessive sweating
- hot flushes
- chills
- watery eyes

Other effects such as:

- toothache or jaw pain
- joint or muscle pain
- chest pain
- hair loss
- irregular menstrual periods
- vaginal dryness
- tingling or numbness of the hands or feet

- fast or irregular heartbeat
- feeling faint when standing up from sitting or lying down
- muscle stiffness
- feeling agitated
- lack of coordination
- unstable blood pressure

Seizures

If you have a seizure, tell your doctor when you have recovered. Do not take any more CONTRAVE tablets.

Symptoms of a seizure include convulsions and 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 the information they need before taking CONTRAVE and following carefully your doctor's directions on how to take CONTRAVE.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- signs of an allergic reaction to CONTRAVE such as:
 - wheezing
 - swelling of the lips, mouth or eyelids
 - difficulty breathing
 - hayfever
 - hives (itchy skin rash)
- seizure
- mental disturbances such as:
 - suicidal thoughts
 - suicide attempts
 - feeling hostile
 - irritability, anxiety or agitation
- bleeding from the rectum
- skin or the whites of your eyes turning yellow
- severe skin blisters, bleeding in the lips, eyes, mouth, nose and

genitals (Stevens Johnson syndrome)

These are all serious side effects of CONTRAVE. You may need urgent medical attention or hospitalisation.

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when CONTRAVE is taken for long periods of time.

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

Some people may get other side effects while using CONTRAVE.

Check with your doctor as soon as possible if you have any problems while taking CONTRAVE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using CONTRAVE

Storage

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.

Keep CONTRAVE in a cool dry place where the temperature stays below 25°C. Do not freeze.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take CONTRAVE if the tablets do not look quite right.

Keep your tablets in the pack they were provided in until it is time to take them.

Disposal

If your doctor tells you to stop taking the tablets or they have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it 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.

Ingredients

Each CONTRAVE tablet contains the following active ingredients: naltrexone hydrochloride 8mg and bupropion hydrochloride 90 mg.

The other ingredients are:

- 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

CONTRAVE tablets contain sugars as lactose.

Sponsor

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