

SCHEDULING STATUS

S5

BUPROPION XR 150 ADCO 150 mg extended-release tablets

Bupropion hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking BUPROPION XR 150 ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BUPROPION XR 150 ADCO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BUPROPION XR 150 ADCO is and what it is used for
2. What you need to know before you take BUPROPION XR 150 ADCO
3. How to take BUPROPION XR 150 ADCO
4. Possible side effects
5. How to store BUPROPION XR 150 ADCO
6. Contents of the pack and other information

1. What BUPROPION XR 150 ADCO is and what it is used for

BUPROPION XR 150 ADCO contains bupropion hydrochloride which belongs to a class of medicines called antidepressants. It's thought to interact with chemicals in the brain called noradrenaline and dopamine, which are linked with depression (mood disorder that causes a persistent feeling of sadness and loss of interest).

BUPROPION XR 150 ADCO is used for the treatment of depression and preventing a relapse and recurrence of further depressive episodes.

2. What you need to know before you take BUPROPION XR 150 ADCO

Do not take BUPROPION XR 150 ADCO:

- if you are 18 years or younger.
- if you are hypersensitive (allergic) to bupropion or any of the other ingredients of BUPROPION XR 150 ADCO listed in section 6.
- if you have a condition that causes fits (seizures), such as epilepsy, or if you have a history of fits.
- if you are being treated with other medicines containing bupropion as this may induce fits.
- if you have a brain tumour.
- if you are undergoing abrupt discontinuation of alcohol, sedatives (medicines used for sleeping), or medicines to treat anxiety (especially benzodiazepines or similar medicines) or if you are going to stop them while you are taking BUPROPION XR 150 ADCO.
- if you have an existing condition or history of eating disorders [such as anorexia (a mental condition, characterised by an obsessive desire to lose weight, by refusing to eat and cause loss of appetite) or bulimia (an emotional disorder characterised by an obsessive desire to lose weight, in which bouts of extreme overeating are followed by fasting or self-induced vomiting or purging)].
- if you are taking medicines for depression or Parkinson's disease called monoamine oxidase inhibitors (MAOIs) or have taken them in the last 14 days.
- if you have moderate to severe liver disease including cirrhosis.

Warnings and precautions

Take special care with BUPROPION XR 150 ADCO

- BUPROPION XR 150 ADCO has been shown to cause fits (seizures). This side effect is more likely to occur:
 - if you have had a serious head injury or a history of head trauma
 - if you ever had any fits or seizures in the past
 - if you have a brain tumour
 - if you are taking certain medicines that can cause fits (see "Other medicines and BUPROPION XR 150 ADCO" below)
 - if you regularly drink a lot of alcohol
 - if you take medicines used for sleeping (sedatives)
 - if you have diabetes for which you use insulin or diabetes treatment tablets
 - if you are using any stimulants or medicine to help you lose weight.

If you have a fit during treatment you should stop taking BUPROPION XR 150 ADCO and see your doctor.

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting BUPROPION XR 150 ADCO, since it takes time to work,

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usually about two weeks but sometimes longer. You are more likely to think like this if you have previously had thoughts about killing yourself or if you are a young adult.

If you experience worsening of your depression and/or have thoughts of harming or killing yourself, whether or not you are taking antidepressant medicines contact your doctor or go to the hospital immediately.

Tell your doctor before you take BUPROPION XR 150 ADCO:

- if you have a bipolar disorder (extreme mood swings) or a family history of suicide, bipolar disorder or depression; BUPROPION XR 150 ADCO could bring on an episode of this illness
- if you have a recent history of heart attack (myocardial infarction) or diagnosed with unstable heart disease
- if you have high blood pressure or are using nicotine patches to stop smoking; your doctor may need to monitor your blood pressure
- if you have glaucoma (increased pressure in the eyeball), are over 60, have had an eye injury, or have high blood pressure; you may be at risk of developing angle-closure glaucoma
- if you have kidney or liver disease as you may be more likely to get side effects; your doctor may need to start your treatment at a low dose and then gradually increase your dose
- if you are older than 65 years as you might be at a higher risk to experience side effects; your doctor may need to start your treatment at a low dose and then gradually increase your dose
- if you have a rare blood disorder called porphyria which is passed down in families (inherited); BUPROPION XR 150 ADCO may worsen your condition.
- if you 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.

If any of the above applies to you, talk to your doctor again before taking BUPROPION XR 150 ADCO. He or she may want to pay special attention to your care or recommend another treatment.

Stop taking BUPROPION XR 150 ADCO immediately if you have any signs of an allergic reaction (see "Possible side effects" below).

Children and adolescents

Do not give this medicine to children younger than 18 years because the safety of BUPROPION XR 150 ADCO has not been established in patients younger than 18 years old.

Other medicines and BUPROPION XR 150 ADCO

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking or have taken other antidepressants called monoamine oxidase inhibitors (MAOIs) in the last 14 days, tell your doctor without taking BUPROPION XR 150 ADCO (see also "Do not take BUPROPION XR 150 ADCO" in Section 2).

BUPROPION XR 150 ADCO might have interactions with other medicines which may result in intensification of side effects of BUPROPION XR 150 ADCO.

There may be a higher than usual chance of seizures/fits:

- if you take other medicines for depression or other mental illness
- if you take theophylline for asthma or lung disease
- if you take tramadol, a strong painkiller
- If you have been taking sedatives, or if you are going to stop them while you're taking BUPROPION XR 150 ADCO (see also "Do not take BUPROPION XR 150 ADCO" in Section 2).
- If you take medicines against malaria (such as mefloquine or chloroquine)
- If you take stimulants or other medicines to control your weight or appetite
- If you take steroids (by mouth or injection)
- If you take antibiotics called quinolones
- If you take some types of anti-histamines that can cause sleepiness
- If you take medicines for diabetes

Tell your doctor before you take BUPROPION XR 150 ADCO if any of the above applies to you.

There may be potentiation of side effects of other medicines when taken together with BUPROPION XR 150 ADCO:

- if you take other medicines for depression (such as nortriptyline, imipramine, desipramine, venlafaxine, paroxetine, sertraline, fluoxetine, or fluvoxamine) or other mental illness (such as haloperidol, risperidone or thioridazine)
- if you take beta-blockers (such as metoprolol)
- if you take medicines for irregular heart rhythm (such as propafenone or flecainide)
- if you take medicines for Parkinson's disease (such as levodopa, amantadine or orphenadrine)
- if you take cyclophosphamide or ifosfamide, mainly used to treat cancer
- if you take valproate, medicine to treat epilepsy
- if you take ticlopidine or clopidogrel, mainly used to prevent stroke
- if you take prasugrel, medicine used to prevent blood clots
- if you use nicotine patches to help you stop smoking.

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If any of these applies to you, talk to your doctor immediately, before taking BUPROPION XR 150 ADCO. Your doctor may need to adjust your dose or recommend an alternative.

The effect of BUPROPION XR 150 ADCO may be weakened:

- if you take medicines that affect your body's ability to break down BUPROPION XR 150 ADCO (such as carbamazepine, phenytoin or phenobarbital (used to treat epilepsy) and medicines to treat HIV infection ritonavir or efavirenz).

If you are taking any of these medicines, your doctor may need to adjust your dose of BUPROPION XR 150 ADCO.

BUPROPION XR 150 ADCO may weaken the effect of tamoxifen, medicine used to treat breast cancer. Tell your doctor if this applies to you.

BUPROPION XR 150 ADCO may cause a false-positive urine tests for amphetamines. Tell your doctor that you are taking BUPROPION XR 150 ADCO if you require a urine test.

If you take digoxin for your heart, BUPROPION XR 150 ADCO may reduce its level in your blood, weakening the effect of digoxin. Your doctor might need to adjust the dose of digoxin and continue to monitor its level in your blood.

BUPROPION XR 150 ADCO with food and alcohol

Alcohol can affect the way BUPROPION XR 150 ADCO works. Minimise your alcohol intake or avoid it completely. Talk to your doctor if you need to stop drinking alcohol before taking BUPROPION XR 150. Do not stop suddenly, it may be risky.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BUPROPION XR 150 ADCO.

You should not take BUPROPION XR 150 ADCO when you are pregnant.

Some studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking BUPROPION XR 150 ADCO.

The safe use of BUPROPION XR 150 ADCO in breastfeeding women has not been established. The ingredients of BUPROPION XR 150 ADCO can pass into breast milk. You should not breastfeed your baby while taking BUPROPION XR 150 ADCO.

Driving and using machines

BUPROPION XR 150 ADCO may cause dizziness, impair your ability to perform tasks requiring judgement or concentration, such as driving and operating machinery.

You should not drive or operate machines until you know how BUPROPION XR 150 ADCO affects you.

3. How to take BUPROPION XR 150 ADCO

Do not share medicines prescribed for you with any other person.

Always take BUPROPION XR 150 ADCO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosage of BUPROPION XR 150 ADCO is one tablet (150 mg) taken daily in the morning.

Your doctor may increase your dose to 300 mg (two tablets) once a day if your depression does not improve.

Do not take more than the prescribed dose of BUPROPION XR 150 ADCO.

BUPROPION XR 150 ADCO must be swallowed whole. Do not chew, crush or split the tablets as this may lead to a higher risk of side effects including fits.

You must wait for at least 24 hours before taking the next tablet.

Your doctor will tell you how long your treatment with BUPROPION XR 150 ADCO will last. Do not stop treatment early because it may take some time for BUPROPION XR 150 ADCO to have an effect on your depression. If you have the impression that the effect of BUPROPION XR 150 ADCO is too strong or too weak, tell your doctor or pharmacist.

BUPROPION XR 150 ADCO should not to be used by children aged less than 18 years.

Please tell your doctor if you are an elderly patient (older than 65 years), have liver or kidney disease as your dose of BUPROPION XR 150 ADCO may need to be adjusted.

If you take more BUPROPION XR 150 ADCO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining BUPROPION XR 150 ADCO with you so the doctor will know what you have taken.

Signs and symptoms of overdosage: If you take too many tablets you may experience fits, drowsiness, hallucinations (seeing or hearing things that are not real), paraesthesia (numbness or tingling sensation), nausea, vomiting, loss of consciousness and/or abnormal reading of the heart (seen on ECG, electric activity of your heart), irregular or fast heartbeat.

If you forget to take BUPROPION XR 150 ADCO

Do not take a double dose to make up for the forgotten individual doses. If you miss a dose, wait and continue to take the next dose at the usual time.

If you stop taking BUPROPION XR 150 ADCO

Do not stop taking BUPROPION XR 150 ADCO or reduce your dose without talking to your doctor first. Your doctor will lower the dose over a time period to avoid the returning of depression or other unwanted effects.

4. Possible side effects

BUPROPION XR 150 ADCO can have side effects.

Not all side effects reported for BUPROPION XR 150 ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUPROPION XR 150 ADCO, please consult your provider for advice.

If any of the following happens, stop taking BUPROPION XR 150 ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions presenting as red skin or rash (like nettle rash) with development of itchiness and wheals (urticaria).
- fits (seizures or convulsions), the chance of this happening is higher if you take too much BUPROPION XR 150 ADCO, if you take certain medicines, or if you are at higher than usual risk of fits; talk to your doctor if you are concerned
- allergic reactions presenting as blisters and peeling skin, unusual wheezing or difficulty in breathing, swollen eyelids, lips or tongue, pains in muscles or joints, collapse or blackout.

These are all very serious side effects. If you have them, you may have had a serious reaction to BUPROPION XR 150 ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain.
- changes in the way your heart beats, for example if you notice it beating faster or irregular.
- thoughts of harming or killing themselves while taking BUPROPION XR 150 ADCO or soon after stopping treatment (see “Take special care with BUPROPION XR 150 ADCO” in section 2).

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- difficulty in sleeping (make sure you take BUPROPION XR 150 ADCO in the morning)
- headache
- dry mouth, feeling sick, vomiting, tummy pain or other upsets (constipation)
- fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)
- shakiness, tremor, weakness, tiredness
- feeling anxious or agitated
- changes in the taste of food, loss of appetite (anorexia)
- increase in blood pressure sometimes severe, flushing
- ringing in the ears, visual disturbances.

Less frequent side effects:

- feeling depressed (see “Take special care with BUPROPION XR 150 ADCO” in section 2).
- difficulty concentrating, feeling confused, restless, irritable, hostile, aggressive, strange dreams, tingling or numbness, loss of memory, fainting
- weight loss, changes in blood sugar levels
- twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination
- yellowing of skin or the whites of your eyes (jaundice) which may be caused by raised liver enzymes, hepatitis
- urinating more or less than usual.
- worsening of psoriasis (thickened patches of red skin)
- feeling unreal or strange (depersonalisation), seeing or hearing things that are not there (hallucinations), sensing or believing things that are not true (delusions), severe suspiciousness (paranoia)
- feeling dizzy or fainting when getting up too quickly.

Side effects with unknown frequency:

- loss of contact with reality and unable to think or judge clearly (psychosis), other symptoms may include hallucinations and/or delusions.
- low sodium levels in the blood

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BUPROPION XR 150 ADCO.

5. How to store BUPROPION XR 150 ADCO

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original packaging.

Store in a cool, dry place.

Protect from moisture and light.

Keep the container tightly closed.

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUPROPION XR 150 ADCO contains

The active substance is bupropion hydrochloride. Each tablet contains 150 mg of bupropion hydrochloride.

The other ingredients are ethyl cellulose, hydroxy propyl cellulose, macrogols 1500, methacrylic acid - ethyl acrylate copolymer (1:1) Type A, Opadry Clear YS-1-7006 (hypromellose, macrogol 400, macrogol 8000), povidone, silica colloidal anhydrous, sodium stearyl fumarate and triethyl citrate.

What BUPROPION XR 150 ADCO looks like and contents of the pack

BUPROPION XR 150 ADCO is white to pale yellow, round, biconvex tablets plain on both the sides.

BUPROPION XR 150 ADCO are packed in white opaque HDPE bottles sealed with an induction seal and child resistant caps (along with silica gel and activated carbon pillow pack, and oxygen and moisture absorber).

Pack sizes available: 28 and 30 tablets per bottle.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

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