

PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S5

BUPROPION 300 ACCORD (Modified release tablets)

Bupropion hydrochloride

Read all of this leaflet carefully before you start taking BUPROPION 300 ACCORD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BUPROPION 300 ACCORD 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 300 ACCORD is and what it is used for
2. What you need to know before you take BUPROPION 300 ACCORD
3. How to take BUPROPION 300 ACCORD
4. Possible side effects
5. How to store BUPROPION 300 ACCORD
6. Contents of the pack and other information

1. What BUPROPION 300 ACCORD is and what it is used for

- BUPROPION 300 ACCORD contains the active substance bupropion hydrochloride.
- BUPROPION 300 ACCORD is a medicine prescribed by your doctor to treat your depression. It's thought to interact with chemicals in the brain called noradrenaline and dopamine, which are linked to depression.

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- It may take a while before you start feeling better. It takes time for the medicine to have its full effect, sometimes weeks or months. When you do start feeling better, your doctor may advise you to keep taking BUPROPION 300 ACCORD to prevent your depression coming back.
- Your doctor has chosen this medicine to suit you and your condition. Don't pass it on to others. Before deciding on treatment with BUPROPION 300 ACCORD, you and your doctor will probably have discussed the risks of harm and the benefits that it is likely to have for you. This leaflet will help you to take BUPROPION 300 ACCORD safely.

2. What you need to know before you take BUPROPION 300 ACCORD

Do not take BUPROPION 300 ACCORD:

- If you are hypersensitive (allergic) to bupropion hydrochloride or any of the other ingredients of BUPROPION 300 ACCORD (listed in section 6)
- If you are less than 18 years of age. There is an increased risk of suicidal thoughts and behaviour when children under 18 years of age are treated with antidepressants.
- If you have been diagnosed with epilepsy or you have a history of epilepsy
- If you are taking any other medicines which contain bupropion.
- If you have a brain tumour
- If you are usually a heavy drinker who has just stopped or are about to stop drinking
- If you recently stopped taking tranquillisers or sedatives, or if you are going to stop them while you are taking bupropion hydrochloride.
- If you have an eating disorder, or used to (for example, bulimia or anorexia nervosa)
- If you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days
- If you have moderate to severe liver disease.
- If you have an illness called bipolar disorder which causes unusual shifts in your mood, energy levels or concentration. BUPROPION 300 ACCORD might increase your symptoms.

If any of these apply to you, talk to your doctor immediately, without taking BUPROPION 300 ACCORD.

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Warnings and precautions

Take special care with BUPROPION 300 ACCORD:

- If you have ever had fits or seizures in the past
- if you have previously had head trauma
- if you have a brain tumour
- if you regularly drink a lot of alcohol
- if you have diabetes for which you use insulin or tablets
- If you experience any allergic reactions (e.g. rash, difficulty breathing, swollen eyelids, lips or tongue)
- If you have had any mental illness other than depression
- If you are over 65 years of age
- If you suffer from high blood pressure
- If you have kidney disease.
- If you have heart disease.

Thoughts of suicide or worsening of your condition:

If you are depressed you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants. These medicines all take time to work – usually about 2 weeks, but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself
- If you are under 25 years old

If you have thoughts of harming or killing yourself at any time: Get medical advice as soon as possible (from a doctor or at a hospital).

Effect on urine tests

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BUPROPION 300 ACCORD may interfere with some urine tests to detect other drugs. If you require a urine test, tell your doctor that you are taking BUPROPION 300 ACCORD.

You should only take BUPROPION 300 ACCORD by mouth. Seizures and/or cases of death have been reported when crushed and inhaled in the nose or injected.

Other medicines and BUPROPION 300 ACCORD

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
 - Other medicines for depression called monoamine oxidase inhibitors, especially if you have taken them in the last 14 days
 - Theophylline for asthma or lung disease, tramadol which is a strong pain killer – these medicines may increase the chance of having seizures
 - Tranquilisers or sedatives or if you are going to stop them while taking BUPROPION 300 ACCORD
 - Medicines to control your weight or appetite
 - Ritonavir (antiretroviral)
 - Tamoxifen (used to treat breast cancer)
- The following medicines increase the chances of side effects when taken with BUPROPION 300 ACCORD.

Tell your doctor if you are taking any of them:

- Other medicines for depression or other mental illness
- Levodopa, amantadine or orphenadrine (for Parkinson's disease)
- Medicines for epilepsy like carbamazepine, phenytoin, phenobarbitone
- Cyclophosphamide or ifosfamide which are used to treat cancer
- Ticlopidine or clopidogrel (used to prevent stroke)
- Beta blockers
- Medicines to regulate heart rhythm
- Nicotine patches to help you stop smoking

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- If you take digoxin for your heart, your doctor may have to adjust the dose.

BUPROPION 300 ACCORD with food and drink

Some people are more sensitive to the effects of alcohol while taking BUPROPION 300 ACCORD. Your doctor may suggest you do not drink alcohol while taking BUPROPION 300 ACCORD, or to drink very little. If you already consume a lot of alcohol, do not suddenly stop.

Pregnancy, breastfeeding and fertility

- 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 healthcare provider for advice before taking this medicine.
- Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking bupropion while pregnant.
- You should not breast-feed while taking BUPROPION 300 ACCORD.

Driving and using machines

- You may experience dizziness or light headedness while taking BUPROPION 300 ACCORD.
- It is not always possible to predict to what extent BUPROPION 300 ACCORD may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BUPROPION 300 ACCORD affects you.

3. How to take BUPROPION 300 ACCORD

- Do not share medicines prescribed for you with any other person.
- Always take BUPROPION 300 ACCORD exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 300 mg once a day.
- Take your dose early in the morning to prevent difficulty sleeping at bedtime.
- Swallow the tablets whole. Do not chew, crush or split them. If you do the medicine will be released into your

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body too quickly and you are more likely to get side effects like seizures.

- This medicine is only for oral use. Do not inhale or inject this medicine as this is very dangerous and can lead to overdose, seizures and death.
- Your doctor will tell you how long to take BUPROPION 300 ACCORD for. It may take a few weeks or months before you notice any improvement. Even once you see an improvement your doctor may advise you to continue with the medicine to prevent the depression coming back. Do not stop taking BUPROPION 300 ACCORD without first discussing it with your doctor.
- If you have the impression that the effect of BUPROPION 300 ACCORD is too strong or too weak, tell your doctor or pharmacist.

If you take more BUPROPION 300 ACCORD than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. You may experience seizures, drowsiness, loss of consciousness and changes in your heart rhythm.

If you forget to take BUPROPION 300 ACCORD

If you forget to take BUPROPION 300 ACCORD, wait and take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BUPROPION 300 ACCORD can have side effects.

Not all side effects reported for BUPROPION 300 ACCORD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUPROPION 300 ACCORD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking BUPROPION 300 ACCORD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing

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- Severe skin rash or itching
- Swollen tongue or lips
- Muscle or joint pain

These are all very serious side effects. If you have them, you may have had a serious reaction to BUPROPION 300 ACCORD. 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:

- Seizures or fits
- Thoughts of harming or killing yourself

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

Tell your doctor if you notice any of the following:

- **Frequent side effects**

- Difficulty sleeping, feeling agitated, or anxious
- Tremors, headache, dizziness, alteration of taste
- Dry mouth, nausea, vomiting, stomach pain, constipation
- Rash, itchy skin or sweating
- Fever
- Changes to vision
- Ringing in ears
- High blood pressure
- Chest pain, weakness or lack of energy

- **Less frequent side effects**

- Loss of weight, changes in blood sugar level (you may experience fatigue, anxiety, sweating)
- Irritability, hallucinations, unusual dreams and nightmares, feeling restless and aggressive, depression,

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difficulty concentrating

- Muscle twitching, slurred speech, difficulty in co-ordination, fainting, memory impairment
 - Heart rate increases
 - Flushing, feeling faint when you wake up from a sitting position
 - Yellowing of eyes, dark urine (could indicate jaundice)
 - Change in frequency of urination
- Depending on the side effects you experience, your doctor may conduct blood tests to check your blood counts, blood sugar levels or to check your liver and kidney function.
 - 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of BUPROPION 300 ACCORD.

5. How to store BUPROPION 300 ACCORD

- Store all medicines out of reach of children.
- Store at or below 25 °C.

6. Contents of the pack and other information

What BUPROPION 300 ACCORD contains

- The active substance is bupropion hydrochloride.
- Each tablet contains 300 mg bupropion hydrochloride.
- The other ingredients are:

Povidone K90

Cysteine hydrochloride monohydrate

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Colloidal anhydrous silica

Glycerol dibehenate

Magnesium stearate

Functional coating

Ethyl cellulose 100 mPas

Povidone K90

Macrogol 1450

Enteric coating

Methacrylic acid-ethyl acrylate copolymer

Colloidal hydrated silica

Macrogol 1450

Triethyl citrate

Printing

Opacode Black S-1 - 17823

What BUPROPION 300 ACCORD looks like and contents of the pack

BUPROPION 300 ACCORD modified release tablets are creamy-white to pale yellow, round, tablets printed with "GS2" on one side and plain on the other side.

BUPROPION 300 ACCORD modified release tablets are packed in Alu-Alu blisters consisting of a cold formable aluminium film (25 µOPA/45 µ Alu foil/60µ PVC) and 0,025 mm aluminium foil hard tempered with HSL coating on bright side. The blisters are packed in cardboard cartons in packs of 30s.

HOLDER OF CERTIFICATE OF REGISTRATION

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This leaflet was last revised in

Registration number

55/1.2/0778