

Bupropion 150mg extended release tablets USP

Package leaflet: Information for the user
Bupropion 150mg extended release tablets
bupropion hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

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

1. What Bupropion is and what it is used for

Bupropion is a medicine prescribed to help you stop smoking, when you also have motivational support such as taking part in a 'stop smoking' programme.

Bupropion will be most effective if you are fully committed to giving up smoking. Ask your doctor or pharmacist for advice on

treatments and other support to help you stop.

2. What you need to know before you take Bupropion

Don't take Bupropion :

- **if you are allergic** to bupropion or any of the other ingredients of this medicine (listed in section 6)
- **if you are taking any other medicines which contain bupropion**
- **if you have a condition that causes fits (seizures)**, such as **epilepsy**, or if you have a history of fits
- **if you have an eating disorder** or had one in the past (for example, bulimia or anorexia nervosa)
- **if you have severe liver problems**, such as *cirrhosis*
- **if you have a brain tumour**
- **if you are usually a heavy drinker** and you have just stopped drinking alcohol, or are going to stop while you're taking Bupropion
- **if you have recently stopped taking sedatives or medicines to treat anxiety** (especially *benzodiazepines* or similar medicines), or if you are going to stop them while you're taking Bupropion
- **if you have a bipolar disorder** (extreme mood swings) as Bupropion could bring on an episode of this illness
- **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. The timing may be shorter for some types of MAOIs, your doctor will advise you.

If any of these applies to you, talk to your doctor straight away, and don't take Bupropion .

Warnings and Precautions

Talk to your doctor or pharmacist before

taking Bupropion . This is because some conditions make it more likely that you will have side effects (see also section 4).

Children and adolescents

Bupropion is not recommended for people under 18 years.

Adults

Fits (*seizures*)

Bupropion has been shown to cause fits (seizures) in about 1 in 1,000 people. (See also Other medicines and Bupropion later in this section and section 4 Possible side effects, for more information).

Fits are more likely:

- **if you regularly drink a lot of alcohol**
- **if you have diabetes** for which you use insulin or tablets
- **if you have had a serious head injury** or a history of head trauma.

If any of these applies to you, don't take Bupropion unless you have agreed with your doctor that there is a strong reason for doing so.

If you have a fit (seizure) during treatment:

Stop taking Bupropion and don't take any more. See your doctor.

You may have more risk of side effects:

- **if you have kidney or liver problems**
- **if you are aged over 65.**

You will need to take a lower dose (see section 3) and be checked closely while you are taking Bupropion .

If you have had any mental health problems...

Some people taking Bupropion have had hallucinations or delusions (seeing, hearing or believing things that are not there), disordered thoughts or extreme mood swings. These effects are more likely in people who have had mental health problems before.

If you feel depressed or suicidal...

Some people become depressed when they try to stop smoking; very occasionally, they may think about committing suicide, or try to do so. These symptoms have affected people taking Bupropion , most often in the first few weeks of treatment.

If you feel depressed or think about suicide:

- **Contact your doctor or go to a hospital straight away.**

High blood pressure and Bupropion ...

Some people taking Bupropion have developed high blood pressure which needs treatment. If you already have high blood pressure, it can become worse. This is more likely if you are also using **nicotine patches** to help you stop smoking.

You will have your blood pressure checked before you take Bupropion and while you are taking it, especially if you already have high blood pressure. If you are also using nicotine patches, your blood pressure needs to be checked every week. If your blood pressure increases, you may need to stop taking Bupropion .

Other medicines and Bupropion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you bought without a prescription.

There may be a higher than usual risk of fits if you take:

- medicines for **depression** or **other mental health problems** (see also Don't take Bupropion at the beginning of section 2)
- **theophylline** for **asthma** or **lung disease**
- **tramadol**, a strong painkiller
- medicines against **malaria**
- **stimulants** or other medicines to control your **weight or appetite**

- **steroids** (except creams and lotions for eye and skin conditions)
- **antibiotics** called **quinolones**
- **some types of anti-histamines** mainly used to treat allergies, that can cause sleepiness
- medicines for **diabetes**.

If you take any medicines in this list, talk to your doctor straight away, before you take Bupropion (see section 3 under Some people need to take a lower dose).

Some medicines can affect how Bupropion works, or make it more likely that you'll have side effects. These include:

- medicines for **depression** (such as desipramine, imipramine, paroxetine) or **other mental health problems** (such as risperidone, thioridazine)
- medicines for **Parkinson's disease** (such as levodopa, amantadine or orphenadrine)
- **carbamazepine, phenytoin or valproate**, to treat **epilepsy** or some **mental health problems**
- some medicines used to treat **cancer** (such as cyclophosphamide, ifosfamide)
- **ticlopidine or clopidogrel**, mainly used to treat **heart disease** or **stroke**
- some **beta blockers** (such as metoprolol), mainly used to treat high blood pressure some medicines for **irregular heart rhythm** (such as propafenone, flecainide)
- **ritonavir** or **efavirenz**, for treatment of HIV infection.

If you take any medicines on this list, check with your doctor. Your doctor will weigh up the benefits and risks to you of taking Bupropion, or may decide to change the dose of the other medicine you are taking.

Bupropion may make other medicines less effective:

- **If you take tamoxifen used to treat breast cancer**

If this applies to you, tell your doctor. It

may be necessary to change to another treatment for smoking cessation.

• **If you take digoxin for your heart**

If this applies to you, tell your doctor. Your doctor may consider adjusting the dose of digoxin.

The dose of some medicines may need to be reduced when you stop smoking

When you smoke, the chemicals absorbed into your body can cause some medicines to be less effective. When you stop smoking, your dose of these medicines may need to be reduced; otherwise, you may get side effects.

If you are taking any other medicines, check with your doctor if you notice any new symptoms that you think may be side effects.

Bupropion with alcohol

Some people find they are more sensitive to alcohol while taking Bupropion. Your doctor may suggest you do not drink alcohol while you're taking Bupropion, or try to drink as little as possible. If you do drink a lot now, don't just stop suddenly, because that may put you at risk of having an fit.

Effect on urine tests

Bupropion may interfere with some urine tests to detect other drugs. If you require a urine test, tell your doctor or hospital that you are taking Bupropion.

Pregnancy and breast-feeding

Don't take Bupropion if you are pregnant, think you may be pregnant or are planning to have a baby. Ask your doctor or pharmacist for advice before taking this medicine. Some, but not all studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking Bupropion. It is not known if these are due to the use of Bupropion.

The ingredients of Bupropion can pass into breast milk. You should ask your

doctor or pharmacist for advice before taking Bupropion .

Driving and using machines

Some of the side effects of Bupropion , such as feeling dizzy or light-headed, may affect your concentration and judgement.

If you are affected, don't drive or operate machinery.

3. How to take Bupropion

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to start and how much to take		
<ul style="list-style-type: none"> • Start taking Bupropion while you are still smoking • Set a Target Stop Smoking Day ideally during the second week you're taking it 		
Week 1 Ideally keep smoking while taking Bupropion	Days 1 to 6	Take one tablet (150mg), once a day
	Day 7	Increase your dose to one tablet, twice a day , at least 8 hours apart, and not near to bedtime
Week 2	Carry on taking one tablet, twice a day . Stop smoking this week, on your Target Stop Smoking Day .	
Weeks 3 to 9	Carry on taking one tablet, twice a day for up to 9 weeks . If you have not been able to stop smoking after 7 weeks , your doctor will advise you to stop taking Bupropion . You may be advised to stop taking Bupropion gradually, after 7 - 9 weeks.	

Some people need to take a lower dose

as they may be more likely to get side effects.

- if you are aged over 65

- if you have liver or kidney disease
- if you have a higher risk of fits (see Warnings and Precautions and Other medicines and Bupropion in section 2)

the maximum recommended dose for you is **one 150mg tablet once a day**.

How to take your tablets

Take your Bupropion tablets at least 8 hours apart. Don't take Bupropion near to bedtime - it may cause difficulty in sleeping.

You can take Bupropion with or without food.

Swallow your Bupropion tablets whole. Don't chew them, crush them or split them - if you do, the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits.

If you take more Bupropion than you should

If you take too many tablets, you may be more likely to have a fit or other side effects.

Don't delay. Contact your doctor or your nearest hospital emergency department immediately.

If you forget to take Bupropion

If you miss a dose, wait and take your next tablet at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Bupropion

You may need to take Bupropion for as long as 7 weeks to have its full effect.

Don't stop taking Bupropion without talking to your doctor first. You may need to reduce your dose gradually.

If you have any further questions about using this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Fits (seizures)

Approximately 1 in every 1,000 people taking Bupropion is at risk of having a fit.

Symptoms of a fit include convulsions and usually loss of consciousness. Someone who has had a fit may be confused afterwards and may not remember what has happened.

Fits are more likely if you take too much, if you take some other medicines or if you are at higher than usual risk of fits (see section 2).

If you have a fit, tell your doctor when you have recovered. **Don't take any more Bupropion**.

Allergic reactions

Rarely (up to 1 in 1,000) people may have potentially serious allergic reactions to Bupropion. Signs of allergic reactions include:

- skin rash (including itchy, bumpy rash). Some skin rashes may need hospital treatment, especially if you also have a sore mouth or sore eyes
- unusual wheezing or difficulty in breathing
- swollen eyelids, lips or tongue
- pains in muscles or joints
- collapse or blackout.

If you have any signs of an allergic reaction, contact a doctor at once. Don't take any more tablets.

Very common side effects

These may affect **more than one in 10** people:

- difficulty in sleeping (make sure you don't take Bupropion near to bedtime).

Common sideeffects

These may affect **up to one in 10** people:

- feeling depressed (see also Warnings and

Precautions in section 2)

- feeling anxious or agitated
- difficulty concentrating
- feeling shaky (tremor)
- headache
- feeling sick (nausea), being sick (vomiting)
- stomach pain or other upsets (such as constipation), changes in the taste of food, dry mouth
- fever, dizziness, sweating, skin rash (sometimes due to an allergic reaction), itching.

Uncommon sideeffects

These may affect **up to one in 100** people:

- ringing in the ears, visual disturbances
- increase in blood pressure (sometimes severe), flushing
- loss of appetite (*anorexia*)
- feeling weak
- chest pain
- feeling confused
- rapid heartbeat.

Rare side effects

These may affect **up to one in 1,000** people:

- fits (see the beginning of this section)
- twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination (*ataxia*)
- palpitations
- fainting, feeling faint when you stand up suddenly, because your blood pressure falls
- feeling irritable or hostile; strange dreams (including nightmares)
- loss of memory
- tingling or numbness
- severe allergic reactions; rash together with joint and muscle pains (see the beginning of this

section)

- urinating (passing water) more or less than usual
- severe skin rashes that may affect the mouth and other parts of the body and can be life-threatening
- worsening of psoriasis (thickened patches of red skin)
- your skin or the whites of your eyes turning yellow (jaundice), increase in liver enzymes, hepatitis
- changes in blood sugar levels
- feeling unreal or strange (*depersonalisation*); seeing or hearing things that are not there (*hallucinations*).

Very rare side effects

These may affect up to one in 10,000 people:

- feeling restless, aggressive
- sensing or believing things that are not true (*delusions*); severe suspiciousness (*paranoia*).
- urinary incontinence (involuntary urination, leakage of urine)

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- thoughts of harming or killing themselves while taking Bupropion or soon after stopping treatment (see section 2, What you need to know before you take Bupropion). If you have these thoughts, **contact your doctor or go to a hospital straight away.**
- loss of contact with reality and unable to think or judge clearly (*psychosis*); other symptoms may include hallucinations and/or delusions.
- reduced number of red blood cells (anaemia), reduced number of white blood cells (leucopenia) and reduced number of platelets (thrombocytopenia).

- blood sodium decreased (hyponatraemia).

Effects of giving up smoking

People who stop smoking are often affected by nicotine withdrawal. This can also affect people taking Bupropion . Signs of nicotine withdrawal include:

- difficulty in sleeping
- tremor or sweating
- feeling anxious, agitated or depressed, sometimes with thoughts of suicide.

Talk to your doctor if you have any concerns about how you feel.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Bupropion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Do not store this medicine above 25 °C. Store it in the original package. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bupropion contains

Each tablet contains 150mg of the active substance, bupropion hydrochloride. The other ingredients are:
Tablet core; microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate.

Tablet coating; hypromellose, macrogol 400, titanium dioxide, carnauba wax. Printing ink;

hypromellose, iron oxide black.

What Bupropion looks like and contents of the pack

Bupropion 150mg tablets

They are available in cartons containing blisters of 60 tablets.

7. Manufactured By:

Taj Pharmaceuticals Ltd.

at: Plot. No. 220, Mahagujarat

Industrial Estate, At & Post-Moraiya,

Tal-Sanand, Dist- Ahmedabad Gujarat

(India)