

Package leaflet: Information for the user

Bupropion HCl Neuraxpharm 300 mg tabletten met gereguleerde afgifte 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 HCl Neuraxpharm 300 mg is and what it is used for
2. What you need to know before you take Bupropion HCl Neuraxpharm 300 mg
3. How to take Bupropion HCl Neuraxpharm 300 mg
4. Possible side effects
5. How to store Bupropion HCl Neuraxpharm 300 mg
6. Contents of the pack and other information

1. What Bupropion HCl Neuraxpharm 300 mg is and what it is used for

Bupropion HCl Neuraxpharm 300 mg 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*.

2. What you need to know before you take Bupropion HCl Neuraxpharm 300 mg

Do not take Bupropion HCl Neuraxpharm 300 mg:

- 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 been diagnosed with epilepsy or have a history of seizures
- If you have an eating disorder, or used to (for example, bulimia or anorexia nervosa)
- 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 have severe liver problems
- If you recently stopped taking sedatives, or if you are going to stop them while you're taking Bupropion HCl Neuraxpharm 300 mg
- If you are taking or have been taking other medicines for depression called *monoamine oxidase inhibitors* (MAOIs) in the last 14 days.

If any of these applies to you, talk to your doctor straight away, without taking Bupropion HCl Neuraxpharm 300 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bupropion HCl Neuraxpharm 300 mg:

- 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.

Children and adolescents

Bupropion HCl Neuraxpharm 300 mg is not recommended to treat children under 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.

Adults

Your doctor needs to know before you take Bupropion HCl Neuraxpharm 300 mg:

- 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

Bupropion HCl Neuraxpharm 300 mg has been shown to cause fits (seizures) in about 1 in a 1000 people. This side effect is more likely to occur in people from the groups listed above. If you have a fit during treatment you should stop taking Bupropion HCl Neuraxpharm 300 mg. Do not take any more and see your doctor.

- If you have a bipolar disorder (extreme mood swings), as Bupropion HCl Neuraxpharm 300 mg could bring on an episode of this illness
- If you are taking other medicines for depression, the use of these medicines together with Bupropion HCl Neuraxpharm 300 mg can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Bupropion HCl Neuraxpharm 300 mg” in this section)
- If you have liver or kidney problems, you may be more likely to get side effects.

If any of the above apply to you, talk to your doctor again before taking Bupropion HCl Neuraxpharm 300 mg. He or she may want to pay special attention to your care, or recommend another treatment.

Thoughts of suicide and worsening of your depression

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two 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 a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Other medicines and Bupropion HCl Neuraxpharm 300 mg

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 HCl Neuraxpharm 300 mg (see also ‘Do not take Bupropion HCl Neuraxpharm 300 mg’ in section 2).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, herbs or vitamins, including products you bought yourself. He or she may alter your dose of Bupropion HCl Neuraxpharm 300 mg, or suggest a change in your other medications.

Some medicines don’t mix with Bupropion HCl Neuraxpharm 300 mg. Some of them may increase the chance of fits or seizures. Other medicines may increase the risk of other side effects. Some examples are listed below, but it is not a complete list.

There may be a higher than usual chance of seizures...

- 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 HCl Neuraxpharm 300 mg (see also 'Do not take Bupropion HCl Neuraxpharm 300 mg' 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.

If any of these applies to you, talk to your doctor straight away, before taking Bupropion HCl Neuraxpharm 300 mg. Your doctor will weigh up the benefits and risks to you of taking Bupropion HCl Neuraxpharm 300 mg.

There may be a higher than usual chance of other side effects...

- If you take other medicines for depression (such as amitriptyline, fluoxetine, paroxetine, citalopram, escitalopram, venlafaxine, desulepin, desipramine or imipramine) or other mental illness (such as clozapine, risperidone, thioridazine or olanzapine). Bupropion HCl Neuraxpharm 300 mg may interact with some medicines used for treatment of depression and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).
- If you take medicines for Parkinson's disease (levodopa, amantadine or orphenadrine)
- If you take medicines that affect your body's ability to breakdown Bupropion HCl Neuraxpharm 300 mg (carbamazepine, phenytoin, valproate)
- If you take some medicines used to treat cancer (such as cyclophosphamide, ifosfamide)
- If you take ticlopidine or clopidogrel, mainly used to prevent stroke
- If you take some beta blockers (such as metoprolol)
- If you take some medicines for irregular heart rhythm (propafenone or flecainide)
- If you use nicotine patches to help you stop smoking.

If any of these applies to you, talk to your doctor straight away, before taking Bupropion HCl Neuraxpharm 300 mg.

Bupropion HCl Neuraxpharm 300 mg may be less effective

- If you take ritonavir or efavirenz, medicines to treat HIV infection.

If this applies to you, tell your doctor. Your doctor will check how well Bupropion HCl Neuraxpharm 300 mg is working for you.

It may be necessary to increase your dose or change to another treatment for your depression. **Do not increase your Bupropion HCl Neuraxpharm 300 mg dose** without advice from your doctor, as this may increase the risk of you having side effects, including seizures.

Bupropion HCl Neuraxpharm 300 mg 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 your depression.

- If you take digoxin for your heart.

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

Bupropion HCl Neuraxpharm 300 mg with alcohol

Alcohol can affect the way Bupropion HCl Neuraxpharm 300 mg works and, when used together can rarely affect your nerves or your mental state. Some people find they are more sensitive to alcohol when taking Bupropion HCl Neuraxpharm 300 mg. Your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking Bupropion HCl Neuraxpharm 300 mg, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may put you at risk of having a fit.

Talk to the doctor about drinking before you start taking Bupropion HCl Neuraxpharm 300 mg.

Effect on urine tests

Bupropion HCl Neuraxpharm 300 mg 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 HCl Neuraxpharm 300 mg.

Pregnancy and breast-feeding

Do not take Bupropion HCl Neuraxpharm 300 mg if you are pregnant, think you may be pregnant or are planning to have a baby unless your doctor recommends it. 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 HCl Neuraxpharm 300 mg. It is not known if these are due to the use of Bupropion HCl Neuraxpharm 300 mg.

The ingredients of Bupropion HCl Neuraxpharm 300 mg can pass into breast milk. You should ask your doctor or pharmacist for advice before taking Bupropion HCl Neuraxpharm 300 mg.

Driving and using machines

If Bupropion HCl Neuraxpharm 300 mg makes you dizzy or light-headed, do not drive or operate any tools or machines.

3. How to take Bupropion HCl Neuraxpharm 300 mg

Always take this medicine exactly as your doctor or pharmacist has told you. These are the usual doses, but your doctor's advice is personal to you. Check with your doctor or pharmacist if you are not sure.

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 HCl Neuraxpharm 300 mg to prevent depression coming back.

How much to take

Bupropion HCl Neuraxpharm 300 mg is available only in 300 mg strength. For the dose of 150 mg, please use the other alternate suitable product available on market.

The usual recommended dose for adults only is **one** 150mg tablet every day.

Your doctor may increase your dose to 300 mg every day if your depression does not improve after several weeks.

Take your dose of Bupropion HCl Neuraxpharm 300 mg in the morning. Do not take Bupropion HCl Neuraxpharm 300 mg more than once each day.

The tablet is covered by a shell that slowly releases medicine inside your body. You may notice something in your stool that looks like a tablet. This is the empty shell passing from your body.

Swallow your tablets whole. Do not chew them, crush them or split them — if you do, there is a danger you could overdose, because the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits (seizures).

Some people will stay on one 150mg tablet every day for the whole of their treatment. Your doctor may have prescribed this if you have liver or kidney problems.

How long to take it for

Only you and your doctor can decide how long you should take Bupropion HCl Neuraxpharm 300 mg. It may take weeks or months of treatment for you to see any improvement. Discuss your symptoms with your doctor regularly to decide how long you should be taking it. When you do start feeling better your doctor may advise you to keep taking Bupropion HCl Neuraxpharm 300 mg to prevent depression coming back.

If you take more Bupropion HCl Neuraxpharm 300 mg than you should

If you take too many tablets, you may increase the risk of a fit or seizure. Don't delay. Ask your doctor what to do or contact your nearest hospital emergency department at once.

If you forget to take Bupropion HCl Neuraxpharm 300 mg

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 tablet.

If you stop taking Bupropion HCl Neuraxpharm 300 mg

Do **not** stop taking Bupropion HCl Neuraxpharm 300 mg or reduce your dose without talking to your doctor first.

If you have any further questions on the use of 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.

Serious side effects

Fits or seizures

Approximately 1 in every 1000 people taking Bupropion HCl Neuraxpharm 300 mg is at risk of a fit (a seizure or convulsion). The chance of this happening is higher if you take too much, if you take certain medicines, or if you are at higher than usual risk of fits. If you are worried, talk to your doctor.

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

Allergic reactions

Some people may get allergic reactions to Bupropion HCl Neuraxpharm 300 mg. These include

- Red skin or rash (like nettle rash), blisters or itchy lumps (hives) on the skin. 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. Allergic reactions can last a long time. If your doctor prescribes something to help with allergic symptoms, make sure you finish the course.

Lupus skin rash or worsening of lupus symptoms

Not known - frequency cannot be estimated from the available data in people taking Bupropion HCl Neuraxpharm 300 mg.

Lupus is an immune system disorder affecting the skin and other organs.

If you experience lupus flares, skin rash or lesions (particularly on sun-exposed areas) while taking Bupropion HCl Neuraxpharm 300 mg, contact your doctor straight away, as it might be necessary to stop the treatment.

Acute Generalised Exanthematous Pustulosis (AGEP)

Not known - frequency cannot be estimated from the available data in people taking Bupropion HCl Neuraxpharm 300 mg.

Symptoms of AGEP include rash with pus filled pimples/blisters.

If you have a rash that has pus filled pimples/blisters, contact your doctor straight away as it might be necessary to stop the treatment.

Other side effects

Very common side effects: these may affect more than one in 10 people

- Difficulty in sleeping. Make sure you take Bupropion HCl Neuraxpharm 300 mg in the morning.
- Headache
- Dry mouth
- Feeling sick, vomiting.

Common side effects: these may affect up to one in 10 people

- Fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)
- Shakiness, tremor, weakness, tiredness, chest pain
- Feeling anxious or agitated
- Tummy pain or other upsets (constipation), changes in the taste of food, loss of appetite (anorexia)
- Increase in blood pressure sometimes severe, flushing
- Ringing in the ears, visual disturbances.

Uncommon side effects: these may affect up to one in 100 people

- Feeling depressed (see also section 2 'Take special care with Bupropion HCl Neuraxpharm 300 mg', under 'Thoughts of suicide and worsening of your depression')
- Feeling confused
- Difficulty concentrating
- Raised heart rate
- Weight loss.

Rare side effects: these may affect up to one in 1,000 people

- Seizures.

Very Rare side effects: these may affect up to one in 10,000 people

- Palpitations, fainting
- Twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination
- Feeling restless, irritable, hostile, aggressive, strange dreams, tingling or numbness, loss of memory
- Yellowing of skin or the whites of your eyes (*jaundice*) which may be caused by raised liver enzymes, hepatitis
- Severe allergic reactions; rash together with joint and muscle pains
- Changes in blood sugar levels
- Urinating more or less than usual
- Urinary incontinence (involuntary urination, leakage of urine)
- 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)

- 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*).

Frequency not known

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 HCl Neuraxpharm 300 mg or soon after stopping treatment (see section 2, 'What you need to know before you take Bupropion HCl Neuraxpharm 300 mg'). 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.
- stuttering
- reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia) and reduced numbers of platelets (thrombocytopenia).
- blood sodium decreased (hyponatraemia).
- mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea), while taking Bupropion HCl Neuraxpharm 300 mg together with medicines used for treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine and venlafaxine).

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. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bupropion HCl Neuraxpharm 300 mg

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 carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 HCl Neuraxpharm 300 mg contains

The active substance is bupropion hydrochloride. Each tablet contains 300 mg of bupropion hydrochloride (equivalent to 260.40 mg bupropion).

The other ingredients are:

Tablet core: Povidone, Cysteine Hydrochloride Monohydrate, Silica, Colloidal Anhydrous, Glycerol Dibehenate, Magnesium Stearate (E 470b),

Tablet coating: Ethyl Cellulose 100 mPas, Povidone, Macrogol, Methacrylic acid-Ethyl Acrylate Copolymer (1:1) containing sodium laurylsulfate and polysorbate 80, Colloidal Hydrated Silica, Triethyl Citrate

Printing ink: Shellac Glaze, Iron Oxide Black (E172) and propylene glycol.

What Bupropion HCl Neuraxpharm 300 mg looks like and contents of the pack

Bupropion HCl Neuraxpharm 300 mg is creamy-white to pale yellow, round, tablet printed with "GS2" on one side and plain on the other side.

The tablet diameter is approximately 9.3 mm.

OPA/Alu/PVC-Alu blister containing 10, 30, 60 and 90 tablets. Also available in OPA/Alu/PVC-Alu perforated unit dose blister containing 30x1 tablets.

Not all pack sizes may be marketed.

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In het register ingeschreven onder: RVG 122815

This medicinal product is authorised in the Member States of the EEA under the following names:

Duitsland	Bupropion-neuraxpharm 300 mg Tabletten mit veränderter Wirkstofffreisetzung
Nederland	Bupropion HCl Neuraxpharm 300 mg tabletten met gereguleerde afgifte
Oostenrijk	Bupropion neuraxpharm 300 mg Tabletten mit veränderter Wirkstofffreisetzung
Polen	Bupropion Neuraxpharm, tabletki o zmodyfikowanym uwalnianiu, 300 mg
Slowakije	Bupropion Neuraxpharm 300 mg tablety s riadeným uvoľňovaním
Tsjechië	Bupropion Neuraxpharm

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