Package leaflet: Information for the user

Bupropion HCl 1A Pharma® retard 150 mg, tabletten met gereguleerde afgifte
Bupropion HCl 1A Pharma® retard 300 mg, tabletten met gereguleerde afgifte

Bupropion hydrochloride

Read all of this leaflet carefully before you start taking 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 [nationally completed name] is and what it is used for

[nationally completed name] is used to treat **depression**. It interacts with chemicals in the brain called noradrenaline and dopamine, which are linked to depression.

2. What you need to know before you take [nationally completed name]

Do not take [nationally completed name]:

if you are/have:
- **allergic** to bupropion or any of the other ingredients of this medicine (listed in section 6)
- **taking** any other medicines which contain **bupropion**
- **epilepsy** or a history of fits
- a **brain tumour**
- undergoing abrupt **withdrawal from alcohol or** any medicines known to be associated with a risk of withdrawal, particularly

- **medicines which calm**, induce sleep or relax muscles with active substance names ending with "azepam"
- or similar sedatives

- a **severe long-lasting liver disease** marked by degeneration and thickening of liver tissue
- an eating disorder or have had one, such as **bulimia or anorexia nervosa**
- **taking** or have been taking other medicines to treat depression called **monoamine oxidase inhibitors**
  A gap of at least 14 days is required following discontinuation of certain monoamine oxidase inhibitors (called irreversible monoamine oxidase inhibitors) and taking [nationally completed name]. For some other monoamine oxidase inhibitors (which are called reversible monoamine oxidase inhibitors), a gap of 24 hours could be sufficient. Ask your doctor for advice.

Warnings and precautions

Talk to your doctor before taking [nationally completed name] if you are/have:
- regularly drinking a lot of alcohol
  Please consider the previous section: “Do not take [nationally completed name]” if you are undergoing abrupt withdrawal from alcohol.
- diabetes for which you use insulin or tablets
- a history of a head injury
- extreme mood swings or mental problems
  Prior to treatment, patients should be checked for risk of disorders with episodes of elevated or agitated mood.
- If you are taking other medicines for depression, the use of these medicines together with [nationally completed name] can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and [nationally completed name]” in this section)
- reduced kidney or mild to moderate reduced liver function
  Patients with reduced liver or kidney function will be monitored by the doctor for possible side effects. Do not use [nationally completed name] if you have the severe liver disease listed in the sixth bullet point under “Do not take [nationally completed name]”.
- require a urine test
  Tell your doctor that you are taking [nationally completed name] as it may interfere with some urine tests to detect other medicines.
- Brugada syndrome
  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.

[nationally completed name] has been shown to cause **fits**. This side effect is more likely in people:
- affected by a condition listed in the first three bullet points under “Warnings and precautions” in section 2 or
- taking a medicine listed in the second to twelfth bullet point under “Other medicines and [nationally completed name]” in section 2

All patients should be assessed for existing risk factors. **Stop taking [nationally completed name] and contact your doctor** if fits occur during treatment.

Thoughts of harming or killing yourself are associated with depression. These may be increased when starting treatment as medicines to treat depression take time to work. This can usually be about two weeks but sometimes longer.
You are more likely to have such thoughts if you:
- have previously had these thoughts

- are a young adult
  Studies show an increased risk of suicidal behavior in adults aged under 25 years with mental problems and using medicines to treat depression.

C**ontact your doctor or go to a hospital immediately,** if you have thoughts of harming or killing yourself. Tell a relative or close friend that you are depressed, and ask them to read this leaflet. Ask them to tell you if they think your depression is getting worse or changes in your behavior occur.

Children under 18 years

[nationally completed name] is not recommended for this age group. An increased risk of suicidal thoughts and behaviour exists in children using medicines to treat depression.

Other medicines and [nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by [nationally completed name], but it is not a complete list. Tell your doctor if you take any of these medicines so that your treatment can be altered if necessary:
- certain medicines to treat depression or Parkinson's disease called **monoamine oxidase inhibitors**
  Consider the last bullet point under "**Do not take [nationally completed name]**" in section 2.
- **medicines to treat depression**, such as amitriptyline, fluoxetine, paroxetine, dosulepin, desipramine, imipramine, citalopram, escitalopram, venlafaxine or medicines to treat **mental diseases,** such as clozapine, risperidone, thioridazine, olanzapine [nationally completed name] 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).
- **theophylline**: a medicine to treat asthma and other breathing diseases
- **tramadol**: a medicine to treat pain
- **sedatives**
  Consider the fifth bullet point under "**Do not take [nationally completed name]**" in section 2 if you intend to stop taking sedatives.
- **medicines to prevent and treat malaria**, such as mefloquine, chloroquine
- **stimulants** or other medicines to control your weight or appetite
- **steroids**, administered by mouth or injection
- **medicines to treat bacterial infection** with active substance names ending in "oxacin"
- **anti-histamines** that can cause sleepiness: used to treat allergies, sleep disturbances or colds; or prevent and treat nausea and vomiting
- **medicines to treat diabetes**
- **levodopa, amandatine:** medicines to treat Parkinson's disease
- **orphenadrine**: a medicine to treat painful muscle tension
- **carbamazepine, phenytoin, valproate**: medicines to treat epilepsy and certain pain conditions
- certain medicines to treat cancer, such as **cyclophosphamide, ifosfamide**
- **ticlopidine, clopidogrel**: medicines to inhibit blood clotting

- **medicines to treat high blood pressure**, heart or other diseases, with active substance names ending with “lol”, such as metoprolol
- **propafenone, flecainide**: medicines to treat heart rhythm disorders
- **nicotine** patches: medicines to stop smoking
- **ritonavir, efavirenz**: medicines to treat HIV infection
- **tamoxifen**: a medicine to treat breast cancer
  Tell your doctor if you take tamoxifen as it may be necessary to change to another treatment for depression.
- **digoxin**, a medicine for your heart
  Tell your doctor if you take digoxin as it’s dose

[nationally completed name] with alcohol

Drinking alcohol is **not recommended** while taking [nationally completed name]. But if you drink a lot now, do not stop suddenly as it may put you at risk of having a fit.

Talk to the doctor about drinking and withdrawal from alcohol before you take [nationally completed name].

Pregnancy and breast-feeding

Do not take [nationally completed name] if you are pregnant, think you may be pregnant or are planning to have a baby, **unless your doctor recommends it**. Some clinical studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking [nationally completed name]. It is not known if these are due to the use of [nationally completed name].
The ingredients of [nationally completed name] can pass into breast milk. If you are breast-feeding, ask your doctor or pharmacist for advice before taking [nationally completed name].

Driving and using machines

Do not drive or operate any tools or machines as [nationally completed name] makes you dizzy or light-headed.

{[nationally completed name]} contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’**.**

3. How to take [nationally completed name]

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

The recommended dose is

One 150 mg tablet once daily

Your doctor may increase your dose to 300 mg tablets once daily if your depression does not improve after several weeks.

Patients with reduced liver or kidney function

The recommended dose is one 150 mg tablet once daily if you have reduced kidney or mild to moderate reduced liver function.
Do not use [nationally completed name] if you have the severe liver disease listed in the sixth bullet point under "Do not take [nationally completed name]" in section 2.

Method of use

Take your tablets whole, in the morning. The tablets can be taken with or withoutfood.

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

You must not chew, crush or split the tablets as you could overdose, because the medicine will release too quickly. This increases the possibility of side effects, including fits.

Duration of use

Your doctor decides how long you should take [nationally completed name].

It may take a while before you start feeling better and have the full effect, sometimes weeks or months. Your doctor may advise you to keep taking [nationally completed name] when you start feeling better, to stop depression returning.

If you take more [nationally completed name] than you should

Contact your doctor immediately or your nearest hospital if an overdose occurs, as this may increase the risk of fits.

If you forget to take [nationally completed name]

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 [nationally completed name]

Do not stop [nationally completed name] use or reduce the dose without your doctor's permission.

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 everybody gets them.

Serious side effects

Tell your doctor straight away, if you notice any of the following serious side effects.

Fits or seizures

Approximately 1 in every 1000 people taking [nationally completed name] 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. 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 immediately. **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 [Nationally completed name]
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 [Nationally completed name], 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 [nationally completed name] 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: may affect up to one in 100 people
- Feeling depressed (see also section 2 'Take special care with [nationally completed name]', under 'Thoughts of suicide and worsening of your depression')
- Feeling confused
- Difficulty concentrating
- Raised heart rate
- Weight loss

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

Very rare side effects: 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
- 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*).

Not known side effects: frequency cannot be estimated from the available data
- Blood sodium decreased (hyponatraemia)

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 [nationally completed name] or soon after stopping treatment (see section 2, 'What you need to know before you take [nationally completed name]'). 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 numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia) and reduced numbers of platelets (thrombocytopenia).
- 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 [nationally completed name] 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 possible 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 [nationally completed name]

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 bottle or blister after EXP. 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. 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 [nationally completed name] contains

- The active substance is bupropion hydrochloride.

  Each modified-release tablet contains 150 mg of bupropion hydrochloride.
  Each modified-release tablet contains 300 mg of bupropion hydrochloride.

- 150 mg modified release tablet: The other ingredients are povidone K90, hydrochloric acid, sodium stearyl fumarate, ethylcellulose 10 mPa.s, hydroxy propylcellulose, methacrylic acid-ethyl acrylate copolymer (1:1) Type A, silica colloidal anhydrous, macrogol 1500, triethyl citrate, Hypromellose 2910, 6 mPa.s, macrogol 400, macrogol8000.

- 300 mg modified release tablet: The other ingredients are povidone K90, cysteine hydrochloride monohydrate, silica, colloidal anhydrous, glycerol dibehenate, magnesium stearate, ethylcellulose 100 mPa.s, povidone K90, silica, colloidal hydrated, methacrylic acid-ethyl acrylate copolymer (1:1), sodium lauryl sulfate, polysorbate 80, macrogol 1450, triethyl citrate, shellac, iron oxide black (E 172), propylene glycol, ammonium hydroxide 28%

What [nationally completed name] looks like and contents of the pack

{[nationally completed name] 150 mg modified-release tablet}
White to pale yellow, round, biconvex tablets (diameter approximately 7.5 mm) plain on both sides.
10, 30 and 90 tablets in White opaque high density polyethylene (HDPE) bottles closed with a child- resistant white polypropylene (PP) screw cap with peelable heat liner and two bags which should not be swallowed, one containing silica gel granules and activated carbon and one containing silica gel granules and oxygen absorber.

{[nationally completed name] 300 mg modified-release tablet}
Creamy-white to pale yellow, round, tablets (diameter approximately 9.3 mm) printed with "GS2" on one side and plain on the other side.
10, 30, 60, 90, tablets in OPA/Alu/PVC-Alu blister

Not all pack size be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
1 A Pharma GmbH
Industriestrasse 18
83607 Holzkirchen
Duitsland

Fabrikant:
150 mg
Batch release:
Lek Pharmaceuticals d.d.
Trimlini 2d
9220 Lendava
Slovenië

Lek S.A.
Ul. Domaniewska 50c
02-672 Warsaw
Polen

Lek Pharmaceuticals d.d.
Verovskova Ulica 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-Von-Guericke-Allee 1
39179 Barleben
Duitsland

Sandoz S.R.L.
Strada Livezeni 7a
540472 Targu Mures
Roemenië

300 mg
Salutas Pharma GmbH
Otto-Von-Guericke-Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
Bupropion HCl 1A Pharma retard 150 mg, tabletten met gereguleerde afgifte - RVG 128743
Bupropion HCl 1A Pharma retard 300 mg, tabletten met gereguleerde afgifte - RVG 128748

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland:	Bupropion HCl 1A Pharma retard 150 mg, tabletten met gereguleerde afgifte
	Bupropion HCl 1A Pharma retard 300 mg, tabletten met gereguleerde afgifte
Polen:	BUXOSAN

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024