LABELLING
<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING CARTON AND BOTTLE LABEL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. NAME OF THE MEDICINAL PRODUCT</strong></td>
</tr>
<tr>
<td>BUPROPION HYDROCHLORIDE GSK 150 mg Modified Release tablets</td>
</tr>
<tr>
<td>Bupropion hydrochloride</td>
</tr>
<tr>
<td><strong>2. STATEMENT OF ACTIVE SUBSTANCE(S)</strong></td>
</tr>
<tr>
<td>Each tablet contains 150 mg of bupropion hydrochloride</td>
</tr>
<tr>
<td><strong>3. LIST OF EXCIPIENTS</strong></td>
</tr>
<tr>
<td><strong>4. PHARMACEUTICAL FORM AND CONTENTS</strong></td>
</tr>
<tr>
<td>7 modified release tablets</td>
</tr>
<tr>
<td>30 modified release tablets</td>
</tr>
<tr>
<td><strong>5. METHOD AND ROUTE(S) OF ADMINISTRATION</strong></td>
</tr>
<tr>
<td>Read the package leaflet before use</td>
</tr>
<tr>
<td>Oral use</td>
</tr>
<tr>
<td>Once Daily</td>
</tr>
<tr>
<td>BUPROPION HYDROCHLORIDE GSK tablets should be swallowed whole and not crushed or chewed.</td>
</tr>
<tr>
<td><strong>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN</strong></td>
</tr>
<tr>
<td>Keep out of the reach and sight of children</td>
</tr>
<tr>
<td><strong>7. OTHER SPECIAL WARNING(S), IF NECESSARY</strong></td>
</tr>
<tr>
<td><strong>8. EXPIRY DATE</strong></td>
</tr>
<tr>
<td>exp {MM YYYY}</td>
</tr>
<tr>
<td><strong>9. SPECIAL STORAGE CONDITIONS</strong></td>
</tr>
<tr>
<td>Store in the original package in order to protect from moisture and light.</td>
</tr>
<tr>
<td><strong>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</strong></td>
</tr>
</tbody>
</table>
11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

lot {XYYYY}

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

BUPROPION HYDROCHLORIDE GSK 150 mg
### PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING CARTON AND BOTTLE LABEL

1. **NAME OF THE MEDICINAL PRODUCT**

   BUPROPION HYDROCHLORIDE GSK 300 mg Modified Release tablets
   Bupropion hydrochloride

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

   Each tablet contains 300 mg of bupropion hydrochloride

3. **LIST OF EXCIPIENTS**

4. **PHARMACEUTICAL FORM AND CONTENTS**

   7 modified release tablets
   30 modified release tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

   Read the package leaflet before use
   Oral use
   Once Daily
   BUPROPION HYDROCHLORIDE GSK tablets should be swallowed whole and not crushed or chewed.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

   Keep out of the reach and sight of children

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

8. **EXPIRY DATE**

   exp {MM YYYY}

9. **SPECIAL STORAGE CONDITIONS**

   Store in the original package in order to protect from moisture and light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

    *Not applicable*
11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]> 

12. MARKETING AUTHORIZATION NUMBER(S) 

<[To be completed nationally]>

13. BATCH NUMBER

lot {XYYYY}

14. GENERAL CLASSIFICATION FOR SUPPLY 

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

BUPROPION HYDROCHLORIDE GSK 300 mg
BUPROPION HYDROCHLORIDE GSK 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 with depression.

Do not take BUPROPION HYDROCHLORIDE GSK

- If you know that you are allergic to BUPROPION HYDROCHLORIDE GSK, bupropion, or any of the other ingredients in BUPROPION HYDROCHLORIDE GSK tablets
- 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 HYDROCHLORIDE GSK
- 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 HYDROCHLORIDE GSK
Take special care with BUPROPION HYDROCHLORIDE GSK

Use in children under 18 years of age

BUPROPION HYDROCHLORIDE GSK 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.

Your doctor needs to know before you take BUPROPION HYDROCHLORIDE GSK:

- 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 HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK. Do not take any more and see your doctor.

- If you have a bipolar disorder (extreme mood swings), as BUPROPION HYDROCHLORIDE GSK could bring on an episode of this illness.

- 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 HYDROCHLORIDE GSK. 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.

Taking other 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 HYDROCHLORIDE GSK (see also Do not take BUPROPION HYDROCHLORIDE GSK in Section 2).

If you are taking any other medicines, herbs or vitamins, including products you bought yourself, tell your doctor. He or she may alter your dose of BUPROPION HYDROCHLORIDE GSK, or suggest a change in your other medications.
Some medicines don’t mix with BUPROPION HYDROCHLORIDE GSK. 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 HYDROCHLORIDE GSK (see also Do not take BUPROPION HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK. Your doctor will weigh up the benefits and risks to you of taking BUPROPION HYDROCHLORIDE GSK.

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

- If you take other medicines for depression (such as amitriptyline, fluoxetine, paroxetine, dosulepin, desipramine or imipramine) or other mental illness (such as clozapine, risperidone, thioridazine or olanzapine).
- 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 HYDROCHLORIDE GSK (carbamazepine, phenytoin, valproate)
- If you take cyclophosphamide or ifosfamide, mainly used to treat cancer
- 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 HYDROCHLORIDE GSK.

BUPROPION HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK 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 HYDROCHLORIDE
GSK dose without advice from your doctor, as this may increase the risk of you having side effects, including seizures.

**Alcoholic drink and BUPROPION HYDROCHLORIDE GSK**

Alcohol can affect the way BUPROPION HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK. Your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking BUPROPION HYDROCHLORIDE GSK, 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 HYDROCHLORIDE GSK.

**Pregnancy and breast-feeding**

**Do not take BUPROPION HYDROCHLORIDE GSK if you are pregnant** unless your doctor recommends it. Ask your doctor or pharmacist for advice before taking any medicine while pregnant.

The ingredients of BUPROPION HYDROCHLORIDE GSK can pass into breast milk. You should ask your doctor or pharmacist for advice before taking BUPROPION HYDROCHLORIDE GSK.

**Driving and using machines**

If BUPROPION HYDROCHLORIDE GSK makes you dizzy or light-headed, do not drive or operate any tools or machines.

3. **HOW TO TAKE BUPROPION HYDROCHLORIDE GSK**

**Always take BUPROPION HYDROCHLORIDE GSK exactly as your doctor has advised you.** These are the usual doses, but your doctor’s advice is personal to you. You should check with your doctor or pharmacist if you are unsure.

**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 HYDROCHLORIDE GSK to prevent depression coming back.

**How much to take**

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 HYDROCHLORIDE GSK tablets in the morning. Do not take BUPROPION HYDROCHLORIDE GSK more than once each day.**

**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 HYDROCHLORIDE GSK.** 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 HYDROCHLORIDE GSK to prevent depression coming back.

If you take more BUPROPION HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK
If you miss a dose, wait and take your next tablet at the usual time. Do not take a tablet to catch up for the dose you forgot.

If you stop taking BUPROPION HYDROCHLORIDE GSK
Do not stop taking BUPROPION HYDROCHLORIDE GSK or reduce your dose without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BUPROPION HYDROCHLORIDE GSK can cause side effects, although not everyone gets them.

**Fits or seizures**

Approximately 1 in every 1000 people taking BUPROPION HYDROCHLORIDE GSK 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 HYDROCHLORIDE GSK. 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.

**Other side effects**

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

- Difficulty in sleeping. Make sure you take BUPROPION HYDROCHLORIDE GSK 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 BUPROPION HYDROCHLORIDE GSK*, 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*).

**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 HYDROCHLORIDE GSK or soon after stopping treatment (see Section 2, *Before you take BUPROPION HYDROCHLORIDE GSK*). 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE BUPROPION HYDROCHLORIDE GSK**

Keep out of the reach and sight of children.
Do not use BUPROPION HYDROCHLORIDE GSK after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store it in the original pack in order to protect from moisture and light. The bottle contains a small sealed canister containing charcoal and silica gel to keep the tablets dry. Keep the canister in the bottle. Do not swallow it.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BUPROPION HYDROCHLORIDE GSK contains

The active substance is bupropion hydrochloride. Each tablet contains 150 mg or 300 mg of bupropion hydrochloride.

The other ingredients are: tablet core: polyvinyl alcohol, glyceryl dibehenate, tablet coating: ethyl cellulose, povidone K-90, macrogol 1450, methacrylic acid ethyl acrylate copolymer dispersion, silicon dioxide, triethyl citrate.

Printing ink: Shellac Glaze, Iron Oxide Black (E172), and Ammonium Hydroxide.

What BUPROPION HYDROCHLORIDE GSK looks like and contents of the pack

BUPROPION HYDROCHLORIDE GSK 150 mg tablets are creamy white to pale yellow round tablets imprinted with “GS5FV” in black ink on one side and the other side plain. They are available in white polyethylene bottles of 7, 30 or 90 (3X30) tablets.

BUPROPION HYDROCHLORIDE GSK 300 mg tablets are creamy white to pale yellow round tablets imprinted with “GS5YZ” in black ink on one side and the other side plain. They are available in white polyethylene bottles of 7, 30 or 90 (3X30) tablets.

Marketing Authorisation Holder and Manufacturer

Manufacturer of BUPROPION HYDROCHLORIDE GSK is Glaxo Wellcome GmbH & Co. KG Industriestrasse 32-36, 23843 Bad Oldesloe, GERMANY

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

Wellbutrin XR: Austria, Belgium, Luxembourg, Cyprus, Greece, Italy, Malta, Poland, Portugal, Slovenia, Switzerland, The Netherlands.

Elontril: Austria, Czech Republic, Estonia, Germany, Hungary, Iceland, Italy, Latvia, Lithuania, Portugal, Romania, Slovakia, Spain, The Netherlands

Magerion: Germany and Sweden

Wellbutrin Retard: Norway

Voxra: Finland, Sweden.

This leaflet was last approved in {MM/YYYY}

[To be completed nationally]

End of MRP procedure: 5 November 2010