

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

DIRENTO SR 150 mg sustained-release tablets

Bupropion hydrochloride 150 mg

Sugar free

Read all of this leaflet carefully before you start taking **DIRENTO SR 150 mg**:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **DIRENTO SR 150 mg** 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 **DIRENTO SR 150 mg** is and what it is used for
2. What you need to know before you take **DIRENTO SR 150 mg**
3. How to take **DIRENTO SR 150 mg**
4. Possible side effects
5. How to store **DIRENTO SR 150 mg**
6. Contents of the pack and other information

1. WHAT DIRENTO SR 150 mg IS AND WHAT IT IS USED FOR:

DIRENTO SR 150 mg is used to treat mental depression.

After a satisfactory response, the continuation of treatment with **DIRENTO SR 150 mg** is effective in preventing relapse and preventing recurrence of further depression episodes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIRENTO SR 150 MG:

Do not take DIRENTO SR 150 mg tablets:

- If you are hypersensitive (allergic) to bupropion or any of the other ingredients in the **DIRENTO SR 150 mg** tablets.
- If you have a condition that causes seizures (fits, such as epilepsy, or if you have a history of fits).
- If you are taking any other medicine containing bupropion.
- If you are usually a heavy drinker and you have just stopped drinking alcohol or are going to stop while you are taking **DIRENTO SR 150 mg** tablets.
- 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 are taking **DIRENTO SR 150 mg** tablets.
- If you have an eating disorder or had one in the past (for example bulimia or anorexia nervosa).
- If you are taking medicines for depression called monoamine oxidase inhibitors (MAOIs), or have taken them in the last 14 days.
- If you have severe liver disorders, such as cirrhosis.
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding.

If any of these applies to you, talk to your doctor straight away, and do not take **DIRENTO SR 150 mg** tablets.

Warnings and precautions:

Take special care with **DIRENTO SR 150 mg** tablets:

- Do not take more **DIRENTO SR 150 mg** tablets than recommended by your doctor as the active ingredient, bupropion, is associated with a dose-related risk of seizures (fits).

Seizures (fits) are more likely:

- if you have or had a serious head injury or brain tumour
 - if you have a history of seizures (fits)
 - if you have taken other medicines that may make seizures more likely
 - if you regularly drink a lot of alcohol
 - if you use excessive tranquillisers
 - if you have diabetes for which you use insulin or antidiabetic medicines
 - if you are using brain stimulants or weight-loss products.
- If you have a seizure (fit) during treatment: contact your doctor immediately who will advise you how to stop taking **DIRENTO SR 150 mg** tablets as your condition may have to be monitored.

If you have kidney and liver problems, you might need a lower daily dosage.

If you feel depressed or suicidal at any time when you are taking **DIRENTO SR 150 mg** tablets, contact your doctor or go to a hospital immediately. Also, if you feel anxious, have panic attacks, irritable, aggressive, suffer from sleeplessness, or have any other emotional problems, contact your doctor, as your treatment may have to be changed.

Other medicines and DIRENTO SR 150 mg:

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- MAO inhibitors (medicines containing moclobemide)
- Orphenadrine, levodopa, amantadine (medicines for Parkinson's disease)
- Cyclophosphamide, ifosfamide (medicines for treating cancer)

- Desipramine (medicine for depression)
- Carbamazepine, phenobarbitone, phenytoin (to treat epilepsy or some mental health disorders)
- Medicines for treating certain heart conditions
- Medicines called beta-blockers (such as metoprolol which is mainly used to treat high blood pressure)
- Citalopram; also selective serotonin re-uptake inhibitors and tricyclic antidepressants, as well as antipsychotics
- Alcohol
- Nicotine transdermal patches (this may result in your blood pressure going up)

DIRENTO SR 150 mg with food and drink:

See **HOW TO TAKE DIRENTO SR 150 mg**.

Pregnancy and Breastfeeding:

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 health care provider for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

However, **DIRENTO SR 150 mg** is excreted in breast milk and you should not breastfeed your baby.

Driving and using machines:

Do not drive or operate machinery if you are unsure of the effect that **DIRENTO SR 150 mg** will have on your abilities. It may affect your ability to concentrate.

3. HOW TO TAKE DIRENTO SR 150 mg:

Do not share medicines prescribed for you with any other person.

Your treatment should be started by a medical practitioner experienced in the treatment of depression.

Always take **DIRENTO SR 150 mg** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Swallow the **DIRENTO SR 150 mg** tablets whole. Do not 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 seizures (fits).

The starting dose is one **DIRENTO SR 150 mg** taken as a single daily dose.

You can take **DIRENTO SR 150 mg** tablets with or without food.

The full antidepressant effect of **DIRENTO SR 150 mg** may not be evident until after several weeks of treatment.

If you are not responding adequately to a dose of one **DIRENTO SR 150 mg** tablet a day, your doctor may decide to increase the dose to a maximum of one **DIRENTO SR 150 mg** tablet twice a day, with an interval of at least 8 hours between doses.

Sleeplessness is a frequent side-effect and may be reduced by avoiding dosing at bedtime (provided there is at least 8 hours between doses), otherwise your doctor may reduce the dose.

If you have kidney or liver disorders, make sure that you inform your doctor so that he can adjust your dose, if necessary.

If you forget to take DIRENTO SR 150 mg:

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

If you missed a dose, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule.

Do not use **DIRENTO SR 150 mg** in persons under the age of 18 years.

If you have the impression that the effect of **DIRENTO SR 150 mg** is too strong or too weak, talk to your doctor or pharmacist.

If you take more DIRENTO SR 150 mg than you should:

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

You may experience some of the following symptoms:

Seizures (fits), dizziness, shaking, confusion, headache, anxiety, chest pain.

If you stop taking DIRENTO SR 150 mg:

If you want to stop taking **DIRENTO SR 150 mg** tablets, talk to your doctor first so that he can advise you on how to stop gradually to minimise these effects.

After you stop using **DIRENTO SR 150 mg** your body may need time to adjust. The length of time this takes depends on the amount of **DIRENTO SR 150 mg** you were using and how long you used it.

4. Possible side effects:

DIRENTO SR 150 mg can have side effects.

Not all side effects reported for **DIRENTO SR 150 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DIRENTO SR 150 mg**, please consult your health care provider for advice.

If any of the following happens, stop taking **DIRENTO SR 150 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylaxis: this is an immediate hypersensitivity reaction resulting in life-threatening breathing difficulty, usually followed by collapse of the arteries and veins and shock.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing and breathing.
- Hives.
- Skin rash (including itchy, bumpy rash). Some skin rashes may need hospitalisation, especially if you have a sore mouth or sore eyes.
- Fainting.
- Pains in muscle or joints.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **DIRENTO SR 150 mg**. 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:

- If you have a seizure (fit). Symptoms of a fit include convulsions (seizures) and usually loss of consciousness. You may be confused afterwards and may not remember what has happened.
- If your skin or the whites of your eyes turn yellow (jaundice) and/or inflammation of your liver (hepatitis).

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:

- loss of appetite (anorexia), weight loss
- sleeplessness, restlessness or anxiety
- headache, feeling shaky (tremor), dizziness, changes in the taste of food
- visual disturbances
- ringing in the ears
- increase in blood pressure, flushing
- dry mouth, nausea, vomiting, stomach pain, constipation
- skin rash (sometimes due to an allergic reaction), itching, sweating
- fever, feeling weak, chest pain

Less frequent side effects:

- pain in a joint, pain in a muscle or muscles, fever in association with rash
- changes in blood sugar levels
- feeling confused, depressed, aggressive, hostile, irritable, restless, strange dreams (including nightmares), 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), thoughts of harming or killing one self while taking **DIRENTO SR 150 mg** or soon after stopping treatment, loss of contact with reality and unable to think or judge clearly (psychosis)
- difficulty with concentration, fits, dystonia, unsteadiness when walking or co-ordination (ataxia), uncontrolled movements, loss of memory, unpleasant tingling feeling in arms or legs (paraesthesia), fainting
- rapid/fast heartbeat
- feeling faint when you stand up suddenly, because your blood pressure falls
- increase in liver enzymes

- 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)
- twitching
- urinating (passing water) more, or less than usual

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. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **DIRENTO SR 150 mg**.

5. HOW TO STORE DIRENTO SR 150 mg:

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep the bottle well closed.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What DIRENTO SR 150 mg contains:

The active substance is bupropion hydrochloride.

Each **DIRENTO 150 mg** sustained-release tablet contains 150 mg of bupropion hydrochloride.

The other ingredients are: Colloidal silicon dioxide, hydrochloric acid, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, stearic acid {colourant: light green opadry II (40L11438); clear aqueous film-coating solution: clear opadry YS-1-7006}.

What DIRENTO SR 150 mg looks like and contents of the pack:

DIRENTO SR 150 mg: A light green film-coated, round, biconvex, beveled edge tablet debossed with **M** over **U12** on one side of the tablet and blank on the other side.

DIRENTO SR 150 mg 60's will be packed using a 120 ml round, beige, opaque high density polyethylene (HDPE) bottle with a 38 mm beige plastic child-resistant closure with a tamper evident inner seal, bonded to a white lined pulp board liner. Three 2 gm, 2 in 1 combination canister desiccants are employed.

DIRENTO SR 150 mg 100's will be packed using a 150 ml round, beige, opaque high density polyethylene (HDPE) bottle with a 38 mm beige plastic child-resistant closure with a tamper evident inner seal, bonded to a white lined pulp board liner. Three 2 gm, 2 in 1 combination canister desiccants are employed.

DIRENTO SR 150 mg 500's will be packed using a 532,26 ml oblong, beige, opaque high density polyethylene (HDPE) bottle, with a 53 mm beige fine ribbed plastic child-resistant closure with a tamper evident inner seal, bonded to a white lined pulp board liner. Five 6 gm, 2 in 1 packet desiccants are employed.

Holder of Certificate of Registration:

TRINITY PHARMA (PTY) LTD.

106 16th Road,

Building 2,

TRINITY PHARMA (PTY) LTD

DIRENTO SR 150 mg

Each sustained-release tablet contains 150 mg of bupropion hydrochloride.

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Sequence 0002 Clinical

Proposed Clean Patient Information Leaflet

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