

PACKAGE LEAFLET: INFORMATION FOR THE USER

SCHEDULING STATUS

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PROPRIETARY NAME (and dosage form)

B-Wellness Hormone Balance Tablets 60's

ACTIVE INGREDIENTS:

EACH SERVING CONTAINS:	mg PER 2 TABs	%NRV*
Withania Somnifera (Ashwagandha) [Root, as a 15:1 extract]	100	***
Actaea Racemose (Black Cohosh) [Root, as a 8:1 extract]	100	***
Eleutherococcus Senticosus (Siberian Ginseng) [Root, as a 10:1 extract]	60	***
Vitex Agnus-Castus (Chaste Tree) [Berry, as a 4:1 extract]	55	***
Lepidium Meyenii (Maca) [Root, as a 4:1 extract]	50	***
Inositol	100	***
Glycyrrhiza; L (Liquorice) [Root, as a 4:1 extract standardised to 20% Glycyrrhizic acid] Providing: Glycyrrhizic acid	15 12	*** **
Angelica Sinensis (Dong Quai) [Root, as a 4:1 extract]	10	***
Rhodiola Rosea (Golden Root) [Root, as a 4:1 extract standardised to 3% Rosavins, 1% Salidroside] Providing: Rosavins Providing: Salidroside	10 1.2 0.4	*** ** **
Alpha-Tocopheryl Acetate 50% Providing: Vitamin E (TE)	33 12	80
Nicotinamide (Vitamin B3)	17.6	110
Calcium D-Pantothenate Providing: Pantothenic Acid (Vitamin B5) elemental	5.5 5.06	101
Methylcobalamin Providing: Cobalamine (Vitamin B12) elemental	2.64 2.64 mcg	108
Pyridoxine HCl Providing: Pyridoxine (Vitamin B6) elemental	2 1.65	97
Thiamine HCl Providing: Thiamine (Vitamin B1) elemental	1.5 1.18	98
Riboflavin-5-Phosphate Providing: Riboflavin (Vitamin B2) elemental	1.43 1.18	91
5-Methyltetrahydrofolate Providing: Folate (Vitamin B9) elemental	0.84 0.44	110

* NRV (Nutrient Reference Values for persons 4 years and older)

** No NRV established

*** DHE = Dried Herb Equivalent

Contains No Sugar, Non-nutritive Sweeteners, colourant or flavourant

Excipients: Micro Crystalline Cellulose, Magnesium Stearate, Silicon Dioxide

Category D

Complementary Medicine

Discipline: Western Herbal Medicine

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you. Keep this leaflet. You may need to read it again.

B-Wellness Hormone Balance Tablets is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use B-Wellness Hormone Balance Tablets carefully to get the best results from it.

Do not share B-Wellness Hormone Balance Tablets with any other person.

Ask your healthcare provider or Pharmacist if you need more information or advice.

What is in this leaflet?

1. What B-Wellness Hormone Balance Tablets is, and what it is used for
2. What you need to know before you take B-Wellness Hormone Balance Tablets
3. How to take B-Wellness Hormone Balance Tablets
4. Possible side effects
5. How to store B-Wellness Hormone Balance Tablets
6. Contents of the pack and other information

1. What B-Wellness Hormone Balance Tablets is, and what it is used for

Hormones are endogenous (produced by the body itself) molecules, which serve as messengers and feed-back agents, while also often fulfilling an active role in myriad biochemical processes. Hormones are a critical component in ensuring that the body-systems function correctly. A disruption in one or more hormones, which may result from nutritional deficiencies, illness, stress or other factors, inevitably leads to dysregulation and imbalance in other systems as well.

The active ingredients of B-Wellness Hormone Balance Tablets have been composed with a view to supporting healthy hormone production and balance for both men and women. The herbs in B-Wellness Hormone Balance Tablets are known as adaptogens - plants that assist the body in balancing all the different hormones. Adaptogens have been used by healers for centuries to assist patients with hormone-based issues.

The range of B-Vitamins as well as Vitamin E have also been shown to be crucial in the production of hormones and the correct functioning of the communication systems.

Possible indications for B-Wellness Hormone Balance Tablets include:

- Support healthy hormone production and balance
 - o Menopause, male midlife changes
 - o PMS
 - o Sexual function
 - o Improved mood
- Stress and trauma management
 - o Improve energy and reduce fatigue
 - o Reduce anxiety, depression, nervous conditions
 - o Improve concentration, memory, sleep
- Endocrine disruption (e.g excessive exposure to PCB's in plastic, DDT, DDE, dioxins and certain plants such as soya)

2. What you need to know before you take B-Wellness Hormone Balance Tablets

Do not take B-Wellness Hormone Balance Tablets:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of B-Wellness Hormone Balance Tablets (listed in section 6)
- If you are receiving warfarin, heparin, or other anticoagulant/antiplatelet therapy (Dong Quai)
- If you have been diagnosed with breast cancer (Dong Quai)
- If you are pregnant or breast feeding. (Dong Quai, Liquorice Root)
- If you have been diagnosed with hormone sensitive prostate cancer (Ashwagandha)
- If you have been diagnosed with bipolar disorder (Rhodiola Rosea)

Warnings and precautions

Keep out of reach of children.

Unless otherwise prescribed, do not exceed the stated daily dose.

If you are using ANY prescribed medication FIRST consult your Doctor or Pharmacist before using B-Wellness Hormone Balance Tablets.

If symptoms develop, worsen or persist, consult a relevant health care provider.

Not suitable for children unless under the care of a relevant health care provider.

Consult a relevant health care provider before use if you suspect that you may have insulin resistance, high blood glucose levels or diabetes (due to inositol content, Liquorice root and Siberian Ginseng).

Consult a relevant health care provider before use if you are using hormone replacement therapy, oral contraceptives, or if you have a history of estrogen-dependent tumors, endometrial cancer, thromboembolic disease, or stroke (Dong Quai).

Consult a relevant health care provider before use (due to Black Cohosh content) if you have been diagnosed with liver disease; have past or present cancer of the breast, ovary, or uterus; have a history of endometriosis or uterine fibroids; have a genetic blood-clotting disorder; or if you have ever had a kidney transplant.

Consult a relevant health care provider (due to Chaste Tree content) if you are taking drugs that contain hormones (such as birth control pills and hormone replacement therapy) or drugs that affect dopamine levels (such as levodopa-carbidopa, ropinirole, and pramipexole) or if you suffer from mental health conditions, Parkinson disease, Restless legs syndrome or Cancer (particularly hormone-sensitive forms such as breast/prostate cancer).

Consult a relevant healthcare practitioner prior to use (due to Siberian Ginseng content) if you are at a high risk for infection (e.g. have had a transplant, are on chemo, or have an autoimmune disease) or if you have heart problems, bleeding problems, blood pressure problems, diabetes, mental health problems or are running a fever.

Consult a relevant healthcare practitioner prior to use (due to Liquorice Root content) if you suffer from high blood pressure, low potassium, edema, liver or kidney problems.

Other medicines and B-Wellness Hormone Balance Tablets

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

Black Cohosh may interact with ANY medication that affects liver function.

Consult a medical practitioner prior to use.

Liquorice Root may interact with anti-hypertensives, cardiac glycosides, anti-coagulants, diuretics, certain anti-psychotic medications (clozapine), estrogen derivatives, corticosteroids and others. Liquorice root may also enhance potassium-depletion which occurs with certain diuretics. Please consult your healthcare practitioner before use if you have been prescribed one of these medications.

Siberian Ginseng (Eleutherococcus senticosus) may assist in lowering blood sugar. Consult your healthcare practitioner prior to use if you are using diabetes medication to prevent hypoglycaemia. Siberian Ginseng may heighten the effect of sleeping medications such as lorazepam, phenobarbital, zolpidem or diphenhydramine - consult your healthcare practitioner and exercise extra care.

Ashwagandha and Rhodiola Rosea may interact with the MAOI type of anti-depressants.

Rhodiola Rosea may interact with other stimulants.

See Warnings and Precautions.

B-Wellness Hormone Balance Tablets with food

Taking B-Wellness Hormone Balance Tablets with alcohol may increase sleepiness or drowsiness.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, do not use this medicine.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

Taking B-Wellness Hormone Balance Tablets may cause sleepiness or drowsiness. Use with care if you are planning to undertake any activity or task requiring mental alertness such as driving or operating machines or equipment.

3. How to take B-Wellness Hormone Balance Tablets

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

Take B-Wellness Hormone Balance Tablets exactly as described in this leaflet or as prescribed by your Doctor or Pharmacist.

Dosage and Directions for use

Adults: Take 2 tablets daily preferably in the evening before bed, or as prescribed by your Doctor or Pharmacist.

Not suitable for use in Children.

Do not exceed the stated daily dosage.

If you take more B-Wellness Hormone Balance Tablets than you should,

you may experience irritability, nervousness, headache, high blood pressure, increased bleeding, acne, gastrointestinal symptoms such as heartburn, bloating, diarrhoea, nausea or abdominal cramping.

In the event of overdosage, stop using B-Wellness Hormone Balance Tablets and consult your Doctor or Pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take B-Wellness Hormone Balance Tablets, do not take a double dose to make up for forgotten doses.

4. Possible side effects

B-Wellness Hormone Balance Tablets can have side effects.

Not all side effects reported for B-Wellness Hormone Balance Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking B-Wellness Hormone Balance Tablets, please consult your healthcare provider for advice.

If any of the following happens, stop taking B-Wellness Hormone Balance Tablets and tell your doctor:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash, acne or itching,
- Diarrhoea, nausea or vomiting, stomach pain, dark urine or very pale stools,
- Difficulty breathing, tightness of chest or throat,
- Increased bleeding, spotting, dizziness, rise in blood pressure,
- Fever, gynecomastia, dry mouth, increased saliva, headache, insomnia.

5. How to store B-Wellness Hormone Balance Tablets

Store all medicines out of reach of children.

- Store in a cool, dry place below 25°C.

6. Contents of the pack and other information

What B-Wellness Hormone Balance Tablets contains

- The active ingredients of B-Wellness Hormone Balance Tablets are (per 2 tablets): Ashwagandha [Root] (100 mg), Black Cohosh [Root] (100 mg), Inositol (100 mg), Siberian Ginseng [Root] (60 mg), Chaste Tree [Root] (55 mg), Maca [Root] (50 mg), Vitamin E (33 mg), Vitamin B3 (17.6 mg), Liquorice Root (15 mg), Dong Quai [Root] (40 mg), Golden Root (10 mg), Vitamin B5 (5.06 mg), Vitamin B12 (2.64 mg), Vitamin B6 (1.65 mg), Vitamin B1 (1.5 mg), Vitamin B2 (1.43 mg) and Vitamin B9 (0.44 mg)
- Excipients: Micro Crystalline Cellulose, Magnesium Stearate, Silicon Dioxide

What B-Wellness Hormone Balance Tablets looks like and contents of the pack

- Round, biconvex, brown-speckled tablet (10 mm diameter)
- 60 tablets in a 140ml glass frosted amber jar with 38 mm aluminum PRET screw cap

Applicant:

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