

✓ lactose-free
✓ gluten-free



Men Active



Patient information leaflet

SCHEDULING STATUS: **S0**

Doppelherz® aktiv Men Active, soft gelatine capsules
Lepidium meyenii (Maca), *Centella asiatica* (Centella, Gotu
cola), *Ginseng radix* (Ginseng), caffeine, D- α -tocopherol
(vitamin E), zinc, selenium.
Sugar-free.

Complementary Medicine.

Discipline specific, combination product for humans.

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.

Doppelherz® aktiv Men Active is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **Doppelherz® aktiv Men Active** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Doppelherz® aktiv Men Active** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **Doppelherz® aktiv Men Active** is and what it is used for.
2. What you need to know before you take **Doppelherz® aktiv Men Active**.
3. How to take **Doppelherz® aktiv Men Active**.
4. Possible side effects.
5. How to store **Doppelherz® aktiv Men Active**.
6. Contents of the pack and other information.

1. What **Doppelherz® aktiv Men Active** is and what it is used for

Doppelherz® aktiv Men Active is a health supplement combined with herbal substances. It offers the following benefits for adult men –

- To maintain good health.
- To have a fulfilling intimate life.
- It temporarily promotes alertness and wakefulness.
- It temporarily assists to relieve fatigue.
- It temporarily assists to increase mental activity.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition, as well as mental and physical performance.

2. What you need to know before you take **Doppelherz® aktiv Men Active**

Do not take **Doppelherz® aktiv Men Active**:

- If you are hypersensitive (allergic) to any of the ingredients of **Doppelherz® aktiv Men Active** (listed in section 6).

Warnings and precautions

Take special care with **Doppelherz® aktiv Men Active**:

- If you have a psychological disorder and/or a condition such as frequent anxiety or depression.
- If you are diabetic, consult with your health care professional before use.
- If you have glaucoma, consult with your health care professional before use.
- If you have high blood pressure, consult with your health care professional before use.
- If you have a problem with your bladder function (overactive bladder syndrome) that causes the sudden need to urinate, consult with your health care professional before use.
- If you have heart disease.

Special precaution is necessary:

- CONTAINS CAFFEINE. Contains 25 mg caffeine per capsule. A cup of instant coffee contains approximately 80 mg caffeine.
- Use of caffeine may result in you not getting enough sleep.

- Consult with your health care professional if you are taking any other medicine (such as lithium) including chronic, complementary or traditional medicines, at the same time as caffeine.
- Consumption with other caffeine-containing products or foods (e.g. medications, coffee, tea, colas, cocoa, quarana, maté) is not recommended.
- Discontinue use two weeks prior to surgery due to caffeine content of this medicine.

Children and adolescents

Doppelherz® aktiv Men Active is not suitable for children under the age of 18 years.

Other medicines and **Doppelherz® aktiv Men Active**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Consult your doctor, pharmacist or other healthcare professional if you are taking or using any of the following:

- *Antidepressants, blood thinners, digoxin* – consult with your health care practitioner before you take any of these medicines at the same time as ginseng.
- *Lithium* – when you stop taking caffeine it can cause an increase in lithium's levels and adverse effects.
- *Medicines that increase blood pressure (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine)* – do not take together with caffeine.
- *Clozapine* – if taken at the same time as caffeine it might increase clozapine's levels and its adverse effects.
- *Selumetinib* – taken with vitamin E, can result in a total daily dose of vitamin E that exceeds safe limits and therefore might increase the risk of bleeding caused by vitamin E.
- *Penicillamine, phosphorous-containing preparations and tetracyclines* – might reduce the absorption of zinc, hence reduce zinc levels.
- *EDTA chelator* – might increase urinary zinc excretion, hence reduce zinc levels.
- *Copper, fluoroquinolones, iron, penicillamine and tetracyclines* – their absorption can be reduced by zinc supplements. Doses should be separated by a number of hours.

Doppelherz® aktiv Men Active with food

- Phytates (found in seeds, nuts, corn, legumes, unprocessed whole grains, cereals, rice) – decrease the gastrointestinal absorption of zinc.

Pregnancy and breastfeeding

This medicine is not indicated for use in women.

Driving and using machines

Doppelherz® aktiv Men Active does not have any influence on these abilities.

It is not always possible to predict to what extent **Doppelherz® aktiv Men Active** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **Doppelherz® aktiv Men Active** affects them.

3. How to take **Doppelherz® aktiv Men Active**

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

Always take **Doppelherz® aktiv Men Active** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adult males 18 years and older:

- Take one capsule orally daily.
- Take at a mealtime to reduce possible gastrointestinal effects.
- Take with enough liquid to swallow the capsule.
- Do not chew the capsule.
- Check with your health care provider if you wish to take these capsules for longer than 3 months.



If you take more Doppelherz® aktiv Men Active than you should

Some of the signs and symptoms of overdosage may include – Feeling anxious, rapid heart rate, irregular heart rate, sleeplessness, restlessness, nervousness, shaking, headache, worsen your bipolar disorder or bring about your next epileptic seizure; gastrointestinal disturbances, blurred vision, feeling dizzy, tiredness, weakness, increased tendency to bleed when taking medicines that reduce blood clotting; kidney disorder.

In the event of overdosage, stop taking the medicine and consult your doctor or pharmacist. If neither is available, seek help at your nearest hospital or poison centre. Take this leaflet and the product container with you for identification.

If you forget to take Doppelherz® aktiv Men Active

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

If you stop taking Doppelherz® aktiv Men Active

You may not achieve the desired benefits if you stop taking it regularly.

4. Possible side effects

Doppelherz® aktiv Men Active can have side effects.

Not all side effects reported for Doppelherz® aktiv Men Active are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Doppelherz® aktiv Men Active please consult your health care provider for advice.

If any of the following happens, stop taking Doppelherz® aktiv Men Active and tell your doctor immediately or go to the casualty department at your nearest hospital: (Take this information leaflet with you)

- Hypersensitivity reactions such as urticaria (body's immune response to a trigger resulting in raised red rash)
- Itching

These are all very serious side effects. If you have them, you may have had a serious reaction to Doppelherz® aktiv Men Active. 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:

- Increase in pressure in the eye if you already have glaucoma
- Diuresis (increase in volume of urine produced)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common/frequent side effects:

- Headache
- Insomnia (not able to sleep)
- Restlessness (not able to relax)
- Gastrointestinal upset or disorders (upset of intestines)
- Gastric irritation, gastritis (irritation of stomach lining)
- Nausea (feeling sick)
- Vomiting (throwing up)
- Diarrhoea (runny stool)
- Abdominal pain (pain in stomach area)
- Abdominal cramps (cramps in stomach area)
- Metallic taste
- Muscle tremors (shaking of arms or legs)

Frequency not known:

- Sleep disturbances (bad sleep patterns)
- Anxiety (feeling worried and fearful)
- Jitteriness (slight shaking of body)
- Nervousness (feeling worried)
- Faecal incontinence (leaking stool contents)
- Constipation (hard stool)
- Heartburn (acid backs up in the throat)
- Indigestion, dyspepsia (discomfort in stomach area)
- Dry mouth
- Mouth irritation (allergic reaction in mouth)
- Flu-like symptoms (feeling flush)

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 or pharmacist. 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 Doppelherz® aktiv Men Active.

Alternatively, side effects may be reported directly to Ivodent cc.

5. How to store Doppelherz® aktiv Men Active

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- Protect from light and moisture.
- Do not use after the expiry date stated on the blister strip and carton.

Do not use Doppelherz® aktiv Men Active if you notice deterioration of the capsules.

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 Doppelherz® aktiv Men Active contains:

- The active substances are:

	Per capsule:
<i>Lepidium meyenii</i> W. (Maca) [roots, 15-25:1 extract standardized to β-sterosterol NLT 2,5 % providing 3750-6250 mg dried herb equivalent]	250 mg
<i>Centella asiatica</i> L. (Centella, Gotu cola) [aerial parts, 2,5-3,5:1 extract standardized to total triterpenoid derivatives NLT 3,0 % asiaticoside providing 62,5-87,5 mg dried herb]	25 mg
<i>Ginseng radix</i> (Ginseng) [root, 4,5-5,5:1 extract standardized to ginsenosides NLT 4,0 % providing 112,5-137,5 mg dried herb]	25 mg
Caffeine	25 mg
D-α-tocopherol (Vitamin E)	5 mg
Zinc oxide providing zinc	9,53 mg 7,5 mg
Sodium selenite providing selenium	60 microgram 25 microgram

- The other ingredients are soybean oil, coconut oil, lecithins (soy), mono- and diglycerides of fatty acids, soft gelatin capsule shell (containing colourant iron oxides and hydroxides red, E172).

What Doppelherz® aktiv Men Active looks like and contents of pack

Red, oblong, soft gelatine capsules.

30 capsules in a cardboard carton as 3 blister strips of 10 capsules each. The blister strips are clear PV-DC foil on aluminium foil.

Holder of Certificate of Registration

Ivodent cc
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Registration number

To be allocated.

Access to the corresponding Professional Information

The Professional Information can be found at www.doppelherz.co.za or can be obtained from Ivodent cc.



Manufactured by:


Queisser
PHARMA

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