



✓ lactose-free
✓ gluten-free

suitable for vegetarians + vegans

Anti-Stress

Patient information leaflet



SCHEDULING STATUS: S0

Doppelherz® aktiv Anti-Stress, film-coated tablets
Ginkgo biloba, *Melissa officinalis*, thiamine (vitamin B1), riboflavin (vitamin B2), niacin, pantothenic acid, pyridoxine (vitamin B6), cyanocobalamin (vitamin B12), biotin, folic acid.
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 Anti-Stress is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **Doppelherz® aktiv Anti-Stress** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Doppelherz® aktiv Anti-Stress** 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 Anti-Stress** is and what it is used for.
2. What you need to know before you take **Doppelherz® aktiv Anti-Stress**.
3. How to take **Doppelherz® aktiv Anti-Stress**.
4. Possible side effects.
5. How to store **Doppelherz® aktiv Anti-Stress**.
6. Contents of the pack and other information.

1. What **Doppelherz® aktiv Anti-Stress** is and what it is used for

Doppelherz® aktiv Anti-Stress is a health supplement combined with herbal substances. It offers the following benefits for adults –

- It supports the nervous function, helping with concentration and alertness.
- It promotes serenity and relaxation, by relieving anxiety and nervousness, and giving you a better night's sleep.

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 Anti-Stress**.

Do not take **Doppelherz® aktiv Anti-Stress**:

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

Warnings and precautions

Take special care with **Doppelherz® aktiv Anti-Stress**:

- If you have epilepsy – taking vitamin B6 may be of some help against the convulsions.
- If you have a bleeding disorder.
- If you have diabetes.
- If you have glucose-6-phosphate dehydrogenase deficiency as there may be a possible increase in haemolytic anaemia.
- If you have an active peptic ulcer.
- If you drink a lot of alcohol.
- If you have heart disease.
- If you are suspected of having vitamin B12 deficiency but it has not yet been confirmed.

As a special precaution stop taking **Doppelherz® aktiv Anti-Stress** at least two weeks before you have an operation, due to the risk of bleeding.

Children and adolescents

Do not give **Doppelherz® aktiv Anti-Stress** to children under 18 years of age.

Other medicines and **Doppelherz® aktiv Anti-Stress**

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

Consult your doctor or pharmacist or other health care professional if you are taking any of the following:

- **Anticoagulants, antiplatelet medicines** – *Ginkgo biloba* may affect platelet aggregation and increase risk of bleeding when taken with warfarin.
- **Diuretics in high doses** – can reduce levels of vitamin B1.
- **Boron** – might reduce levels of vitamin B2.
- **Aspirin in large doses** – might reduce the clearance (removal) of niacin from the body.
- **Medicines that bind bile acids (such as colestyramine)** – can bind and reduce levels of niacin.
- **Insulin, oral hypoglycaemics** – niacin can increase blood sugar levels and thereby may increase requirements for these substances.
- **Cycloserine** – can reduce vitamin B6 levels.
- **Levodopa** – its metabolism may be increased and its effects reduced by vitamin B6.
- **Altretamine** – its activity is reduced by vitamin B6.
- **Phenobarbital, phenytoin** – their serum concentrations and effects are reduced by vitamin B6.
- **Neomycin, aminosalicilic acid, histamine H2-antagonists, omeprazole, colchicine** – may reduce vitamin B12 levels.
- **Phenytoin** – its serum concentration has been reduced by folic acid.
- **Phenobarbital** - its anticonvulsant effect may be reduced by folic acid, resulting in seizures.

Doppelherz® aktiv Anti-Stress with food

- **Psyllium (a dietary fibre)** – might reduce absorption of vitamin B2 from supplements.

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.

The safety of taking **Doppelherz® aktiv Anti-Stress** during pregnancy and breastfeeding has not been established, therefore avoid using.

Driving and using machines

Doppelherz® aktiv Anti-Stress should not have any influence on these abilities.

It is not always possible to predict to what extent **Doppelherz® aktiv Anti-Stress** 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 Anti-Stress** affects them.

3. How to take **Doppelherz® aktiv Anti-Stress**

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

Always take **Doppelherz® aktiv Anti-Stress** 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 adults is:

- One tablet orally daily.
- Take at a mealtime to reduce possible gastrointestinal effects.
- Take with enough liquid to swallow the tablet.
- Do not chew the tablet.
- Do not exceed the recommended dose without consulting your health care provider.

If you take more **Doppelherz® aktiv Anti-Stress** than you should

Some of the signs and symptoms of overdosage include –

Yellow urine; gastrointestinal disturbances, jaundice, effects on the eyes; damage to nerves that results in numbness and pain usually in hands and feet.

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 Anti-Stress**

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



If you stop taking Doppelherz® aktiv Anti-Stress

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

4. Possible side effects

Doppelherz® aktiv Anti-Stress can have side effects.

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

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

- Seizures (fits)
- Oedema (swollen tissue due to fluid build-up)
- Breast soreness or enlargement
- Bleeding disorders (less frequent)
- Dermatitis (irritation of skin) (less frequent)
- Other allergic reactions (frequent)
- Hypersensitivity reactions (body's immune response to a trigger) (less frequent)
- Skin hypersensitivities (dry, burning, itchy skin)
- Allergic skin reactions (skin irritated by something usually harmless)
- Rash (irritated, swollen skin)
- Itching
- Erythema (redness of skin)
- Urticaria (raised, itchy, red bumps)
- Photosensitivity (immune system reaction triggered by sunlight)
- Acneiform (pus filled bumps, acne) (less frequent) and bullous eruptions (fluid filled blisters on skin).

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

- Heart palpitations (fast beating, pounding heart rate)
- Arrhythmia (irregular heartbeat) (less frequent)
- Wheezing (whistling sound while breathing) (less frequent)

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
- Dizziness (feeling unsteady)
- Somnolence (desire to sleep)
- Abdominal pain (pain in stomach area)
- Gastrointestinal disturbances
- Nausea (feeling sick)
- Vomiting (throwing up)
- Diarrhoea (runny stool)
- Heartburn (stomach acid backs up into your throat)
- Loss of appetite (not feeling hungry)

Uncommon/less frequent side effects:

- Mild gastrointestinal discomfort or pain
- Dry mouth
- Constipation (hard stool)

Frequency not known:

- Increased desire to sleep, sedation (feeling sleepy)
- Paraesthesia (tingly, prickly feeling in arms, legs, hands or feet)
- Fever (raised body temperature)
- Chills (shivering)
- Hot flushing (sudden feeling of warmth)
- Malaise (feeling of illness)
- Tremor (shaking or trembling)
- Mild diarrhoea

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 Anti-Stress.

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

5. How to store Doppelherz® aktiv Anti-Stress

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 blister strip and carton.

Do not use Doppelherz® aktiv Anti-Stress if you notice deterioration of the tablets.

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 Anti-Stress contains:

- The active substances are:

	Per tablet:
<i>Ginkgo biloba</i> L. (Ginkgo) [leaves, 50:1 extract standardized to ginkgo flavonol glycosides 25 % providing 2500 mg of dried herb equivalent]	50 mg
<i>Melissa officinalis</i> L. (Melissa) [leaves 5,6:1 extract standardized to rosmarinic acid NLT 2,0 % providing 224 mg of dried herb equivalent]	40 mg
Thiamine mononitrate providing thiamine (Vitamin B1)	1,37 mg 1,1 mg
Riboflavin (Vitamin B2)	1,4 mg
Niacin (Vitamin B3)	16 mg
Calcium-D-pantothenate providing pantothenic acid (Vitamin B5)	6,04 mg 6 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B6)	1,69 mg 1,4 mg
Cyanocobalamin (Vitamin B12)	2,5 microgram
Biotin (Vitamin H)	50 microgram
Folic acid	200 microgram

- The other ingredients are dicalcium phosphate, microcrystalline cellulose, silicon dioxide, sodium carboxy methylcellulose, magnesium salts of fatty acids, cellulose. Tablet coating includes hydroxypropyl methyl cellulose, magnesium hydroxy carbonate, calcium carbonate, hydroxypropyl cellulose, talc, polyethylene glycol, yellow iron oxides (colourant, E172).

What Doppelherz® aktiv Anti-Stress looks like and contents of pack

Light green, round, film-coated tablets.

30 tablets in a cardboard carton as 2V blister strips of 15 tablets each. The blister strips are clear PV-DC foil on aluminium foil.

Holder of Certificate of Registration

Ivodent cc
Unit 14, St Michael's Park
Cnr St Michaels Rd and Howe St
Observatory 7925
Cape Town
Telephone: 0860 456 123
E-mail: doppelherz@ivohealth.co.za

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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

GmbH & Co. KG
Schleswiger Str. 74
24941 Flensburg
GERMANY

