



aktiv

Vitamins for Diabetics

Patient information leaflet



SCHEDULING STATUS:

Doppelherz® aktiv Vitamins for Diabetics, film-coated tablets
Thiamine (vitamin B₁), riboflavin (vitamin B₂), niacin, panto-
thenic acid, pyridoxine (vitamin B₆), cyanocobalamin (vitamin
B₁₂), ascorbic acid (vitamin C), D- α -tocopherol (vitamin E),
biotin, folic acid, magnesium, zinc, chromium, selenium.

Sugar-free

Complementary Medicine.

Health Supplement 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 impor-
tant information for you**

Doppelherz® aktiv Vitamins for Diabetics is available with-
out a doctor's prescription, for you to maintain your health.
Nevertheless, you still need to use **Doppelherz® aktiv Vita-
mins for Diabetics** carefully to get the best results from it.

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

1. What **Doppelherz® aktiv Vitamins for Diabetics** is and what it is used for

Doppelherz® aktiv Vitamins for Diabetics is a health supple-
ment. It offers the following benefits for adults –

- It provides vitamins and minerals that supplement the nutri-
tional needs of diabetics.
- Its combination of ingredients contributes to the main-
tenance of good health, as well as helping the body to meta-
bolize nutrients thereby contributing to energy production.
- It provides support for healthy glucose metabolism.

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 Vitamins for Diabetics**

Do not take **Doppelherz® aktiv Vitamins for Diabetics:**

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

Warnings and precautions

Take special care with **Doppelherz® aktiv Vitamins for
Diabetics**:

- If you have kidney disease, kidney failure or kidney stones.
- If you have increased urinary excretion of oxalate.
- If you have active ulcers in your gastrointestinal tract.
- 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 been confirmed.

Children and adolescents

Do not give **Doppelherz® aktiv Vitamins for Diabetics** to
children.

Other medicines and **Doppelherz® aktiv Vitamins for Diabetics**

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

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

- *Diuretics in high doses* – can reduce vitamin B₁ levels.
- *Boron* – might reduce vitamin B₂ levels.
- *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 (treat diabetes)* – niacin can increase your blood sugar levels and thereby increase requirements for these medicines.
- *Cycloserine* – can reduce vitamin B₆ levels.
- *Levodopa, altretamine* – their effectiveness may be reduced by vitamin B₆.
- *Phenobarbital, phenytoin* – their concentrations in the blood and effects are reduced by vitamin B₆ and folic acid.
- *Neomycin, aminosalicilic acid, histamine H₂-antagonists (H₂ blockers), omeprazole, colchicine* – may reduce vitamin B₁₂ levels.
- *Vitamin C* – may increase iron absorption in iron deficiency states.
- *Desferrioxamine (binds iron)* – achieves better iron excretion in presence of vitamin C.
- *Selumetinib* – can result in high levels of vitamin E and increase risk of bleeding.
- *Aminoglycoside antibiotics* – taken with magnesium can increase the risk for neuromuscular weakness.
- *Potassium-sparing diuretics* – can cause increased levels of magnesium.
- *Tetracyclines, quinolone antibiotics and bisphosphonates* – their absorption is decreased by oral magnesium salts. Doses should be separated by a number of hours.
- *Penicillamine antibiotics, phosphorus containing preparations, tetracycline antibiotics, EDTA chelator (binder)* – might reduce zinc levels.
- *Copper, fluoroquinolones, iron, penicillamine and tetracyclines* – their absorption is reduced by zinc supplements. Doses should be separated by a number of hours.

Doppelherz® aktiv Vitamins for Diabetics with food

- *Psyllium (a dietary fibre)* – might reduce absorption of vitamin B₂ from supplements.
- *Phytates (found in seeds, nuts, corn, legumes, unprocessed whole grains, cereals, rice)* – decrease the gastrointestinal absorption of zinc.

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.

Doppelherz® aktiv Vitamins for Diabetics is safe to take during pregnancy and breastfeeding at the recommended dosage.

Driving and using machines

Doppelherz® aktiv Vitamins for Diabetics should not have any influence on these abilities.

It is not always possible to predict to what extent **Doppelherz® aktiv Vitamins for Diabetics** 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 Vitamins for Diabetics** affects them.

3. How to take **Doppelherz® aktiv Vitamins for Diabetics**

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

Always take **Doppelherz® aktiv Vitamins for Diabetics** 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:

- Take 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 daily dose without consulting your health care provider.

If you take more **Doppelherz® aktiv Vitamins for Diabetics than you should**

Some of the signs and symptoms of overdosage may include –
Yellow urine; increased blood glucose levels, jaundice, effects on the eyes; numbness and pain due to nerve damage;
diarrhoea and other gastrointestinal disturbances; blurred vision, dizziness, tiredness, weakness, increased tendency to bleed;

heart and blood vessels complications, allergic skin reactions, change in sleep patterns, realistic dreams, irritability, excitability, hyperactivity, confusion, affected judgement;
thirst, low blood pressure, central nervous system depression, skeletal muscle paralysis, loss of tendon reflexes, difficulty breathing, irregular heartbeat, slow heart rate;
bleeding and blood loss into the gastrointestinal tract;

✓ lactose-free
✓ gluten-free



hair loss, nail changes, skin irritation, metallic taste, garlic odour of breath, fever, liver or kidney functional impairment, muscle tenderness, shaking, facial flushing.

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 Vitamins for Diabetics

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

If you stop taking Doppelherz® aktiv Vitamins for Diabetics

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

4. Possible side effects

Doppelherz® aktiv Vitamins for Diabetics can have side effects.

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

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

- Dermatitis (skin irritation) (frequent)
- Other allergic reactions (frequent)
- Hypersensitivity reactions (body's immune response to a trigger) (less frequent)
- Rash
- Itching
- Erythema (redness of skin)
- Urticaria (itchy, red, raised bumps)
- Systemic contact dermatitis (skin sensitive to an allergen, an allergy causing agent)
- Acute generalized exanthematous pustulosis (pimples on a background of red skin rash)
- Anaphylaxis (severe allergic reaction)
- Photosensitivity (immune system reaction triggered by sunlight)
- Breast soreness or enlargement

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

- Vision loss (less frequent)
- Acneiform eruptions (skin disease that looks like acne) (less frequent)
- Bullous eruptions (fluid-filled blisters)

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
- Somnolence (feeling sleepy)
- Diarrhoea (runny stool)
- Nausea (feeling sick)
- Vomiting (getting sick)
- Gastritis (inflamed stomach lining)
- Heartburn (acid backs up in the throat)
- Dyspepsia or indigestion (discomfort in upper abdomen)
- Abdominal pain (pain in stomach area)
- Abdominal cramps (cramps in stomach area)
- Loss of appetite (not feeling hungry)
- Gastrointestinal irritation (irritation of the stomach lining)
- Metallic taste

Frequency not known:

- Paraesthesia (tingling of hands)
- Fever (increase in body temperature)
- Chills (feeling cold)
- Hot flushing (feeling hot and sweaty)
- Dizziness (feeling unsteady)
- Malaise (general feeling of sickness)
- Tremor (trembling, shaking)
- Mild diarrhoea
- Watery diarrhoea
- Gastrointestinal disturbances (stomach upsets)
- Dry mouth
- Flu-like symptoms (feeling flush)
- Mouth irritation

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 Vitamins for Diabetics.

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

5. How to store Doppelherz® aktiv Vitamins for Diabetics

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 Vitamins for Diabetics 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 Vitamins for Diabetics contains:

- The active substances are:

	Per tablet:
Thiamine mononitrate providing thiamine (Vitamin B ₁)	2,47 mg 2 mg
Riboflavin (Vitamin B ₂)	1,6 mg
Niacin (Vitamin B ₃)	18 mg
Calcium-D-pantothenate providing pantothenic acid (Vitamin B ₅)	6,5 mg 6 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B ₆)	3,66 mg 3 mg
Cyanocobalamin (Vitamin B ₁₂)	9 microgram
L-ascorbic acid (Vitamin C)	200 mg
DL- α -tocopheryl acetate providing D- α -tocopherol (Vitamin E)	62,5 mg 42 mg
Biotin (Vitamin H)	150 microgram
Folic acid	450 microgram
Magnesium oxide providing magnesium	330,88 mg 200 mg
Zinc gluconate providing zinc	35,04 mg 5 mg
Chromium (III) chloride providing chromium	307 microgram 60 microgram
Sodium selenate providing selenium	73 microgram 30 microgram

• The other ingredients are microcrystalline cellulose, starch, silicon dioxide, palm fat (fully hydrogenated), gum arabic, mono- and diglycerides of fatty acids, magnesium salts of fatty acids, purified water. Tablet coating includes hydroxypropyl methyl cellulose, magnesium hydroxide carbonate, calcium carbonate, hydroxypropyl cellulose, talc, polyethylene glycol, iron oxide yellow (colourant, E172).

What Doppelherz® aktiv Vitamins for Diabetics looks like and contents of pack

Ocher, mottled, oval, oblong film-coated tablets, with a snap tab on both sides.

30 Tablets in a cardboard carton as 3 blister strips of 10 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

This leaflet was last revised in

First publication March 2024.

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:



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

