

✓ lactose-free
✓ gluten-free

suitable for
vegetarians



Active Meno



Patient information leaflet

SCHEDULING STATUS: **S0**

Doppelherz® aktiv Active Meno, film-coated tablets
Soy isoflavones, thiamine (vitamin B₁), riboflavin (vitamin B₂),
pyridoxine (vitamin B₆), cyanocobalamin (vitamin B₁₂), chole-
calciferol (vitamin D₃), biotin, folic acid, calcium.
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 Active Meno is available without a doctor's
prescription, for you to maintain your health. Nevertheless, you
still need to use **Doppelherz® aktiv Active Meno** carefully to
get the best results from it.

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

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

Doppelherz® aktiv Active Meno is a health supplement. It
offers the following benefits for adults –

- It provides soy isoflavones, vitamins and a mineral for the
woman's well-being during and after menopause.
- It reduces the symptoms associated with menopause, such
as hot flashes and night sweats.
- Calcium intake, when combined with sufficient vitamin D,
a healthy diet, and regular exercise, may reduce the risk of
developing osteoporosis in adults over 50 years of age.

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 Active Meno**

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

- If you are hypersensitive (allergic) to any of the ingredients
of **Doppelherz® aktiv Active Meno** (listed in section 6).
- If you have high levels of vitamin D.
- If you have high levels of calcium.
- If you currently have or previously had breast cancer or breast
tumours, or a predicted chance of getting breast cancer,
as shown on the mammogram or the biopsy, or a family
member has breast cancer.

Warnings and precautions

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

- If you have kidney disease, kidney failure or kidney stones.
- If you have histoplasmosis (infection caused by fungal
spores), sarcoidosis (collection of inflammatory cells in the
body) or hyperparathyroidism (production of too much
parathyroid hormone in the body), then vitamin D may
increase your calcium levels.
- If you have heart disease.
- If you have high levels of calcium.
- If you are suspected of having vitamin B₁₂ deficiency but it
has not yet been confirmed.

Consult your health care provider:

- If your symptoms get worse while taking this medicine.
- If you are taking blood thinning medicine.
- If you have a history of hormonal or gynaecological disease,

such as cancer of the ovaries, endometriosis or fibroids
(growths) in the uterus.

- If you have liver disease or you develop liver type symptoms
such as pain in the abdomen (stomach area), jaundice or dark
urine.
- If you are taking hormone replacement therapy (HRT),
including thyroid hormone replacement therapy.
- If you are getting breast pain, feeling of discomfort or
tenderness, or you are repeatedly menstruating (having your
periods too often) or getting uterine spotting. If you have any
of these, stop taking this medicine.

Special precaution is necessary if you have high phosphate levels
that need to be controlled while you are also taking vitamin D.

Children and adolescents

Do not give **Doppelherz® aktiv Active Meno** to children.

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

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 health care profes-
sional if you are taking or using any of the following:

- *Antidiabetes medicines* – their lowering of blood glucose levels
can be enhanced by soy isoflavones.
- *Levothyroxine* – its absorption might be reduced by soy
products.
- *Diuretics in high doses* – can reduce vitamin B₁ levels.
- *Boron* – might reduce vitamin B₂ levels.
- *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, aminosalicylic acid, histamine H₂-antagonists (H₂
blockers), omeprazole, colchicine* – may reduce vitamin B₁₂
levels.
- *Calcipotriene (vitamin D analog), thiazide diuretics, calcium or
phosphate* – used or taken with vitamin D increases the risk
of high levels of calcium.
- *Digitalis glycosides* – their effects on the heart are increased
by calcium.
- *Biphosphonates, fluoride, some fluoroquinolones, and
tetracyclines* – their absorption is reduced by calcium salts.
Doses should be separated by at least 3 hours.

Doppelherz® aktiv Active Meno with food

- *Psyllium (a dietary fibre)* – might reduce absorption of
vitamin B₂ from supplements.
- *Bran (such as wheat, rice, oats, rye)* - decreases the gastro-
intestinal absorption of calcium.

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 Active Meno is not recommended for use
during pregnancy and breastfeeding.

Driving and using machines

Doppelherz® aktiv Active Meno should not have any influence
on these abilities.

It is not always possible to predict to what extent **Doppelherz®
aktiv Active Meno** 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 Active Meno affects them.

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

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

Always take **Doppelherz® aktiv Active Meno** 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.
- The tablet can be divided in two halves if necessary.
- Use for a minimum of 2 weeks to see beneficial effects.
- Do not exceed the recommended daily dose without consulting your health care provider.
- Check with your health care provider if you wish to take these tablets for longer than 6 months.

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

The signs and symptoms of overdose may include – Yellow urine; numbness and pain due to nerve damage; weight loss, tiredness, nausea and vomiting, constipation or diarrhoea, frequent urination, frequent urination at night, sweating, headache, thirst, drowsiness, dizziness; cardiovascular complications, allergic skin reactions, altered sleep patterns, vivid dreams, irritability, excitability, hyperactivity, confusion, impaired judgement; pain in stomach area, muscle weakness, mental disturbances, calcium deposits in kidneys, kidney stones.

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 Active Meno

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

If you stop taking Doppelherz® aktiv Active Meno

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

4. Possible side effects

Doppelherz® aktiv Active Meno can have side effects.

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

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

- Dermatitis (skin irritation) (less frequent)
- Skin and other allergic reactions (frequent)
- Hypersensitivity reactions (body's immune response to a trigger) (less frequent)
- Rash
- Itching
- Erythema (redness of skin)
- Urticaria (raised red 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 Active Meno**. 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:

- Acneiform eruptions (skin disease that looks like acne)
- 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)
- Constipation (hard stool)
- Nausea (feeling sick)
- Vomiting (throwing up)
- Heartburn (acid backs up in the throat)
- Abdominal pain (pain in stomach area)
- Loss of appetite (not feeling hungry)
- Stomach upset
- Belching (burping)
- Bloating (full, tight stomach, gas build up)
- Flatulence (passing gas)

Frequency not known:

- Paraesthesia (tingling of hands)
- Fever (increase in body temperature)
- Chills (feeling cold)
- Hot flushing (feeling hot and sweaty)
- Gastrointestinal disturbances, irritation, discomfort (stomach upset, irritation or feeling uncomfortable)
- Malaise (general feeling of sickness)

- Tremor (trembling, shaking)
- Mild diarrhoea (soft stool)
- Dizziness (feeling unsteady)
- Dry mouth

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 Active Meno**.

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

5. How to store Doppelherz® aktiv Active Meno

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 Active Meno** if you notice any 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 Active Meno** contains:

- The active substances are:

	Per tablet:
Soy isoflavones concentrate from <i>Glycine max</i> L. [seed/soybean] providing soy isoflavones (equivalent to 33,43 mg AIE total isoflavones with 17,74 mg from genistein)	125 mg 50 mg
Thiamine hydrochloride providing thiamine (Vitamin B ₁)	1,78 mg 1,4 mg
Riboflavin (Vitamin B ₂)	1,6 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B ₆)	2,39 mg 2 mg
Cyanocobalamin (Vitamin B ₁₂)	3 microgram
Cholecalciferol providing vitamin D ₃	1,81 mg 5 microgram
D-biotin (Vitamin H)	150 microgram
Folic acid	400 microgram
Calcium carbonate providing calcium	1253,25 mg 500 mg

• The other ingredients are microcrystalline cellulose, polyvinylpyrrolidone, fatty acids, cross-linked sodium carboxy methyl cellulose, magnesium salts of fatty acids. Tablet coating: hydroxypropyl methyl cellulose, talc, microcrystalline cellulose, iron oxide yellow (colourant, E172), glycerol.

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

Mottled ochre, 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
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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:



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