



**aktiv**

# Pregna

## Patient information leaflet

### SCHEDULING STATUS: [50]

**Doppelherz® aktiv Prega**, soft gelatine capsules  
Fish oil (providing DHA), β-carotene, thiamine (vitamin B<sub>1</sub>),  
riboflavin (vitamin B<sub>2</sub>), niacin, pantothenic acid, pyridoxine (vitamin B<sub>6</sub>),  
cyanocobalamin (vitamin B<sub>12</sub>), ascorbic acid (vitamin C),  
cholecalciferol (vitamin D<sub>3</sub>), D-α-tocopherol (vitamin E), biotin,  
folic acid, magnesium, iron, zinc, copper, iodine.  
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 important information for you.**

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

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

**1. What **Doppelherz® aktiv Prega** is and what it is used for**  
**Doppelherz® aktiv Prega** is a health supplement. It offers the following benefit –

It provides vitamins, minerals and omega-3 fatty acids to support the health and wellbeing of a woman trying to have a baby, throughout her pregnancy and while she is breastfeeding her baby.

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 Prega****  
**Do not take **Doppelherz® aktiv Prega**:**

- If you are hypersensitive (allergic) to any of the ingredients of **Doppelherz® aktiv Prega** (listed in section 6).
- If you have high levels of vitamin D.
- If you have high levels of the mineral calcium.

### Warnings and precautions

Take special care with **Doppelherz® aktiv Prega**:

- If you have a high level of a certain type of fat (triglycerides) in your blood.
- If you have a bleeding disorder.
- If you have asthma and also have a sensitivity to aspirin.
- If you are allergic to seafood (fish) or to shellfish.
- If you have liver disease or liver failure.
- 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 an infection caused by the fungus histoplasma.
- If you have sarcoidosis (swollen tissue called granulomas in your organs).
- If your parathyroid glands produce large quantities of parathyroid hormone.
- If you have heart disease.
- If you are at increased risk of organ damage from high blood levels of calcium.
- If you are suspected of having vitamin B<sub>12</sub> deficiency but it has not yet been confirmed.
- If you have an iron storage disease or an iron absorption disease.
- Active: concentrated omega-3 triglycerides - fish (only for oral use).

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

Consult a health care provider prior to use:

- If you have a bleeding disorder or take blood thinning medicine.
- If you are an asthmatic with a sensitivity to aspirin.
- If you are a tobacco smoker.
- If you have cardiovascular (heart) disease.
- If you use statins to lower cholesterol.

### Children and adolescents

Do not give **Doppelherz® aktiv Prega** to children younger than 14 years.

### Other medicines and **Doppelherz® aktiv Prega**

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 professional if you are taking or using any of the following:

- **Anticoagulants** (prevent or reduce blood clots) – together with fish oil may increase risk of bleeding.

✓ **lactose-free**  
✓ **gluten-free**

- *Cyclosporine, sirolimus, tacrolimus* – their adverse effects may be increased if taken with fish oil.
- *Diuretics in high doses* – can reduce vitamin B<sub>1</sub> levels.
- *Boron* – might reduce vitamin B<sub>2</sub> 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 B<sub>6</sub> levels.
- *Levodopa, altretamine* – their effectiveness may be reduced by vitamin B<sub>6</sub>.
- *Phenobarbital, phenytoin* – their concentrations in the blood and effects are reduced by vitamin B<sub>6</sub> and folic acid.
- *Neomycin, aminosallylic acid, histamine H<sub>2</sub>-antagonists (H<sub>2</sub> blockers), omeprazole, colchicine* – may reduce vitamin B<sub>12</sub> levels.
- *Vitamin C* – may increase iron absorption in iron deficiency states.
- *Desferrioxamine (binds iron)* – achieves better iron excretion in presence of vitamin C.
- *Calcipotriene (vitamin D analog), thiazide diuretics, calcium or phosphate* – used or taken with vitamin D increases the risk of high levels of calcium.
- *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.
- *Calcium and magnesium salts* – can reduce iron levels.
- *Tetracycline antibiotics* – can reduce iron levels, and iron can reduce tetracycline levels. Take them 2-3 hours apart.
- *Trientine (copper binder)* – can reduce iron levels. Take them apart from each other.
- *Acetohydroxamic acid* – bonds with iron so that levels of both are reduced.
- *Dimercaprol* – may form toxic complexes with iron. Take them apart from each other.
- *Cefdinir, bisphosphonates, entacapone, fluoroquinolones, tetracycline antibiotics, levodopa, methyldopa, mycophenolate mofetil and penicillamine* – their absorption can be decreased by iron salts. Doses should be separated by a few hours.
- *Levothyroxine* – its efficacy may be reduced by iron salts. Doses should be separated by at least 2 hours.
- *Penicillamine antibiotics, phosphorous 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.
- *Amiodarone* – might cause very high levels of iodine that adversely affect thyroid function.
- *Lithium* – combined with iodine adds to the hypothyroid effects, and can inhibit thyroid function.
- *Antithyroid medicines* – their effects can be altered by iodine.

### **Doppelherz® aktiv Prega** food

- *Psyllium (a dietary fibre)* – might reduce absorption of vitamin B<sub>2</sub> from supplements.
- *Food* – may impair absorption of iron. Iron should be taken on an empty stomach, unless its gastrointestinal side effects cannot be tolerated.
- *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 Prega** is safe to take during pregnancy and breastfeeding at the recommended dosage.

### Driving and using machines

**Doppelherz® aktiv Prega** should not have any influence on these abilities.

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

### 3. How to take **Doppelherz® aktiv Prega**

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

Always take **Doppelherz® aktiv Prega** 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 and children 14 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.
- 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 capsules for longer than 6 months.

### If you take more **Doppelherz® aktiv Prega** than you should

Some of the signs and symptoms of overdose may include –  
Gastrointestinal disturbances; yellow urine;  
increased blood glucose levels; jaundice, effects on the eyes; numbness and pain due to nerve damage;  
weight loss, tiredness, frequent urination, frequent urination at night, sweating, headache, thirst, drowsiness, dizziness;  
blurred vision, weakness;  
cardiovascular complications, allergic skin reactions, altered sleep patterns, vivid dreams, irritability, excitability, hyperactivity, confusion, impaired judgement;





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thirst, low blood pressure, central nervous system depression, skeletal muscle paralysis, loss of tendon reflexes, respiratory depression, irregular heartbeat, slow heart rate;

vomiting blood; lack of oxygen and blood flow to kidneys; inflamed kidneys; abdominal pain, cramps, bloody diarrhea, liver damage, poor kidney function, cardiovascular collapse;

sore teeth and gums, burning in mouth and throat, increased salivation, inflammation in the nose, eye irritation and eyelid swelling, fluid in the lungs, infection of salivary glands, inflammation of airways, skin reactions that look like acne, thyroid dysfunction.

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 with you for identification.

#### If you forget to take Doppelherz® aktiv Pregna

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

#### If you stop taking Doppelherz® aktiv Pregna

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

#### 4. Possible side effects

Doppelherz® aktiv Pregna can have side effects.

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

If any of the following happens, stop taking Doppelherz® aktiv Pregna 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)
- Other allergic reactions (less frequent)
- Hypersensitivity reactions (less frequent)
- Angioedema (swollen parts of the body)
- Cutaneous haemorrhage (burst blood vessels under the skin) or purpura (rash causing blood to collect under the skin)
- Mucosal haemorrhage (blood on the mucosa such as in the mouth)
- Fever (raised body temperature)
- Arthralgia (pain in joints)
- Swollen lymph nodes (glands in your body)
- Skin and other allergic reactions such as rash (frequent)
- Itching
- Skin irritation
- Erythema (red skin)
- Urticaria (raised red rash)
- Anaphylaxis (severe allergic reaction)
- Photosensitivity (immune system reaction triggered by sunlight)
- Arthralgia (pain in joint) (less frequent)
- 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 Pregna. 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)
- Nasopharyngitis (inflammation of nasal passages)
- Upper respiratory infection
- Worsening asthma
- Apnea (stop breathing)
- Acne (pimples) (less frequent)
- Eczema (itchy, dry skin) (less frequent)
- Slightly yellow skin (frequent)
- Bruising (bleeding under the skin) (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 (throwing up)
- Heartburn (acid backs up in the throat)
- Abdominal pain (pain in stomach area)
- Abdominal cramps (cramps in stomach area)
- Loss of appetite
- Gastrointestinal disturbances, obstruction (blockage), irritation
- Belching (burping)
- Metallic taste

#### Uncommon/less frequent side effects:

- Dizziness

#### Frequency not known:

- Paraesthesia (tingling of hands)
- Fever (increase in body temperature)
- Chills
- Hot flushing (feeling hot and sweaty)
- Malaise (general feeling of sickness)
- Tremor (trembling, shaking)
- Depression (sad mood)
- Insomnia (sleeplessness)
- Bloody diarrhea (blood in runny stool)
- Black faeces
- Constipation (hard stool)
- Indigestion (discomfort in upper abdomen)
- Dry mouth
- Flu-like symptoms (feeling fluish)
- Mouth irritation
- Thirst

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 Pregna. Alternatively, side effects may be reported directly to Ivovent cc.

#### 5. How to store Doppelherz® aktiv Pregna

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 Pregna 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 Pregna contains:

- The active substances are:

	Per capsule:
Fish oil providing docosahexaenoic acid (DHA, 43 % m/m)	294 mg 126 mg
β-carotene providing Vitamin A (RAE)	2 mg 333 microgram
Thiamine mononitrate providing thiamine (Vitamin B1)	1,48 mg 1,2 mg
Riboflavin (Vitamin B2)	1,57 mg
Niacin (Vitamin B3)	15 mg
Calcium-D-pantothenate providing Pantothenic acid (Vitamin B5)	6,67 mg 6 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B6)	2,46 mg 2 mg
Cyanocobalamin (Vitamin B12)	2 microgram
L-ascorbic acid (Vitamin C)	80 mg
Cholecalciferol providing Vitamin D3	67 microgram 5 microgram
D-α-tocopherol (Vitamin E)	12 mg
D-biotin (Vitamin H)	60 microgram
Folic acid	400 microgram
Magnesium oxide providing magnesium	99,49 mg 60 mg
Ferrous fumarate providing iron	42,59 mg 14 mg
Zinc oxide providing zinc	6,22 mg 5 mg
Cupric sulphate providing copper	2,51 mg 1 mg
Potassium iodate providing iodine	250 microgram 150 microgram

- The other ingredients are soybean oil, lecithins (soy) and soft gelatin capsule shell (includes iron oxides yellow, red and black as colourants, E172).

#### What Doppelherz® aktiv Pregna looks like and contents of pack

Brown, 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

Ivovent 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](http://www.doppelherz.co.za) or can be obtained from Ivovent cc.



Manufactured by:

  
**Queisser**  
PHARMA

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