

# STAVID TABLET

Simvastatin (20 mg, 40 mg, 80 mg)

## What is in this leaflet

1. What Stavid is used for
2. How Stavid works
3. Before you use Stavid
4. How to use Stavid
5. While you are using Stavid
6. Side effects
7. Storage and Disposal of Stavid
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Stavid is used for

Stavid is used:

- To reduce cholesterol level or elevated fat levels in your blood (primary hypercholesterolaemia or mixed hyperlipidaemia) when response to diet and other non-pharmacological measures is not sufficient.
- To reduce inherited high levels of cholesterol (homozygous familial hypercholesterolaemia) together with diet and other non-dietary measures when response to these is not adequate.
- For coronary heart disease (CHD). Stavid may reduce the risk of death associated with heart disease, reduce the risk to undergo heart surgery, and slow the progression of the arteries being clogged up by fatty substances (atherosclerosis), even if your cholesterol is normal.

You should stay on a cholesterol-lowering diet while taking this medicine.

## How Stavid works

Stavid belongs to a group of medicine called statins. These work by inhibiting the enzyme HMG-CoA reductase, which controls the rate of cholesterol synthesis in the body. Stavid lowers levels of “bad” cholesterol (LDL cholesterol and VLDL cholesterol), and triglycerides in the blood. Stavid also raises levels of “good” cholesterol (HDL cholesterol).

## Before you use Stavid

### - When you must not use it

Do not take this medicine if:

- you are allergic (hypersensitive) to simvastatin or any of the other ingredients listed at the end of the leaflet
- you currently have liver problem or unexplained persistent elevations of serum transaminase (liver enzyme)
- you have inherited blood disorder called porphyria
- you are pregnant or breast-feeding
- you are taking one or more than one of the following drugs at the same time:
  - itraconazole or ketoconazole (anti-fungal medicine)
  - erythromycin or clarithromycin (antibiotics for infections)
  - HIV protease inhibitors such as boceprevir, and telaprevir (medicines for HIV infections)
  - nefazodone (anti-depressant medicine)
  - gemfibrozil (cholesterol-lowering medicine)
  - cyclosporine (medicine often used in organ transplant patients)
  - danazol (man-made hormone used to treat endometriosis)

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

### - Before you start to use it

Tell your doctor/pharmacist if:

- you have allergies to any other medicines, foods, dyes or preservatives
- you drink large amounts of alcohol
- you have past history of liver disease
- you are going to have an operation. You may need to stop taking Stavid for a short time.
- you have severe lung diseases

Your doctor

- should do a blood test before and after you start taking Stavid to check how well your liver is working and detect any symptoms of liver problems.
- should advise on the risk of myopathy (muscle disease) and the need to report to your doctor immediately if you experience unexplained muscle pain, tenderness or weakness.

The risk of muscle breakdown is greater at higher doses of Stavid, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain individuals.

Talk with your doctor if any of the following applies:

- you consume large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates
- you or a close family member have a hereditary muscle disorder.

Eye evaluation/ Examination

An increase of lens blurring is expected as a result of aging in the absence of any drug treatment. However, current data from conducted studies do not indicate a negative effect of Stavid on the human lens.

### - Taking other medicines

It is particularly important to tell your doctor if you are taking any of the following drugs. Taking Stavid with any of these drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Before you use Stavid – When you must not take it”).

- itraconazole or ketoconazole
- erythromycin or clarithromycin
- HIV protease inhibitors such as boceprevir, or telaprevir
- nefazodone
- fibrates like gemfibrozil and bezafibrate
- niacin (nicotinic acid)

# STAVID TABLET

Simvastatin (20 mg, 40 mg, 80 mg)

- amiodarone (treatment of irregular heartbeat)
- verapamil, diltiazem or amlodipine (treatment of high blood pressure)
- cyclosporine (prevent organ rejection)
- danazol (treatment of fibrocystic breast cancer)

Other than the medicines listed above, tell your doctor or pharmacist if you are also taking medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants).

Also tell your doctor if you are Chinese and are taking niacin-containing product.

You should also tell any doctor who is prescribing a new medicine for you that you are taking Stavid.

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

## How to use Stavid

### - How much to use

Oral. Always take Stavid exactly as prescribed by your doctor. Check with your doctor or pharmacist if you are not sure. You should stay on a cholesterol-lowering diet while taking this medicine.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.

### Adults

The usual starting dose is 10 mg, 20 mg, or in some cases 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day, depending on your response to the medicine. Your doctor may prescribe lower doses, particularly if you are taking certain medicines listed above or have certain kidney conditions.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not

reached their cholesterol goal on lower doses.

### Elderly

The dose does not need to be changed in elderly patients.

### - When to take it

Stavid is recommended to be taken in the evening.

### - How long to use it

You are advised to take Stavid as long as your doctor tells you to.

### - If you forget to use it

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

If you realize you have forgotten to take your dose soon after its due time, take it as soon as possible. Skip the missed dose if it is almost time for your next dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using Stavid

### - Things you must do

- Tell your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- Take Stavid exactly as prescribed by your doctor.

### - Things you must not do

Do not:

- give Stavid to anyone else even if they have the same condition as you
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist

- take more than the recommended dose unless your pharmacist or doctor tells you to
- stop taking the medicine unless advised by your doctor

### - Things to be careful of

Grapefruit juice contains one or more components which inhibits metabolism of some drugs, including Stavid. Consuming large quantities of grapefruit juice should be avoided.

## Side effects

Like all medicines, Stavid can cause side effects, although not everybody gets them. These effects can be serious but most of the time, they are mild and temporary.

Stop using Stavid and tell your doctor immediately or go to the emergency room at your nearest hospital if you think you are experiencing any of these following possible unwanted side effects while taking the medicine.

- Muscle pain, tenderness or weakness. These muscle problems can be serious on rare occasions, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- hypersensitivity (allergic) reactions including:
  - swelling of the face, tongue and throat which may cause difficulty in breathing
  - severe muscle pain usually in the shoulders and hips
  - rash with weakness of limbs and neck muscles
  - pain or inflammation of the joints
  - inflammation of the blood vessels
  - unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
  - shortness of breath and feeling unwell
  - lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
- inflammation of the liver with yellowing of the skin and eyes,

# STAVID TABLET

Simvastatin (20 mg, 40 mg, 80 mg)

itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite; liver failure (very rare)

- inflammation of the pancreas often with severe abdominal pain

The following side effects have also been reported:

- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- low red blood cell count (anaemia)
- muscle pain, numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- rash, itching, hair loss

## Laboratory Test Findings

Elevations of some serum liver enzymes and a muscle enzyme (creatin phosphokinase) have been observed.

Consult your doctor/ pharmacist for further information. Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of Stavid

### - Storage

Keep out of reach of children.

### Stavid Tablet 20 mg

Store below 30°C. Protect from heat and moisture.

### Stavid Tablet 40 mg

Store below 30°C.

### Stavid Tablet 80 mg

Store below 30°C.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product description

- What it looks like?

### Stavid Tablet 20mg

Oval, peach film-coated tablet, shallow convex with "HD" and break bar embossed on one face.

### Stavid Tablet 40mg:

Oval, red film-coated tablet, shallow convex and scored on one face.

### Stavid Tablet 80mg:

Caplet-shape, red filmcoated tablet, bevel-edged, shallow convex and scored on one face

## - Ingredients

### Stavid Tablet 20 mg

#### - Active ingredients

Each Stavid Tablet 20 mg contains 20 mg simvastatin

#### - Inactive ingredients

Microcrystalline cellulose  
Lactose monohydrate  
Magnesium stearate  
Partially pregelatinised starch  
Butylated hydroxyl anisole  
Ascorbic acid  
Citric acid anhydrous  
Colloidal silicon dioxide  
Hydroxypropyl Methylcellulose  
Titanium Dioxide  
Iron Oxide Yellow  
Iron Oxide Red  
Talc  
Propylene Glycol  
Isopropyl Alcohol  
Purified Water

### Stavid Tablet 40 mg

#### - Active ingredients

Each Stavid Tablet 40 mg contains 40 mg simvastatin

#### - Inactive ingredients

Microcrystalline cellulose  
Lactose monohydrate

Magnesium stearate  
Partially pregelatinised starch  
Butylated hydroxyl anisole  
Ascorbic acid  
Citric acid anhydrous  
Colloidal silicon dioxide  
Hydroxypropyl Methylcellulose  
Titanium Dioxide  
Iron Oxide Yellow  
Iron Oxide Red  
Talc  
Propylene Glycol  
Isopropyl Alcohol  
Purified Water

### Stavid Tablet 80 mg

#### - Active ingredients

Each Stavid Tablet 80 mg contains 80 mg simvastatin

#### - Inactive ingredients

Microcrystalline cellulose  
Lactose monohydrate  
Magnesium stearate  
Partially pregelatinised starch  
Butylated hydroxyl anisole  
Ascorbic acid  
Citric acid anhydrous  
Colloidal silicon dioxide  
Hydroxypropyl Methylcellulose  
Titanium Dioxide  
Iron Oxide Yellow  
Iron Oxide Red  
Talc  
Propylene Glycol  
Isopropyl Alcohol  
Purified Water

#### - MAL Number (s):

**Stavid Tablet 20mg**  
MAL05041945AZ

### Stavid Tablet 40mg

MAL17035045AZ

### Stavid Tablet 80mg

MAL17035037AZ

## Manufacturer

HOVID Bhd.  
Lot 56442, 7 ½ Miles,  
Jalan Ipoh/ Chemor,  
31200 Chemor, Perak, Malaysia.

## Product Registration Holder

HOVID Bhd.  
121, Jalan Tunku Abdul Rahman,  
30010 Ipoh, Perak, Malaysia.

# STAVID TABLET

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