

DXM-ROSUVASTATIN FILM COATED TABLET

Rosuvastatin 10mg & 20mg

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What DXM-ROSUVASTATIN is used for

You have been prescribed DXM-ROSUVASTATIN because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

How DXM-ROSUVASTATIN works

DXM-ROSUVASTATIN is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- DXM-ROSUVASTATIN can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol.
- It works by helping to block your body’s production of ‘bad’ cholesterol. It also improves your body’s ability to remove it from your blood.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking DXM-ROSUVASTATIN, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again and causing build up of fatty deposits.

Before you use DXM-ROSUVASTATIN

-When you must not use it

Do not take DXM-ROSUVASTATIN:

- If you have ever had an allergic reaction to DXM-ROSUVASTATIN or similar medicines, or to any of its ingredient. DXM-ROSUVASTATIN contains lactose, which may cause a problem in a small number of patients who are allergic to lactose.
- If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking DXM-ROSUVASTATIN stop taking it immediately and tell your doctor.
- If you have liver disease.
- If you have repeated or unexplained muscle aches or pains.

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

-Before you start to use it

Take special care with DXM-ROSUVASTATIN and tell your doctor or pharmacist:

- If you have ever been told that you have problems with your kidneys.
- If you have ever been told that you have problems with your liver.

- If you have had unexplained muscles aches or pains, a history of muscle pains, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia – please see “Side Effects”.
- If you regularly drink large amounts of alcohol.
- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol.
- If you take medicines used to fight the HIV infection alone or in combination e.g. lopinavir, ritonavir, atazanavir, simeprevir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir (used to treat infections including HIV or hepatitis C infections), capmatinib, regorafenib and darolutamide (used to treat cancer). Please see “Taking other medicines”.
- If you have high blood sugar or raised HbA_{1c}.
- If you are over 70 (as your doctor needs to choose the right start dose of DXM-ROSUVASTATIN to suit you).
- If you have severe respiratory failure.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

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Tell your doctor if you are taking any of the following:

- Ciclosporin (used for example, after organ transplants).
- Warfarin (or any other drug used for thinning the blood).
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicines used to lower cholesterol (such as ezetimibe).
- Antacid (used to neutralize acid in your stomach).
- Erythromycin (an antibiotic), or medications used to fight the HIV infection (please see “*Before you start to use it*”).
- Fostamatinib (used to treat low platelet count).
- Febuxostat (used to treat and prevent high blood levels of uric acid)
- Teriflunomide (used to treat multiple sclerosis).

The effects of these medicines could be changed by DXM-ROSUVASTATIN or they could change the effects of DXM-ROSUVASTATIN.

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

How to use DXM-ROSUVASTATIN

-How much to use

Always take DXM-ROSUVASTATIN as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Starting dose:

In adults, treatment with DXM-ROSUVASTATIN is usually started with the 10 mg dose taken once daily, even if you have taken a higher dose of a different statin before.

Some people may be asked to start treatment with one 5 mg tablet taken once a day. The choice of your start dose will depend upon:

- Your cholesterol level.

- The level of risk you have of experiencing a heart attack or stroke.
- Whether you may be more sensitive to possible side effects.

Increasing the dose and maximum daily dose:

After checking the amount of lipids in your blood, your doctor may decide to increase your dose until you are taking the amount of DXM-ROSUVASTATIN that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of Rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and at high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg. A dosage of 40 mg once daily should only be initiated under specialist supervision.

In children 10-17 years of age the maximum daily dose is 20 mg. DXM-ROSUVASTATIN should not be given to children younger than 10 years.

-When to use it

Take DXM-ROSUVASTATIN once daily. You can take it in the morning or evening. Try to take your tablet at the same time every day to help you to remember to take it.

Regular cholesterol checks:

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

Your doctor may decide to increase your dose so that you are taking the amount of DXM-ROSUVASTATIN that is right for you.

-How long to use it

Do not stop taking your DXM-ROSUVASTATIN even if you are feeling well, unless your doctor tells

you to or unless you become pregnant.

Talk to your doctor if you want to stop taking DXM-ROSUVASTATIN. Your cholesterol levels might increase again if you stop taking DXM-ROSUVASTATIN.

-If you forget to use it

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

-If you use too much (overdose)

If you take more DXM-ROSUVASTATIN than prescribed by your doctor, talk to your doctor or pharmacist straight away.

While you are using it

-Things you must do

Take your medication daily as prescribed.

-Things you must not do

Do not take other medications together with DXM-ROSUVASTATIN without speaking to your doctor or pharmacist first.

-Things to be careful of

Pregnancy and breast-feeding:

Do not take DXM-ROSUVASTATIN if you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking DXM-ROSUVASTATIN stop taking it immediately and tell your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

DXM-ROSUVASTATIN is not expected to affect your ability to drive a car or to operate machinery.

Side effects

Like all medicines, DXM-ROSUVASTATIN can cause side

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effects, although not everybody gets them.

It is important that you are aware of what these side effects may be.

Stop taking DXM-

ROSUVASTATIN and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Also, stop taking DXM-

ROSUVASTATIN and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life-threatening muscle damage known as rhabdomyolysis.

If you have muscle problems that do not go away even after your doctor has told you to stop taking DXM-ROSUVASTATIN, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Common side effects (these may affect between 1 in 10 and 1 in 100 patients):

- Headache
- Muscle pain
- Stomach pain
- General feeling of weakness
- Constipation
- Dizziness
- Feeling sick

- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only Rosuvastatin 40 mg)

Uncommon side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- Skin rash
- Itching
- Hives
- An increase in the amount of protein in the urine, this usually returns to normal on its own without having to stop taking your DXM-ROSUVASTATIN tablets (only DXM-ROSUVASTATIN 10 mg and 20 mg).

Rare side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking DXM-ROSUVASTATIN and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking DXM-ROSUVASTATIN and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.
- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.

Very rare side effects (these may affect less than 1 in 10,000 patients):

- Jaundice (yellowing of the skin and eyes).
- Hepatitis (an inflamed liver).
- Joint pain.
- Memory loss.

Side effects of not known frequency and reported less frequently than 1% may include:

- Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares.
- Depression
- Traces of blood in your urine (generally temporary and not associated with worsening kidney function).
- Increases in HbA_{1c} (a measure of the average amount of sugar in your blood over time).
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscle used when breathing), Ocular myasthenia (a disease causing eye muscle weakness). Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 [*Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*].

Storage and disposal of DXM-ROSUVASTATIN

-Storage

Keep out of the reach and sight of children.

Do not use DXM-ROSUVASTATIN after the expiry date which is stated on the box/blisters after EXP. The expiry date refers to the last day of the month.

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Store at temperatures below 30°C.
Store in the original package.

-Disposal

Remember to return any unused
medicine to your pharmacist
(chemist).

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

DXM-ROSUVASTATIN 10 MG

White, round, and shallow-biconvex
tablet with diameter 7 mm. Marked
'DEXA' on side I, unmarked on side
II.

DXM-ROSUVASTATIN 20 MG

White, round, and shallow-biconvex
tablet with diameter 9 mm. Marked
'DEXA' on side I, unmarked on side
II

-Ingredients

Active ingredients

Each **DXM-ROSUVASTATIN 10
MG** film-coated tablet contains 10
mg rosuvastatin as rosuvastatin
calcium

Each **DXM-ROSUVASTATIN 20
MG** film-coated tablet contains 20
mg rosuvastatin as rosuvastatin
calcium

Inactive ingredients

Microcrystalline cellulose PH-102,
spray dried lactose DCL-11,
crospovidone XL-10, magnesium
stearate, opadry II 85G58977 white,
purified water.

-MAL Numbers

10 mg: MALXXXXXXXXXX

20 mg: MALXXXXXXXXXX

Manufacturer

PT Dexa Medica (Plant)

Palembang

Jl. Jenderal Bambang Utoyo No.138,
Kel. 5 Ilir, Kec. Ilir Timur li, Kota
Palembang, Sumatera Selatan,
Indonesia.

Product Registration Holder

Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Date of revision

13/09/2024

Serial number

NPRA (R2) 23/140