



**Dosage adjustment in kidney or liver disorder**

The typical dose is 10 mg pravastatin taken once per day but may be higher. Your doctor will tell you how much to take.

**Use with other medicines**

If you take pravastatin and other medicines containing colestyramine or colestipol (medicines also used for the treatment of high cholesterol levels), you should take Pravastatin Mylan at least one hour before or four hours after these medicines.

If you are also taking a medicine which lowers the body's immune system (ciclosporin), your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor. Your doctor will tell you how much to take.

Take Pravastatin Mylan once daily, preferably in the evening, with or without food. Swallow the tablets with a sufficient quantity of liquid (e.g. one glass of water).

20 mg and 40 mg Tablets: The tablet can be divided into equal doses

Your doctor will tell you how long you have to take Pravastatin Mylan. This depends on why you are taking this medicine.

If you have the impression that the effect of Pravastatin Mylan is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Pravastatin Mylan than you should**

If you have taken too many tablets, or if someone has accidentally taken your tablets, contact your doctor or pharmacist immediately.

**If you forget to take Pravastatin Mylan**

If you miss a dose do not worry. Simply take your normal dose when it is next due. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Pravastatin Mylan**

Take Pravastatin Mylan as long as your doctor has told you. If you stop taking Pravastatin Mylan, your cholesterol levels may increase again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor immediately if you develop one of these side effects during the use of Pravastatin Mylan:****Very rare (may affect up to 1 in 10,000 people)**

- hypersensitivity reactions:
  - serious allergic reaction causing swelling of the face, lips, throat, tongue and excessive fluid in your body which can produce difficulty in swallowing or breathing (angioedema, anaphylaxis)
  - skin rash, possibly with pain in the joints (Lupus erythematosus-like syndrome)
- destruction of muscle fibres (rhabdomyolysis) that may be associated with acute kidney failure (see also section 2. "What you need to know before you take Pravastatin Mylan"), inflammation of the muscles/many muscles (myositis/polymyositis). This may cause aching muscles, muscle tenderness or weakness not caused by exercise, decreased urine, dark coloured urine and increased creatinine kinase which can be seen in a blood test. Presence of myoglobin in the urine which can be seen in a urine test (myoglobinuria).
- serious liver problems including yellowish discoloration of the skin and/or eyes (jaundice), tissues and body fluids, liver inflammation (hepatitis) sudden rapid destruction of liver tissue (fulminant hepatic necrosis). This may cause you to feel or be sick, lose appetite, feel generally unwell, fever, itchy skin, dark urine, pale stools
- inflammation of the pancreas. This causes moderate to severe pain in the stomach, which spreads to the back (pancreatitis)
- problems with touch including burning/tingling sensation, numbness or pins and needles (paresthesia) may occur which may be a sign of damage to the nerve endings (peripheral polyneuropathy)
- a condition characterised by an inflammation of the muscles and the skin (dermatomyositis)

**Not known (cannot be estimated from the available data)**

- diabetes. This is more likely if you have high levels of sugars or fats in your blood, are overweight or have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- breathing problems including persistent cough with shortness of breath and/or fever (interstitial lung disease)
- muscle weakness that is constant (Immune –mediated necrotising myopathy)

**Other possible side effects include:****Common (may affect up to 1 in 10 people)**

- painful joints (arthralgia)
- increased production of liver enzymes which can be seen in a blood test.

**Uncommon (may affect up to 1 in 100 people)**

- dizziness, headache, sleep disturbances, difficulty sleeping
- problems with eyesight, blurred vision or double vision
- digestive problems or slow digestion, indigestion/heartburn, abdominal pain, feeling/being sick, difficulty or delay emptying bowels, diarrhoea, wind

- itching, rash, hives, scalp and hair problems (inclusive of hair loss)
- abnormal urination, e.g. pain, frequency, frequent urination at night
- problems with sexual functions
- tiredness
- inflamed tendons, sometimes associated with tearing

**Rare (may affect up to 1 in 1,000 people)**

- increased sensitivity to light (photosensitivity)

**The following side effects have been seen with other medicines similar to pravastatin, and may be seen with this medicine.****Not known (cannot be estimated from the available data)**

- nightmares
- memory loss
- depression

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 FREE Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Pravastatin Mylan**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

Store in the original packaging in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Pravastatin Mylan contains**

- The active substance is pravastatin sodium. Pravastatin Mylan 10 mg tablets: each tablet contains 10 mg of pravastatin sodium. Pravastatin Mylan 20 mg tablets: each tablet contains 20 mg of pravastatin sodium. Pravastatin Mylan 40 mg tablets: each tablet contains 40 mg of pravastatin sodium.

- The other ingredients are lactose monohydrate (see section 2 "Pravastatin Sodium contains lactose"), dihydroxy aluminium sodium carbonate, sodium stearyl fumarate, iron oxide red (E172) (for the 10 mg and 40 mg tablets only) and iron oxide yellow (E172) (for the 20 mg tablet only).

**What Pravastatin Mylan looks like and contents of the pack**

10 mg Tablets: Light pink colour, mottled, round, flat, bevelled tablets debossed with "10" on one side and plain on the other.

20 mg Tablets: Light yellow colour, mottled, round tablet debossed with "20" on one side and break line on the other side. The tablet can be divided into equal halves.

40 mg Tablets: Light pink colour, mottled, round tablet debossed with "40" on one side and break line on the other side. The tablet can be divided into equal halves.

Pravastatin Mylan is available in blister packs with 10, 14, 20, 28, 30, 50, 60, 84, 90, 98 or 100 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoye Industrial Estate, Grange Road, Dublin 13, Ireland

**Manufacturer**

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary


**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Pravastatine Mylan Pharma 10 mg, 20 mg, 40 mg Tablets
France	Pravastatine Mylan Pharma 10 mg, 20 mg, 40 mg Tablets
Ireland	Pravastatin Mylan 10 mg, 20 mg, 40 mg Tablets
Italy	Pravastatina Mylan 20 mg, 40 mg compresse
Netherlands	Pravastatinenatrium Mylan 10 mg, 20 mg, 40 mg Tabletten
Portugal	Pravastatina Mylan 10 mg, 20 mg, 40 mg comprimidos
Romania	Pravastatină Mylan 10 mg, 20 mg, 40 mg comprimate
Spain	Pravastatina Mylan Pharmaceuticals 10 mg, 20 mg, 40 mg comprimidos EFG
United Kingdom	Pravastatin Sodium 10 mg, 20 mg, 40 mg Tablets

**This leaflet was last revised in February 2018.**

 **Mylan**

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				<b>Date: 13 MAR 2018</b>		<b>Time: 15:59</b>	
<b>Description</b>	Pravastatin Sodium 40 mg,10 mg,20 mg 28			<b>No. of colours</b>	1	<b>Page Count</b>	2/2
<b>Component Type</b>	Leaflet	<b>Pharma Code</b>	5445	<b>Colours</b>	Black		
<b>Affiliate Item Code</b>	1453025	<b>SAP No.</b>	NA	<b>Non-Print Colours</b>			
<b>Superceded Affiliate Item Code</b>	1124545	<b>Vendor Job No.</b>	335871	<b>Equate CMYK with</b>			
<b>TrackWise PR No.</b>	1453025	<b>Trackwise Proof No.</b>	2	<b>Main Font</b>	Times New Roman	<b>Body Text Size</b>	10 pt
<b>MA No.</b>	NA	<b>Client Market</b>	Ireland	<b>Dimensions</b>	170 x 480 mm	<b>Min Text Size used</b>	10 pt
<b>Packing Site/Printer</b>	Komarom	<b>Keyline/Drawing No.</b>	NA				
<b>Supplier Code</b>	50066348	<b>Barcode Info</b>	NA				
		<b>3D Render ID</b>	NA				
<b>Sign-offs</b>							

v3/July 2017