

PACKAGE LEAFLET: INFORMATION FOR THE USER

Carmil[®] 20mg Tablets Carmil[®] 40mg Tablets

(Isosorbide-5-mononitrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:

1. What Carmil[®] Tablets are and what are they used for
2. What you need to know before you take Carmil[®] Tablets
3. How to take Carmil[®] Tablets
4. Possible side effects
5. How to store Carmil[®] Tablets
6. Content of the pack and other information

1. What Carmil[®] Tablets are and what are they used for

This medicine contains an active ingredient called Isosorbide Mononitrate, which belongs to a group of medicines called organic nitrates. Organic nitrates work by widening the blood vessels in your heart to allow an increased amount of blood to flow to areas which need it.

Carmil[®] tablets are used to prevent angina pectoris. Angina usually feels like a tight pain in the chest, neck or arm area. The pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen for the amount of work it is doing. Carmil[®] 20 mg and 40 mg Tablets can also be used to treat congestive heart failure. Heart failure can happen when the heart muscle is not strong enough to pump the blood around the body. It may cause problems with breathing and swelling of the legs.

2. What you need to know before you take Carmil[®] Tablets

Do not take Carmil[®] Tablets

- If you are allergic to isosorbide mononitrate, other nitrates or to any of the other ingredients of this medicine (listed in section 6)
- If you suffer from severe anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- If you have had a heart attack (myocardial infarction)
- If you have had a brain haemorrhage (bleeding)
- If you have had a head injury (trauma)
- If you have a low blood volume (hypovolaemia)
- If you have severely low blood pressure (hypotension)
- If your blood has stopped circulating around your body properly (circulatory failure)
- If you are suffering from "shock" or vascular collapse
- If you take sildenafil ("Viagra") or any other phosphodiesterase inhibitor
- If you have an eye disease called glaucoma
- If you have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and diseases associated

- with raised intra-cranial (head) pressure
 - If you take products that contain riociguat a medicine used in treating pulmonary hypertension.
- If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to you doctor or pharmacist before taking Isosorbide mononitrate

- If you have had a recent heart attack
- If you suffer from low blood pressure (hypotension)
- If you have a poor diet or do not have enough to eat (malnutrition)
- If you are suffering from low body temperature (hypothermia)
- If you have problems with your liver or kidneys
- If you suffer from hypothyroidism (underactivity of the thyroid gland)
- If you have alcohol problem as you should not drink with these tablets

Other medicines and Carmil[®] Tablets

- **Do not take Carmil[®] Tablets with phosphodiesterase inhibitors such as Sildenafil, Tadalafil, Alprostadil and Vardenafil used for impotence. Using Carmil[®] with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Carmil[®] Tablets to take Sildenafil as this will increase your chances of having an angina attack.**
- **Do not take Carmil[®] Tablets with products that contain riociguat a medicine used in treating pulmonary hypertension.**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines to lower your blood pressure. Especially, the following:

- Medicines which lower blood pressure, such as beta blockers (atenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glyceryl trinitrate, methyldopa), angiotensin receptor blockers (olmesartan medoxomil, candesartan cilexetil)
 - Tricyclic antidepressants (used to treat depression) such as amitriptyline, clomipramine, and neuroleptics (used to treat anxiety)
 - Dihydroergotamine (a drug to treat migraine). The hypertensive effect of this drug may be strengthened
 - Sapropterin containing medicines (used to treat phenylketonuria or tetrahydrobiopterin deficiency)
 - Aldesleukin (a drug to treat metastatic cancer of the kidney).
- If any of the above applies to you, talk to your doctor.

Pregnancy and breast-feeding

Do not take Carmil[®] Tablets if you are pregnant, planning to become pregnant or are breastfeeding. Ask your doctor for advice before taking any medicine.

Your doctor will decide whether you should take this medicine.

Driving and using machines

You may experience dizziness, tiredness or blurred vision when you start taking Carmil[®] Tablets. You should therefore know how you react to these tablets before you drive or use machines.

Carmil[®] Tablets contain Lactose

This product contains lactose - if you know you have intolerance to some sugars, contact your doctor before use.

PHARMACODE

3. How to take Carmil® Tablets

Always take Carmil® Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Dosage:

The usual dose to be taken orally is:-

Adults

- The usual dose is one tablet two or three times a day.
- Your doctor will tell you when you should take your tablets. You will need to have a period of time (usually when you are sleeping) when no tablets are taken. This is called a "nitrate low" period and is needed to make sure your medicine remains effective.
- Swallow the tablets whole with a drink of water.
- Your doctor may increase your dose, up to a maximum of 120 mg per day.

Do not use Carmil® Tablets to treat an acute angina attack. Your doctor will give you a different medicine such as GTN (glyceryl trinitrate) spray or tablet for this.

Elderly: The usual dose is the same as the adult dose.

Children: Not recommended for use in children.

If you take more Carmil® Tablets than you should

Too much Carmil® Tablets may cause your blood pressure to fall too low, making you feel sick, faint and dizzy. The symptoms are headache, weak pulse, flushed skin and sweating, fast heart beat, restlessness and blurred vision. A very large dose could cause a coma or collapse and require immediate resuscitation. If you have taken more of this medicine than you should, contact your doctor or the nearest hospital casualty department immediately. Take the medicine carton with you. Your doctor or pharmacist will then know exactly what you have taken. The symptoms of an overdose are pulsing headache, reddening of the skin, cold perspiration, nausea and vomiting.

If you forget to take Carmil® Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose though, do not double up on the dose just carry on as before.

If you stop taking Carmil® Tablets

Carry on using your medicine until your doctor says you can stop. Do not stop using it just because you feel better. If you stop using the tablets, your condition may get worse. This medicine must be taken regularly. It does not work if you take it only when you suffer symptoms. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Carmil® tablets can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms:

- Fainting or collapse
- Allergic reactions e.g. skin rash, swelling of the face, lips, tongue or throat, difficulty in breathing or swallowing.

Very common (may affect more than 1 in 10 people)

- Headaches

Common (may affect up to 1 in 10 people)

- Dizziness
- Sleepiness
- Feeling weak
- Fast heartbeat
- Lowering of blood pressure when standing up

They may occur for the first few days of treatment or after your dosage has been increased.

Uncommon (may affect up to 1 in 100 people)

- Feeling sick or being sick
- Looking pale
- Flushing
- Excessive sweating
- Restlessness
- Increase in chest pain/angina.

Very rare (may affect up to 1 in 10,000 people)

- Heartburn

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

- Red or scaly skin (exfoliative dermatitis)
- Low blood pressure

You may also suffer with increase chest pain due to a lack of oxygen to the heart muscle and areas around the chest.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

PHARMACODE

5. How to store Carmil® Tablets

Keep out of the reach and sight of children.

Store your tablets in the original package. Do not store above 25°C

Do not use your medicine after the expiry date shown on the label.

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.

6. Content of the pack and other information

What Carmil® Tablets contain

The active substance is isosorbide-5- mononitrate.

- each 20mg tablet contains 20 mg of isosorbide-5- mononitrate.
- each 40mg tablet contains 40 mg of isosorbide-5- mononitrate.

The other substances are: Microcrystalline cellulose, Lactose Monohydrate, Colloidal Anhydrous Silica, Maize starch, Talc and Magnesium stearate.

What Carmil® Tablets looks like and contents of the pack

The tablets are white to off-white, round, flat, debossed with '115' (20mg) or '116' (40mg) on one side.

They are available in blister packs of 56 and 60 tablets.



Marketing Authorization Holder and Manufacturer

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N19163

	Product Name	Component	Item Code	Date & Time	
	Carmil-20mg, 40mg	Leaflet	N19163	02.11.2023 & 11:33 AM	
	Customer / Country	Version No.	Reason of Issue	No. of Colours : 1	
Team Leader	Ramesh	Dimensions	Font Type	Font Size	■ Black
Initiator	Nazela	210 x 240 mm	Arial	9 pt	
Design Agency		Pharmacode			
	NA				
Date - Designer - Run:			Reviewed / Approved by		
1. 11-OCT-2023 (Vikas) - FR	8.	15.			
2. 02-NOV-2023 (Rohan) - RR1	9.	16.			
3.	10.	17.			
4.	11.	18.			
5.	12.	19.			
6.	13.	20.			
7.	14.				
Additional Information: Supercede Item Code: NA			Sign / Date		