

Package leaflet: Information for the patient

DICYCLOVERINE HYDROCHLORIDE

10MG & 20MG TABLETS

Read all of this leaflet carefully before you start using 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dicycloverine Hydrochloride Tablets are and what they are used for
2. What you need to know before you take Dicycloverine Hydrochloride Tablets
3. How to take Dicycloverine Hydrochloride Tablets
4. Possible side effects
5. How to store Dicycloverine Hydrochloride Tablets
6. Contents of the pack and other information

1. WHAT ARE DICYCLOVERINE HYDROCHLORIDE TABLETS AND WHAT ARE THEY USED FOR

Dicycloverine hydrochloride, the active ingredient of Dicycloverine hydrochloride Tablets is one of a group of medicines called anticholinergic antispasmodics. It is used to relieve painful bowel cramps. The anticholinergic action helps to relax the muscles of the intestine and relieve the painful symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICYCLOVERINE HYDROCHLORIDE TABLETS

You should not take Dicycloverine Hydrochloride Tablets until you are sure it is safe for you to do so.

Do not take Dicycloverine Hydrochloride Tablets

- If you are allergic to dicycloverine hydrochloride or any other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Dicycloverine Hydrochloride Tablets if you:

- are pregnant or think that you may be pregnant
- are breast-feeding
- have glaucoma (an eye condition involving increased pressure within the eye and resulting in poor vision)
- have an enlarged prostate gland (this causes difficulty in passing urine)
- have a hiatus hernia (a condition with symptoms such as acid and food regurgitation and heartburn).

Other medicines and Dicycloverine Hydrochloride Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Dicycloverine Hydrochloride Tablets with food and drink

Dicycloverine Hydrochloride Tablets may be taken before or after meals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

The safety of dicycloverine hydrochloride for use during pregnancy has not been fully established. Hence, it should be taken only if there is a clear need for it.

Breast-feeding

As it has not been established that dicycloverine does not pass in the breast milk, it should be used with caution in lactating mothers.

Driving and using machines

The effects of dicycloverine hydrochloride on the ability to drive and operate machinery have not been established. Hence do not drive or use machinery when you are on Dicycloverine Hydrochloride Tablets unless you are sure your judgement and co-ordination are not affected.

Dicycloverine Hydrochloride Tablets contains Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DICYCLOVERINE HYDROCHLORIDE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and Children over 12 years old

10mg to 20mg three times a day. Your doctor will tell you which dose to use.

Use in children

Children aged 2 - 12 years old

10mg three times a day

Take your tablets with water. Tablets may be taken before or after meals.

If you take more Dicycloverine Hydrochloride Tablets than you should

It is important to stick to the dose on the label of the medicine. If you or someone else swallows several of these tablets all together, contact your doctor or nearest hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets.

If you forget to take Dicycloverine Hydrochloride Tablets

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

4. POSSIBLE SIDE EFFECTS

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

Not known: frequency cannot be estimated from the available data

- Some people may feel dizzy or thirsty or have a dry mouth.

Rare: may affect up to 1 in 1,000 people:

- drowsiness/tiredness
- blurred vision
- constipation
- sickness or lack of appetite
- headache
- rash
- difficulty in passing urine
- vomiting.

If you experience any of the above problems or any other unwanted effects, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

5. HOW TO STORE DICYCLOVERINE HYDROCHLORIDE TABLETS

- 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 label and carton. The expiry date refers to the last day of the month.
- Store your tablets in the original package. Do not store above 25°C.
- Store away from heat and direct sunlight.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dicycloverine Hydrochloride Tablets contains

The name of this medicine is Dicycloverine Hydrochloride 10mg or 20mg Tablets.

The active substance in your tablet is dicycloverine hydrochloride. Each tablet contains 10mg or 20mg of dicycloverine hydrochloride respectively. Other ingredients include Lactose monohydrate, maize starch, povidone K-30, colloidal anhydrous silica, talc and magnesium stearate.

What Dicycloverine Hydrochloride Tablets looks like and contents of the pack

Dicycloverine Hydrochloride 10mg Tablets are white to off-white, round flat bevelled edged tablets with '10' embossed on one side.

Dicycloverine Hydrochloride 20mg Tablets are white to off-white, round flat bevelled edged tablets with '20' embossed on one side and scoring on the other.

Dicycloverine Hydrochloride 10mg Tablets are supplied in blisters of 100 tablets.

Dicycloverine Hydrochloride 20mg Tablets are supplied in blisters of 84 tablets.

Marketing Authorisation Holder

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This leaflet was prepared in January 2020

LF-119580-01