

Dicycloverine Hydrochloride 10 mg and 20 mg Tablets

Package leaflet: Information for the patient

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 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 is and what it is used for
2. What you need to know before you take Dicycloverine Hydrochloride
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1 What Dicycloverine Hydrochloride is and what it is used for

What Dicycloverine Hydrochloride is Dicycloverine Hydrochloride Tablets contain a medicine called dicycloverine hydrochloride. This belongs to a group of medicines called antispasmodics.

What Dicycloverine Hydrochloride is used for

- Cramps.
- Pain in the stomach or intestine (gut).
- Stomach or intestine (gut) problems - such as irritable bowel.

How Dicycloverine Hydrochloride works

Dicycloverine Hydrochloride Tablets work by relaxing the muscles in your stomach and gut (intestine). It stops sudden muscle contractions (spasms). In doing this, it relieves cramps, pain, bloating, wind and discomfort.

2 What you need to know before you take Dicycloverine Hydrochloride

Do not take Dicycloverine Hydrochloride:

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

Warnings and precautions

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

- glaucoma (signs include painful eyes with blurred vision)
- an enlarged prostate

- indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm).

Other medicines and Dicycloverine Hydrochloride

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

Dicycloverine Hydrochloride should not be taken at the same time as other medicines. This is because Dicycloverine Hydrochloride may affect the way other medicines work. Also some medicines may affect the way Dicycloverine Hydrochloride works.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel dizzy, tired or sleepy or have blurred eyesight whilst taking Dicycloverine Hydrochloride. If this happens, do not drive or use any tools or machines.

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

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

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets with a glass of water.
- Take before or after meals.

How much to take:

Dicycloverine Hydrochloride 10 mg Tablets:

Adults and children 12 years of age or older

- One or two 10 mg tablets 3 times each day.

Children 2 to 11 years of age

- One 10 mg tablet 3 times each day.

Dicycloverine Hydrochloride 20 mg Tablets:

Adults and children 12 years of age or older

- One 20 mg tablet 3 times each day.

Children 2 to 11 years of age

- Dicycloverine Hydrochloride 20 mg Tablets should not be used in this age group.
- For administration in this age group, other pharmaceutical strengths/forms may be available.

If you take more Dicycloverine Hydrochloride than you should

Talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.

The following effects may happen: headache, feeling dizzy, feeling sick, dry mouth or difficulty in swallowing, blurred eyesight and hot dry skin.

If you forget to take Dicycloverine Hydrochloride Tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

If you stop taking Dicycloverine Hydrochloride Tablets

Keep taking Dicycloverine Hydrochloride until your doctor tells you to stop. Do not stop taking Dicycloverine Hydrochloride just because you feel better. If you stop, your cramps or pain may come back.

4 Possible side effects

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

Stop taking Dicycloverine Hydrochloride Tablets and see a doctor or go to a hospital straight away if:

- you have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:

- dry mouth or thirst
- feeling dizzy
- feeling tired or sleepy
- blurred eyesight
- rash
- loss of appetite (anorexia)
- feeling sick (nausea) or being sick (vomiting)
- constipation
- headache
- difficulty or pain on passing water (urine).

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 Website: 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

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 blister or

carton after EXP. The expiry date refers to the last day of that month.

PVC/Al blisters:

Do not store above 25°C.

PVC/PVdC/Al blisters and PVC/PVdC/PVC (amber)/Al blisters:

This medicinal product does not require any special storage conditions.

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 Dicycloverine Hydrochloride Tablets contains**

- The active substance in Dicycloverine Hydrochloride Tablets is dicycloverine. Each Dicycloverine Hydrochloride 10 mg Tablet contains 10 mg of dicycloverine hydrochloride. Each Dicycloverine Hydrochloride 20 mg Tablet contains 20 mg of dicycloverine hydrochloride.
- The other ingredients are lactose monohydrate; cellulose, microcrystalline; starch, pregelatinised (maize); magnesium stearate.

What Dicycloverine Hydrochloride Tablets look like and contents of the pack

- Dicycloverine Hydrochloride 10 mg Tablets are a round, white, biconvex tablet, 6 mm in diameter, 3.15 mm in thickness, marked with A151 on one side. Available in pack sizes of: 100 tablets.
- Dicycloverine Hydrochloride 20 mg Tablets are a round, white, biconvex tablet, 8 mm in diameter, 3.60 mm in thickness, marked with A203 on one side. Available in pack sizes of: 84 tablets.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:

Actavis Ltd. BLB 015-016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

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