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160 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER **Dicycloverine Hydrochloride 10mg Tablets Dicycloverine Hydrochloride 20mg Tablets**

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 symptoms 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

WHAT DICYCLOVERINE HYDROCHLORIDE TABLETS ARE AND WHAT THEY ARE USED FOR

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

Dicycloverine hydrochloride Tablets are used for

Cramps

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

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 TABLETS

Do not take Dicycloverine hydrochloride Tablets:

 If you are allergic to dicycloverine hydrochloride or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Dicycloverine hydrochloride Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dicycloverine hydrochloride Tablets

- If you have glaucoma (signs include painful eyes with blurred vision)
- If you have an enlarged prostate
- If you have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)

If you are not sure if any of the above apply to you, talk

to your doctor or pharmacist before taking Dicycloverine hydrochloride Tablets.

Other medicines and Dicycloverine hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

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

Pregnancy, breastfeeding and fertility

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 Tablets. If this happens, do not drive or use any tools or

Dicycloverine hydrochloride Tablet 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.

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

The usual dose is:

Adults and children 12 years of age or older

- 10 mg: One or two tablets 3 times each day
- 20 mg: One tablet 3 times each day

Children 2 to 11 years of age

- 10 mg: One tablet 3 times each day
- Dicycloverine hydrochloride 20 mg Tablets should not be used in this age group
- Dicycloverine hydrochloride Syrup is also available for use in this age group

If you take more Dicycloverine hydrochloride Tablets than you shou**l**d

If you take more Dicycloverine hydrochloride Tablets than you should, contact 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 to take Dicycloverine hydrochloride Tablets, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet dose.

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

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, 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. The expiry date refers to the last day of that month.

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 10 mg and 20 mg **Tablets contains**

- Each tablet contains 10 mg or 20 mg of the active substance, dicycloverine hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, povidone, purified talc, colloidal anhydrous and magnesium stearate.

What Dicycloverine hydrochloride 10 mg and 20 mg Tablets looks like and contents of the pack

Dicycloverine Hydrochloride 10 mg Tablets are white to off white, circular, flat beveled edge, uncoated tablet debossed with "S10" on one side and plain on other side.

Dicycloverine Hydrochloride 20 mg Tablets are white to off white, circular, flat beveled edge uncoated tablet debossed with "S" and "20" separated by break-line on one side and plain on other side. The score line is only to facilitate breaking for ease of

swallowing and not to divide into equal doses.

Dicycloverine Hydrochloride 10 mg Tablets are available in cartons containing Aluminium-PVC/PVDC blister packs of 100's along with a leaflet inside and Dicycloverine Hydrochloride 20 mg Tablets are available in cartons containing Aluminium-PVC/PVDC blister packs of 84's, 100's along with a leaflet inside. Not all pack sizes may be marketed.

Marketing Authorization Holder

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