PACKAGE LEAFLET: INFORMATION FOR THE USER Dicycloverine hydrochloride 10mg Tablets

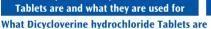
Read all of this leaflet carefully before you start taking this medicine

- 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

In this leaflet:

- 1. What Dicycloverine hydrochloride Tablets are and what they are used for
- 2. 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. Further information

1. 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.

What Dicycloverine hydrochloride Tablets are used for

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

How Dicycloverine hydrochloride Tablets work

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. Before you take Dicycloverine hydrochloride Tablets



Do not take Dicycloverine hydrochloride Tablets if:

× You are allergic (hypersensitive) to dicycloverine hydrochloride or any of the other ingredients in Dicycloverine hydrochloride Tablets (see Section 6: Further information)

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.

Take special care with Dicycloverine hydrochloride Tablets. Check with your doctor or pharmacist before taking your medicine if:

- ▲ You have glaucoma (signs include painful eyes with blurred vision)
- ▲ You have an enlarged prostate
- ▲ 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.



Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy 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 and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if:

- · You are pregnant, might become pregnant, or think you may be pregnant
- You are breast-feeding or planning to breast-feed



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 machines

Important information about some of the ingredients of Dicycloverine hydrochloride Tablets

Dicycloverine hydrochloride Tablets contain sugars (lactose, sucrose and glucose). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine

3. How to take Dicycloverine hydrochloride Tablets

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

One or two tablets 3 times each day

Children 2 to 11 years of age

- One tablet 3 times each day
- Dicycloverine hydrochloride Syrup is also available for use in this age group



If you take more Dicycloverine hydrochloride Tablets 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

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

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.

4. Possible side effects

Like all medicines, Dicycloverine hydrochloride Tablets 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 evesight
- 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 at www.mhra.gov.uk/yellowcard. 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 in a safe place where children cannot see or reach it

Do not use Dicycloverine hydrochloride Tablets 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.

Do not store above 25°C.

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. Further Information

What Dicycloverine hydrochloride hydrochloride **Tablets contains**

- Each tablet contains 10mg of the active substance, dicycloverine hydrochloride
- The other ingredients are: lactose, calcium hydrogen phosphate, icing sugar (sucrose and starch), maize starch, glucose liquid, magnesium stearate and purified water

What Dicycloverine hydrochloride Tablets looks like and contents of the pack

Dicycloverine hydrochloride 10mg Tablets are white, round, biconvex tablets with a 'M' in two concentric circles on one side. They are supplied in blister packs of 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva.

One Onslow Street,

Guildford, Surrey,

GU1 4YS, UK

Manufacturer

Sanofi-Aventis Sp. z o.o.

ul. Lubelska 52

35-233 Rzeszów

Poland

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in April 2014

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One Onslow Street,

Guildford, Surrey, GU1 4YS, UK

Manufacturer

Sanofi Synthelabo Limited

Fawdon Manufacturing Centre

Edgefield Avenue, Fawdon

Newcastle Upon Tyne

NE3 3TT United Kingdom

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This leaflet was last revised in January 2011

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