

Package leaflet: Information for the user

Dicycloverine Hydrochloride 10 mg/5 ml Oral Solution

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

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1. What Dicycloverine Hydrochloride Oral Solution is and what it is used for

What Dicycloverine Hydrochloride Oral Solution is

Dicycloverine Hydrochloride Oral Solution contains a medicine called dicycloverine hydrochloride. This belongs to a group of medicines called antispasmodics.

What Dicycloverine Hydrochloride Oral Solution is used for:

- cramps
- pain in the stomach or intestine (gut)
- stomach or intestine (gut) problems – such as irritable bowel.

How Dicycloverine Hydrochloride Oral Solution works

Dicycloverine Hydrochloride Oral Solution works 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 Oral Solution

Do not take Dicycloverine Hydrochloride Oral Solution 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.
- the person being given this medicine is under 6 months of age.

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 Oral Solution.

Warnings and precautions

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

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

Other medicines and Dicycloverine Hydrochloride Oral Solution

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

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

Dicycloverine Hydrochloride Oral Solution contains glucose, ethanol, sodium, propylene glycol, and sodium benzoate (E211)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Each measuring syringe with 5 ml of oral solution contains 4.8 g of glucose. May be harmful to the teeth. This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

This medicine contains less than 1 mmol sodium (23 mg) per measuring syringe with 5 ml of oral solution, that is to say essentially 'sodium-free'.

This medicine contains 7 mg propylene glycol in each measuring syringe with 5 ml of oral solution, which is equivalent to 1.4 mg/ml.

This medicinal product contains 4 mg benzoate salt in each measuring syringe with 5 ml of oral solution.

3. How to take Dicycloverine Hydrochloride Oral Solution

Taking this medicine

Take this medicine by mouth. This medicine may be diluted. If this is done, take the oral solution immediately after dilution.

How much to take

The recommended dose is:

Adults

- 5-10 ml (10-20 mg) three times each day.
- Take the oral solution before or after meals.

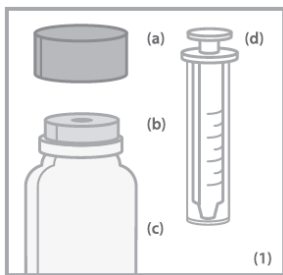
Children aged 2 to 12 years

- 5 ml (10 mg) three times each day.
- Take the oral solution before or after meals.

Children aged 6 months to 2 years

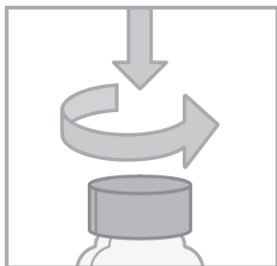
- 2.5-5 ml (5-10 mg) three or four times each day.
- Give 15 minutes before feeds.
- Do not give more than 20 ml (40 mg) in a 24 hour period.

Please follow the instructions carefully to ensure proper dosing of the oral solution.

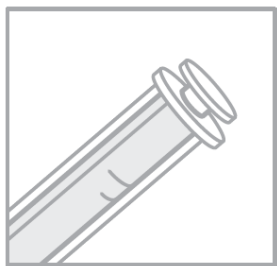


- (a) Child Resistant Bottle Cap
- (b) Bottle Adaptor
- (c) Bottle
- (d) Syringe

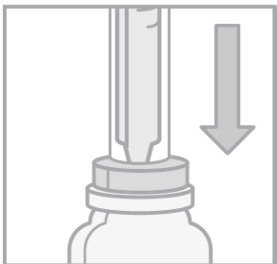
1. Open child proof cap by pressing down and turning counterclockwise.



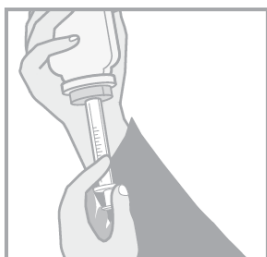
2. Push the syringe plunger completely down.



3. Insert the oral syringe firmly into the opening of the bottle adaptor.



4. Turn the entire unit (bottle and oral syringe) upside down. Pull out the syringe plunger until the correct amount is withdrawn.



If you take more Dicycloverine Hydrochloride Oral Solution 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 Oral Solution

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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dicycloverine Hydrochloride Oral Solution

Keep taking Dicycloverine Hydrochloride Oral Solution until your doctor tells you to stop. Do not stop taking Dicycloverine Hydrochloride Oral Solution 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 Oral Solution 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 Oral Solution

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

This medicine does not require any special storage conditions.

Shelf life after first opening: 6 months.

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 Oral Solution contains

- The active substance is dicycloverine hydrochloride. 1 ml of Dicycloverine Hydrochloride 10 mg/5 ml Oral Solution contains 2 mg dicycloverine hydrochloride.
- The other ingredients are: glucose liquid, citric acid monohydrate (E330), sodium benzoate (E211), cherry flavour (contains ethanol and propylene glycol), raspberry flavour (contains ethanol and propylene glycol), blackcurrant flavour (contains propylene glycol), vanilla flavour (contains ethanol and propylene glycol) and purified water.

What Dicycloverine Hydrochloride Oral Solution looks like and contents of the pack

Dicycloverine Hydrochloride Oral Solution is clear, slightly brownish-yellow solution supplied in 120 ml Type III, EP amber glass bottles closed with child resistant screw caps with a polyethylene adaptor.

Each carton contains 1 bottle and a calibrated PP 10 ml measuring syringe with HDPE plunger. The syringe is scaled at 0.5 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

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**Only the actual site of batch release will appear on the printed version of the leaflet.*