

**Package leaflet: Information for the patient**  
**DICYCLOVERINE 10MG/5ML ORAL SOLUTION**

**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 Oral Solution is and what it is used for
2. What you need to know before you take Dicycloverine Oral Solution
3. How to take Dicycloverine Oral Solution
4. Possible side effects
5. How to store Dicycloverine Oral Solution
6. Contents of the pack and other information

**1. WHAT DICYCLOVERINE ORAL SOLUTION IS AND WHAT IT IS USED FOR**

Dicycloverine hydrochloride, the active ingredient of Dicycloverine Oral Solution 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 ORAL SOLUTION**

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

**Do not give or take Dicycloverine Oral Solution**

- If you are allergic to dicycloverine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- To babies under 6 months old as it may be dangerous for them.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Dicycloverine Oral Solution 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 Oral Solution**

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

**Dicycloverine Oral Solution with food and drink**

Dicycloverine Oral Solution 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 Oral Solution unless you are sure your judgement and co-ordination are not affected.

#### Information about ingredients of Dicycloverine Oral Solution

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

Contains 2.33 g (5ml) and 4.67 g (10ml) of sucrose per dose. This should be taken into account in patients with diabetes mellitus.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. This medicine contains 0.25 mg of sodium benzoate in each 1ml.

### 3. HOW TO TAKE DICYCLOVERINE ORAL SOLUTION

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

One to Two 5ml spoonfuls three times a day. Your doctor will tell you which dose to use.

#### Use in children

##### Children aged 2 - 12 years old

One 5ml spoonful three times a day

The above doses may be taken before or after meals.

##### Children aged 6 months - 2 years old

Half to One 5ml spoonful three or four times a day. This should be given 15 minutes before feeding. Do not give more than four 5ml spoonfuls in any one day.

#### If you take more Dicycloverine Oral Solution than you should

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

#### If you forget to take Dicycloverine Oral Solution

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.

#### 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.

**Not known: frequency cannot be estimated from the available data**

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

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](http://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 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 label and carton. The expiry date refers to the last day of that month.
- Store your medicine in the original container. 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 medicines you no longer use. These measures will help to protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Dicycloverine Oral Solution contains**

The name of this medicine is Dicycloverine Oral Solution.

The active substance in your oral solution is dicycloverine hydrochloride. Each 5ml Spoonful contains 10mg of the active ingredient dicycloverine hydrochloride respectively. Other ingredients include Sodium benzoate, Sucrose, Citric acid monohydrate, Sodium citrate, Flavour Cherry-ST4545/25, Flavour Raspberry-AF-2283, Flavour Vanilla-AF-2268 and Flavour Blackcurrant-AF-2285.

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

Dicycloverine Oral solution is a Pale yellow coloured, clear, flavoured Solution. Each Bottle contains 120ml of Solution.

**Marketing Authorisation Holder**

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK

**Manufacturer**

Mercury Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BL, UK.

**This leaflet was prepared in January 2024.**