

Package leaflet: Information for the user
Dicycloverine Hydrochloride 10mg/5ml 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.

The name of your medicine is Dicycloverine Hydrochloride 10mg/5ml Oral Solution but it will be referred as Dicycloverine throughout this leaflet.

What is in this leaflet:

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

1. What Dicycloverine is and what it is used for

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

What Dicycloverine is used for:

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

How Dicycloverine works

Dicycloverine 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

Do not take Dicycloverine if:

- ▶ You are allergic (hypersensitive) 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dicycloverine 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.

Other medicines and Dicycloverine

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 and herbal medicines.

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

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

Dicycloverine contains:

This medicine contains 3.696g of a mixture of fructose, glucose and sucrose per 5ml dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth, if the product is used for two weeks or more. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicine also contains 4mg sodium benzoate and 14.735mg propylene glycol per 5ml dose.

This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

3. How to take Dicycloverine

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

How much to take

The usual dose is:

Adults

- ▶ One to two 5ml spoonful (10-20mg) three times each day
- ▶ Take the solution before or after meals.

Children aged 2 to 12 years

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

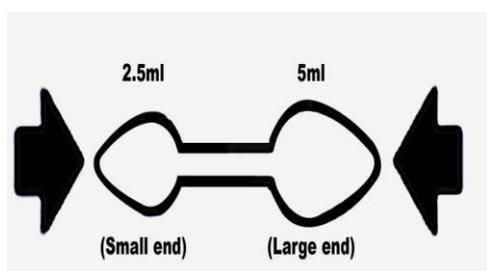
Children aged 6 months to 2 years

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

Method of administration:

- ▶ Take this medicine by mouth.
- ▶ Use the 2.5-5ml double-ended spoon supplied in the pack (see below) to measure the required dose.
- ▶ This medicine may be diluted. If this is done, take the oral solution immediately after dilution.

Double-ended Spoon



If you take more Dicycloverine than you should

Talk to your doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you, this is so that 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

If you forget a dose, take it as soon as you remember. 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

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Dicycloverine 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 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 gets 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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dicycloverine

- ▶ Keep this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date, which is printed on the carton and bottle after 'Exp'. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special storage conditions.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dicycloverine contains

The active substance is dicycloverine hydrochloride.

Each 5ml solution contains 10mg dicycloverine hydrochloride.

The other ingredients are citric acid monohydrate (E330), sucralose (E955), invert syrup (contains glucose, sucrose and fructose), sodium benzoate (E211), strawberry flavour (contains propylene glycol (E1520) and natural flavouring substances) and purified water.

What Dicycloverine looks like and contents of the pack

Dicycloverine is a clear, light yellow to yellow oral solution with a strawberry flavour. It is supplied in an amber glass bottle with a tamper-evident child-resistant plastic screw cap.

The pack also contains a 2.5-5ml double ended spoon.

Dicycloverine is supplied in bottles containing 100ml, 120ml and 300ml solution.
Not all pack sizes may be marketed

POM

Marketing Authorisation Holder:

Syri Pharma Limited t/a Thame Laboratories
Floor 0, 1 WML,
1 Windmill Lane,
Dublin 2, D02 F206, Ireland.

Manufacturer:

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OR

Syri Limited t/a SyriMed,
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OR

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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 revised in 10/2020.