

Colese

contains the active ingredient mebeverine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Colese.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Colese against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Please read this leaflet carefully and keep this leaflet with your medicine.

You may need to read it again.

What Colese is used for

Colese is used to relieve the symptoms of irritable bowel syndrome such as:

- * stomach cramps or pain
- * bowel spasms
- * diarrhoea, which may alternate with periods of constipation
- * flatulence (wind).

Colese contains the active ingredient mebeverine hydrochloride. It belongs to a group of medicines called antispasmodic agents. These medicines work by relaxing the muscles in the gut, thereby relieving the contractions or spasms.

Ask your doctor if you have any questions about why Colese has been prescribed for you.

Your doctor may have prescribed Colese for another reason.

Colese is available only with a doctor's prescription.

There is no evidence that Colese is addictive.

Before you take Colese

When you must not take it

Do not take Colese if you are allergic to:

- * medicines containing mebeverine hydrochloride (eg. Colofac)
- * any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Colese if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Colese if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or intend to become pregnant.

Colese is not recommended during the first three months of pregnancy. Your doctor will discuss the risks and benefits of taking Colese during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Colese passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Colese when breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- * angina or other heart problems
- * liver problems
- * kidney problems
- * lactose intolerance.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking Colese.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Colese, or may affect how well it works.

How to take Colese

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual adult dose is one tablet three times a day.

Your doctor may gradually reduce the dose after several weeks if your symptoms improve while on Colese.

How to take Colese

Swallow the tablets with a glass of water.

When to take Colese

Take Colese at about the same time each day.

This will allow Colese to have its best effect and also help you remember when to take it.

Take Colese immediately before or with food.

How long to take Colese for

Keep taking Colese for as long as your doctor recommends.

If you forget to take Colese

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have any questions or are not sure what to do, ask your doctor or pharmacist.

If you take too much Colese (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much Colese.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Colese

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Colese.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Colese.

If you become pregnant while taking Colese, tell your doctor.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use Colese to treat any other conditions unless your doctor tells you to.

Do not give Colese to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Colese affects you.

Colese may cause dizziness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Colese.

Colese helps most people with their irritable bowel syndrome symptoms, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The incidence of side effects reported with this medicine is low.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * dizziness
- * headache
- * heartburn, indigestion
- * constipation
- * loss of appetite
- * feeling generally unwell
- * difficulty sleeping
- * slow heart beat.

The above list includes the milder side effects of your medicine.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * skin rash, itching or hives
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.

The side effects listed above are serious and require urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Colese

Storage

Keep Colese where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Colese or any other medicine in the bathroom or near a sink.

Do not leave Colese in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Colese, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Colese is a round, white, film-coated tablet, blank on one side and marked "MV" over "135" on the other.

Each pack contains 30 or 90 tablets.

Ingredients

The active ingredient in Colese is mebeverine hydrochloride.

Each Colese tablet contains 135 mg of mebeverine hydrochloride.

The tablets also contain the following inactive ingredients:

- * lactose (100 mg per tablet)
- * microcrystalline cellulose
- * povidone
- * sodium starch glycollate
- * purified talc
- * magnesium stearate
- * Opadry White Y-1-7000 [includes hypromellose, macrogol 400, titanium dioxide CI77891 (E171)].

The tablets are gluten free.

Supplier

Colese is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

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Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

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Australian registration number:

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