

Package leaflet: Information for the user

Coloprep 1500 mg Tablets

Sodium dihydrogen phosphate monohydrate
Disodium phosphate anhydrous

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

1. What Coloprep is and what it is used for

Coloprep contains the active substances sodium dihydrogen phosphate monohydrate and disodium phosphate anhydrous which belong to a group of medicines that are described as purgatives (very strong laxatives). They are used to clean the bowel by causing large amounts of water to be drawn into the bowel resulting in diarrhoea.

Coloprep is used for cleansing the bowel before certain diagnostic procedures such as colonoscopy.

Coloprep is indicated in adults over the age of 18 years.

2. What you need to know before you take Coloprep

Do not take Coloprep if you have:

- an allergy (hypersensitivity) to sodium phosphate salts or to any of the other ingredients of this medicine (listed in section 6).
- been told that you have kidney failure or that your kidneys have been damaged by the formation of phosphate crystals (phosphate nephropathy).
- a problem with your parathyroid gland known as primary hyperparathyroidism.
- problems with your heart, heart failure or severe chest pains.
- an accumulation of fluid in your abdomen (ascites).
- bowel problems such as blockages or severe chronic constipation or problems with emptying your bowels.
- inflammatory bowel disease or an enlarged colon (megacolon) or bowel perforation.
- ever undergone gastric bypass surgery.

- hypomotility syndrome (hypothyroidism, scleroderma).
- If you are under 18 years of age, or over 75 years of age.

You must not use any other laxatives, particularly those containing sodium phosphate, while you are using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using Coloprep.

Before you start taking this medicine you should tell your doctor if you:

- have any heart problems, such as, arrhythmias, cardiomyopathy, recent history of myocardial infarction, cardiac surgery, including coronary artery bypass graft surgery
- have ever had any problems with your kidneys.
- have ever had any problems with your stomach or intestine (guts).
- have ever had problems with the salts in your blood such as high / low levels of sodium or phosphate, or low levels of calcium or potassium.
- have ever suffered from fits (seizures).
- have an underactive thyroid.
- have low blood pressure.
- are elderly or weak.
- have diabetes.
- have hypertension (high blood pressure).
- have been told you are dehydrated or you cannot drink a lot of liquid.
- have been told you have syndrome of inappropriate ADH secretion (SIADH).
- have stopped drinking alcohol after a period of excessive consumption.
- take **Benzodiazepines** (such as valium, medicines used to treat anxiety)
- take **Diuretics** (water tablets)
- take **Calcium channel blockers or ACE Inhibitors** (medicines used for angina, heart conditions or high blood pressure)
- take **Angiotensin receptor blockers** (such as losartan, used to treat high blood pressure)
- take **NSAIDs** (medicines used for pain relief such as ibuprofen)
- take **Tricyclic antidepressants** (medicines used to treat depression)

Your doctor may ask you to have some blood tests before and after you take this medicine to check the levels of salts (electrolytes) in your body.

Further precautions:

Coloprep can lead to excessive loss of fluid as diarrhoea. You must ensure that you drink the recommended amount of clear liquid or water to replace the large amounts of fluid that may be lost during bowel evacuation. However, drinking **excessive amounts** liquid can lead to over-hydration (also known as water intoxication – see Section 3).

Notify your doctor if you experience severe or persistent abdominal pain and/or anal bleeding occurs after treatment with Coloprep. Coloprep has been associated with rare cases of intestinal inflammation (colitis)

Children and adolescents

Do not give Coloprep to children and adolescents under 18 years of age

REMEMBER you need to be close to toilet facilities whilst you are taking Coloprep as you can expect to have frequent and watery stools. The medicine usually acts 30 minutes to 6 hours after taking the tablets.

If you have not had a bowel movement after 6 hours, do not take any more medicine and contact your doctor immediately.

Other medicines and Coloprep

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

It may still be alright for you to use Coloprep and your doctor will be able to decide what is suitable for you.

In particular, please tell your doctor if you take or use any of the medicines mentioned below as their effects may change:

- **Calcium channel blockers or ACE Inhibitors** (medicines used for angina, heart conditions or high blood pressure)
- **Diuretics** (water tablets)
- **Lithium containing medicines** (used to treat mental illness)
- **Medicines containing aluminium, calcium or magnesium salts** (may reduce the absorption of phosphate salts)
- **Vitamin D containing medicines** (may increase phosphate absorption)
- **Medicines such as oral contraceptives, antibiotics, medicines used to treat diabetes and medicines used to treat epilepsy** (the effects of these medicines may be delayed or prevented)
- **NSAIDs** (medicines used for pain relief such as ibuprofen)
- **Tricyclic antidepressants** (medicines used to treat depression)
- **Benzodiazepines** (such as valium, medicines used to treat anxiety)
- **Parathyroid hormone** (used for treating osteoporosis)
- **Angiotensin receptor blockers** (such as losartan, used to treat high blood pressure)
- Medicines that alter the rhythm of your heart

DO NOT take any other laxatives, rectally administered medicines or other medication containing sodium phosphate while taking Coloprep.

Patients should not repeat taking this purgative agent for at least 7 days.

You may see undigested or partially digested Coloprep Tablets or undigested tablets of other medications in the watery diarrhoea stools.

Coloprep with food and drink

See Section 3 of this leaflet.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant, think you may be pregnant or planning to have a baby, you should only use Coloprep if your doctor tells you to. If you are breastfeeding your baby, you should not breastfeed whilst taking Coloprep and not restart breastfeeding until 24 hours after taking the last dose has passed.

Driving and using machines

This medicine may make you feel dizzy. If you are affected by this, you should not drive or use machines until this feeling has gone.

Coloprep contains sodium

This medicine contains 10 016 mg of sodium (main component of cooking/table salt) per course of treatment. This is equivalent to 500% of the recommended maximum daily intake of sodium for an adult. A course of treatment consists of 32 tablets of Coloprep. This is to be taken into consideration by patients on a controlled sodium diet’.

3. How to use Coloprep

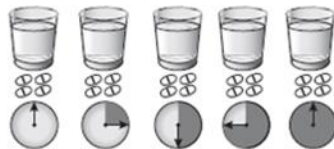
Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken by mouth in the following manner.

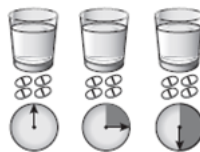
Dosage for adults (over 18 years of age):

The recommended dose is 32 tablets. The tablets are usually taken in the following manner:

The **evening before** the colonoscopy procedure, take 4 Tablets with 250 mL of water (or another clear liquid) every 15 minutes until you have taken a total of 20 tablets.



The **day of the** colonoscopy procedure, (starting 3-5 hours before the procedure) take 4 Tablets with at least a glass (250 mL) of water (or another clear liquid) every 15 minutes for a total of 12 tablets.



Coloprep should **not** be taken with food. On the day prior to colonoscopy you may have a light, low fibre breakfast (coffee or tea with or without sugar, toast, butter or equivalent, honey or fruit jam without fruit bits or smooth jam may be used, but you should not have jam with any fruit bits/residue) before 12 noon. After 12 noon you should only drink clear liquids such as water, any clear carbonated (fizzy) drink with or without bicarbonate, light soup, diluted fruit juice with no pulp, black coffee and weak tea before taking Coloprep and while you are taking the tablets.

Coloprep can make you dehydrated. It is important that you take this medicine and the quantities of clear liquid as directed above, and drink plenty of clear liquid to replace the large amounts of fluid that may be lost during bowel evacuation. However, drinking **excessive amounts** of liquid can lead to over-hydration (also known as water intoxication).

Signs and symptoms of water intoxication can include: nausea and vomiting, headache, blurred vision, twitching, slowed breathing, personality and behavioural changes, (hallucinations, confusion or disorientation). If left untreated, over-hydration can lead to low levels of sodium in the blood (hyponatremia). This can cause more severe symptoms, such as: muscle weakness, spasms and cramps, seizures, unconsciousness. If you experience one or more of any of these symptoms, do not drink any more liquid and contact your doctor or pharmacist immediately.

A tablet check-off chart is provided below to help you make sure that you take all the tablets at the right time. You should record the start date and the time you take each dose. After swallowing each dose you should check-off the corresponding box for that dose. You should ensure that you have a clock or watch nearby before you start taking Coloprep.

First Dosing Regimen

Start Date	Date	Time	Dosage	Check-Off
Dose 1	Start Time	:	4 tablets	<input type="checkbox"/>
Dose 2	+ 15 min	:	4 tablets	<input type="checkbox"/>
Dose 3	+ 30 min	:	4 tablets	<input type="checkbox"/>
Dose 4	+ 45 min	:	4 tablets	<input type="checkbox"/>
Dose 5	+ 1 hr	:	4 tablets	<input type="checkbox"/>

Total = 20 tablets

Second Dosing Regimen

Start Date	Date	Time	Dosage	Check-Off
Dose 1	Start Time	:	4 tablets	<input type="checkbox"/>
Dose 2	+ 15 min	:	4 tablets	<input type="checkbox"/>
Dose 3	+ 30 min	:	4 tablets	<input type="checkbox"/>

Total = 12 tablets

If your examination is early morning, it is possible to take all of the tablets in the evening before the procedure. You will need to start taking the tablets at least 4 and a half hours before you go to bed. For example, if you are planning on going to bed at 11pm, you should take dose 1 at 6.30pm. So, at 6.30pm, you would take 4 tablets with 250 mL of water (or another clear liquid), and repeat this every 15 minutes until you have taken a total of 20 tablets. You must then wait 3 hours after dose 5 before starting the second dosage regimen. With this example, you would take another 4 tablets at 10.30pm with 250 mL of water (or another clear liquid) every 15 minutes until you have taken a total of 12 tablets. Your last dose would be at 11pm.

REMEMBER you need to be close to toilet facilities whilst you are taking Coloprep as you can expect to have frequent and watery stools. The medicine usually acts 30 minutes to 6 hours after taking the tablets. If you have not had a bowel movement after 6 hours, do not take any more medicine and contact your doctor immediately.

If you take more Coloprep than you should

Contact a doctor immediately if you have taken more than the recommended dose of Coloprep.

If you forget to take Coloprep

Do not take a larger than normal dose of Coloprep next time, but take your next dose of Coloprep as soon as you remember and continue taking the tablets every 15 minutes until you have completed the course.

When you stop taking Coloprep

Bowel movements may continue for several hours after your last dose of Coloprep has been taken.

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.

All medicines can cause allergic reactions although serious allergic reactions are rare. If you get any of the following symptoms after taking this medicine, you should contact your doctor immediately:

- **Rash or skin itching**
- **Tightness or swelling of the throat, lips and face**
- **Tingling of the lips and tongue**
- **Seizures or loss of consciousness**
- **Abnormal heart rhythm, muscle twitching or spasms**
- **Breathing difficulties**
- **Chest pain**

See your doctor as soon as possible if you notice any of the following:

- Kidney failure and / or other problems with the kidneys (symptoms may include, weight gain, swollen ankles, feet or hands, blood or protein in your urine, an increased need to urinate, weakness, muscle cramps)
- Electrolyte levels in your blood have changed (symptoms may include, feeling tired, thirsty, feeling sick, tingles, weakness, irregular heartbeat)

The following side effects have also been reported:

Very common: (may affect more than 1 in 10 people)

- Abdominal bloating, abdominal pain and nausea
- Chills, feeling weak

Common: (may affect up to 1 in 10 people)

- Headache, dizziness, vomiting
- Ulcers in the lower gut (near your bottom). These clear up after treatment.
- Superficial gastric erosions in your stomach, which may cause some pain or discomfort in this area. These clear up after treatment.

Uncommon: (may affect more than 1 in 100 people)

- Dehydration

Rare: (may affect up to 1 in 1,000 people)

- Low magnesium level in your blood

Very rare: (may affect up to 1 in 10,000 people)

- Low blood pressure
- Kidney failure and / or other problems with the kidneys
- Electrolyte abnormalities

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 Coloprep

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

Keep the bottle tightly closed in order to protect from moisture.

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 Coloprep contains

The active substances are 1102 mg of sodium dihydrogen phosphate monohydrate and 398 mg of disodium phosphate anhydrous.

The other ingredients are macrogol 8000 and magnesium stearate.

What Coloprep looks like and contents of the pack

Coloprep are white to off-white oval tablets, with “SLX” printed on the left side and “102” printed on the right side of the breakline. The reverse side of the tablets is unmarked.

Coloprep is available in bottles containing 32 tablets. The bottle contains all the tablets you need for a complete dose. The bottle also contains two desiccants, which should not be swallowed.

Marketing Authorisation Holder and Manufacturer

Laboratoires MAYOLY SPINDLER

6, Avenue de l'Europe – BP 51

78401 CHATOU CEDEX

FRANCE

Manufacturer

Laboratoires Galeniques Vernin

20, rue Louis-Charles Vernin

77190 Dammarie-les-Lys,

France

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland	Coloprep
Belgium	Colowash
Spain	Mayprep
United Kingdom (Northern Ireland), Germany, Poland, Portugal	Coloclear

This leaflet was last revised in 09/2021