

ARX-COLCHICINE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARX-COLCHICINE?

ARX-COLCHICINE contains the active ingredient colchicine. ARX-COLCHICINE is used to relieve pain in acute attacks of gout.

For more information, see Section [1. Why am I using ARX-COLCHICINE?](#) in the full CMI.

2. What should I know before I use ARX-COLCHICINE?

Do not use if you have ever had an allergic reaction to ARX-COLCHICINE or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARX-COLCHICINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-COLCHICINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARX-COLCHICINE?

- Your doctor will tell you how much ARX-COLCHICINE to take.
- The usual dose is 2 tablets at the first sign of the flare followed by 1 tablet one hour later. The maximum recommended dose for treatment of gout flares is 3 tablets over a one-hour period.
- **Do not repeat the course within 3 days.**
- **ARX-COLCHICINE may be taken before or after food. Swallow the tablet whole with a full glass of water.**

More instructions can be found in Section [4. How do I use ARX-COLCHICINE?](#) in the full CMI.

5. What should I know while using ARX-COLCHICINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARX-COLCHICINE.• Keep all your doctor's appointments so that your progress can be checked.• Call your doctor straight away if you become pregnant while taking ARX-COLCHICINE
Things you should not do	<ul style="list-style-type: none">• Do not take ARX-COLCHICINE to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ARX-COLCHICINE affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• If you drink alcohol while taking this medicine, you may develop stomach problems.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

For more information, see Section [5. What should I know while using ARX-COLCHICINE?](#) in the full CMI.

6. Are there any side effects?

Common side effects of ARX-COLCHICINE include stomach pain, nausea, vomiting, and diarrhoea. Serious side effects of ARX-COLCHICINE include loss of appetite and loss of hair. Very serious side effects of ARX-COLCHICINE include a burning feeling in the stomach or throat; severe stomach pain, nausea, or vomiting; severe diarrhoea with bloody or black tarry stools; itchy skin; skin rash; hives; unusual bleeding or bruising under the skin; difficulty in passing urine or blood in urine; confusion; convulsions; fever; muscle weakness; and numbness or weakness in the fingers and toes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARX-COLCHICINE

Active ingredient(s): *Colchicine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-COLCHICINE.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARX-COLCHICINE.

Where to find information in this leaflet:

- [1. Why am I using ARX-COLCHICINE?](#)
- [2. What should I know before I use ARX-COLCHICINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-COLCHICINE?](#)
- [5. What should I know while using ARX-COLCHICINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARX-COLCHICINE?

ARX-COLCHICINE contains colchicine as the active ingredient. ARX-COLCHICINE belongs to a group of medicines called antipain drugs.

ARX-COLCHICINE is used for the relief of pain in acute attacks of gout. It is not an analgesic and does not provide relief from other types of pain. ARX-COLCHICINE has a preventative effect that helps to reduce the incidence of acute attacks. It will not reduce the amount of uric acid in the body.

Ask your doctor if you have any questions about why ARX-COLCHICINE has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ARX-COLCHICINE?

Warnings

Do not use ARX-COLCHICINE if

- you have any of the following:**
 - combined kidney and liver disease
 - serious kidney or liver disease
 - serious heart disease
 - a severe stomach disorder
 - a blood disorder
 - a rare genetic condition where the body can't properly digest certain sugars like galactose, lactose or glucose
- you are allergic to colchicine, or any of the ingredients listed at the end of this leaflet.

- the expiry date on the label has passed
- the package shows signs of tampering

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - stomach problems
 - kidney or liver disease
 - heart disease
 - alcoholism.
- take any medicines for any other condition.
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ARX-COLCHICINE may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of you taking ARX-COLCHICINE when breastfeeding.

Use in children

Do not give this medicine to children under 2 years of age.

This medication may be dangerous to children. It is important that it is kept out of the reach of children at all times.

Use in the elderly or debilitated

Elderly or debilitated patients may be more sensitive to the effects or side effects of this medicine.

3. What if I am taking other medicines?

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

Some medicines may interfere with ARX-COLCHICINE and affects how it works. These include:

- cyclosporin - a medicine used to suppress the immune system

- erythromycin, clarithromycin and telithromycin - antibiotics used to treat bacterial infection
- protease inhibitors, including atazanavir, indinavir, nelfinavir, ritonavir and saquinavir, used to treat HIV and other viral infections
- ketoconazole and itraconazole, used to treat certain fungal infections
- nefazodone, used to treat depression
- acidifying and alkalinising agents, such as ammonium chloride, ascorbic acid (vitamin C), sodium bicarbonate
- medicines to help you sleep
- alcohol
- NSAIDs or aspirin - anti-inflammatory drugs used to treat pain
- medicines used to treat cancer including radiation therapy
- vitamin B12
- anticoagulants such as coumarin, heparin
- antithyroid medicines.

This list is not exhaustive.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-COLCHICINE.

4. How do I use ARX-COLCHICINE?

How much to take

The dosage of ARX-COLCHICINE varies and depends on the patient, any other health conditions and the response to the treatment. Your doctor will tell you how much ARX-COLCHICINE to take.

The usual dosage is 2 tablets at the first sign of the flare followed by 1 tablet one hour later. The maximum recommended dose for treatment of gout flares is 3 tablets over a one hour period.

Do not repeat the course within 3 days.

When to take ARX-COLCHICINE

ARX-COLCHICINE may be taken before or after food.

How to take ARX-COLCHICINE

Swallow the tablet whole with a full glass of water.

How long to take ARX-COLCHICINE for

Continue taking your medicine for as long as your doctor tells you.

This will depend on your condition and your response to the treatment. ARX-COLCHICINE helps to control your condition but does not cure it.

Immediately stop taking ARX-COLCHICINE at the first sign of stomach pain, nausea, vomiting or diarrhoea. Do this even if your symptoms have not been relieved.

Your doctor will want to know how many tablets you have taken prior to the appearance of these symptoms and during subsequent attacks of gout to use smaller doses.

If you forget to use ARX-COLCHICINE

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

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much ARX-COLCHICINE

If you think that you have used too much ARX-COLCHICINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ARX-COLCHICINE?

Things you should do

- **Immediately stop taking ARX-COLCHICINE at the first sign of stomach pain, nausea, vomiting or diarrhoea. Do this even if your symptoms have not been relieved.**
Remember to take note of the number of tablets you took before the onset of these symptoms so that you can take fewer tablets during subsequent attacks.
- **Tell your doctor, surgeon or anaesthetist that you are taking ARX-COLCHICINE if you are about to undergo surgery or an operation.**
- **If you are about to have any blood tests remind your doctor that you are taking ARX-COLCHICINE.** It may interfere with the results of some tests.
- **Keep all your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you become pregnant while taking ARX-COLCHICINE.

Remind any doctor, dentist or pharmacist you visit that you are using ARX-COLCHICINE.

Things you should not do

- **Do not take ARX-COLCHICINE to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-COLCHICINE affects you.

Possible drowsiness and dizziness should be taken into account.

Drinking alcohol

Tell your doctor if you drink alcohol

If you drink alcohol while taking this medicine, you may develop stomach problems.

Looking after your medicine

Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light. For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• stomach pain• nausea• vomiting• diarrhoea	Immediately stop taking ARX-COLCHICINE at the first sign of these side effects. Do this even if your symptoms have not been relieved.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• loss of hair• loss of appetite• change in menstrual cycle	Tell your doctor as soon as possible if you notice any of

	these serious side effects
<ul style="list-style-type: none">• burning feeling in the stomach or throat• severe stomach pain, nausea, vomiting• severe diarrhoea with bloody or black tarry stools• itchy skin, skin rash, hives, unusual bleeding or bruising under the skin• difficulty in passing urine or blood in urine• confusion, convulsions• fever• muscle weakness• numbness or weakness in the fingers and toes.	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARX-COLCHICINE contains

Active ingredient (main ingredient)	Each uncoated tablets contain 500 microgram of colchicine as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• pregelatinised maize starch• microcrystalline cellulose• lactose monohydrate• sodium starch glycollate• magnesium stearate
Potential allergens	contains lactose

Do not take this medicine if you are allergic to any of these ingredients.

What ARX-COLCHICINE looks like

ARX-COLCHICINE Round, off white coloured biconvex, uncoated tablets embossed "C5" on one upper side and plain on the bottom face.

ARX-COLCHICINE available in a

- HDPE bottle of 30 tablets.

Bottle (Aust R 484784)

Who distributes ARX-COLCHICINE

ARX-COLCHICINE is supplied in Australia by:

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia
www.pharmacor.com.au

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