

PYRALIN EN[®]

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 taking PYRALIN EN?

PYRALIN EN contains the active ingredient sulfasalazine. PYRALIN EN is used to treat and manage ulcerative colitis and Crohn's disease which are inflammatory bowel diseases.

PYRALIN EN is also used to treat rheumatoid arthritis which is a painful joint disease.

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

2. What should I know before I take PYRALIN EN?

Do not take if you have ever had an allergic reaction to sulfasalazine, sulfur-containing medicines, some oral sugar-controlling medicines, some diuretics (thiazide diuretics) salicylates, 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, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take PYRALIN EN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PYRALIN EN 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 take PYRALIN EN?

- Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.
- Continue taking PYRALIN for as long as your doctor recommends.
- PYRALIN EN tablets are usually taken whole after meals at evenly spaced intervals over a 24 hour period.
- Do not crush, break or chew PYRALIN EN tablets

More instructions can be found in Section [4. How do I take PYRALIN EN?](#) in the full CMI.

5. What should I know while taking PYRALIN EN?

Things you should do	<ul style="list-style-type: none">● Remind any doctor or dentist you visit that you are using PYRALIN EN.● Drink plenty of fluids while on PYRALIN EN.● Protect your skin when you are in the sun, especially between 10am and 3pm.
Things you should not do	<ul style="list-style-type: none">● Do not take PYRALIN EN to treat any other complaints unless your doctor tells you to.● Do not stop taking PYRALIN EN or change the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">● PYRALIN EN may cause dizziness or hallucinations in some people. If you have any of these symptoms, do not drive, operate machinery or do

	anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight in original container and below 25°C.

For more information, see Section [5. What should I know while taking PYRALIN EN?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea or vomiting, diarrhoea and cold and flu symptoms. More serious side effects may be severe allergic reactions, serious skin infections or reactions or liver disease.

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.

PYRALIN[®] EN tablets

Active ingredient(s): Sulfasalazine

Consumer Medicine Information (CMI)

This leaflet provides important information about using PYRALIN EN. **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 PYRALIN EN.**

Where to find information in this leaflet:

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

1. Why am I taking PYRALIN EN?

PYRALIN EN contains the active ingredient sulfasalazine.

It has a number of effects in the body. It suppresses the immune system and is an anti-inflammatory medicine.

PYRALIN EN is used to treat and manage ulcerative colitis and Crohn's disease which are inflammatory bowel diseases.

PYRALIN EN is also used to treat rheumatoid arthritis which is a painful joint disease.

PYRALIN EN helps prevent damage to your joints. It works to slowly reduce the swelling and stiffness in your joints. It is usually given when a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) are not working.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that Pyralin EN is addictive.

2. What should I know before I take PYRALIN EN?

Warnings

Do not take PYRALIN EN:

1. If you are allergic to:

- sulfasalazine,
- sulfur-containing medicines e.g. sulfonamides;
- some oral sugar-controlling medicines for diabetes (hypoglycaemics) e.g. glipizide;

- medicines known as thiazide diuretics e.g. chlorothiazide
- medicines known as salicylates e.g. aspirin
- any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

2. if you have the following medical conditions:

- kidney or liver problems
- any form of blood disorder
- any form of intestinal or urinary obstruction
- porphyria (rare disease of blood pigments)

3. the packaging is torn or shows signs of tampering or the tablets do not look quite right

4. the expiry date (Exp.) on the carton has passed

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

Do not give PYRALIN EN to children under two years of age.

Check with your doctor if you:

- have any other medical conditions, including if you:
 - have a glucose-6-phosphate dehydrogenase (G-6-P) deficiency. This is a rare blood disorder which means that your body cannot get rid of some medicines
 - have bronchial asthma (wheezing or shortness of breath)
 - have a history of recurring or chronic infections.
 - Are allergic to any other medicines or any other substances such as foods, preservatives or dyes
- take any medicines for any other condition – see above under ‘ Do not take PYRALIN EN’.

Your doctor will send you to have blood tests to help assess your liver and kidney function and the levels of various cells in your bloodstream before you start treatment with PYRALIN EN. You may also have a urine test to monitor your kidney function.

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.

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

Your doctor will discuss the possible risks and benefits of taking PYRALIN EN during pregnancy and breast-feeding.

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 PYRALIN EN and affect how it works.

- oral medicines used to prevent blood clots e.g. warfarin
- methotrexate, a medicine used to treat arthritis and some cancers
- medicines to lower blood sugar or control diabetes
- mercaptopurine and azathioprine, medicines used to treat some cancers
- antacids: medicines that help to control heartburn or symptoms of indigestion
- digoxin: a medicine used to treat heart failure
- oxyphenbutazone, phenylbutazone, indomethacin and sulfinpyrazone which are medicines used to treat arthritis and gout
- salicylates: medicines used to treat minor relief of pain e.g. aspirin
- oxacillin and penicillins which are types of antibiotics
- certain local anaesthetics

- medicines used to make the urine more acidic
- iron tablets.

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

4. How do I take PYRALIN EN?

How much to take and when to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines. Continue taking PYRALIN EN for as long as your doctor recommends.

Inflammatory Bowel Disease

- Adults:
 - The usual initial dose is 2 to 4 tablets, four times a day.
 - The usual maintenance dose is 4 tablets a day.
- Children:
 - Your doctor will determine the proper dose, taking into account the age and weight of the child.

Rheumatoid Arthritis

- Adults:
 - The usual dose is 2 tablets, two to three times a day.
 - It is usual to start taking PYRALIN EN at a lower dose and gradually increase. Your doctor will advise whether you should do this and how to do this.
- Children: PYRALIN EN is not recommended for treating rheumatoid arthritis in children.

How to take

- PYRALIN EN should be swallowed whole after meals with a full glass of water.
- PYRALIN EN is usually taken at evenly spaced intervals over a 24 hour period.
- It is important to maintain adequate fluid intake while taking PYRALIN EN
- Do not crush, break or chew PYRALIN EN tablets

Continue taking PYRALIN EN for as long as your doctor recommends.

If you forget to take PYRALIN EN

PYRALIN should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose at the normal time it's due.

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.

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

If you take too much PYRALIN EN

If you think that you have taken too much PYRALIN EN, 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.

The symptoms of taking too many PYRALIN EN tablets may include stomach discomfort and other effects listed under the heading "Are there any Side effects" in this leaflet.

5. What should I know while taking PYRALIN EN?

Things you should do

- Drink plenty of fluids while on PYRALIN EN.

- Protect your skin when you are in the sun, especially between 10am and 3pm.
- PYRALIN EN may cause your skin to be more sensitive to sunlight than it is normally. If outdoors, wear protective clothing sunscreen. If your skin does appear to be burning, tell your doctor immediately. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.
- Tell all doctors, dentists, pharmacists and specialists who are treating you that you are taking Pyralin EN.
- Make sure that you keep all doctor's appointments for check-ups and any tests that your doctor may order for you while you are taking PYRALIN EN.

Call your doctor straight away if you:

- notice any unusual symptoms.
- become pregnant while taking PYRALIN EN.

Remind any doctor or dentist you visit that you are using PYRALIN EN.

Things you should not do

- Do not take PYRALIN EN to treat any other complaints unless your doctor tells you to.
- Do not stop taking PYRALIN EN or change the dose without first checking with your doctor.
- Do not give PYRALIN EN 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 PYRALIN EN affects you.

PYRALIN EN may cause dizziness in some people

This medicine may cause dizziness or hallucinations in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight in original container and below 25°C; for example, do not store it:

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

Make sure the container is closed after use.

Do not take this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take 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.

Common side effects

Common side effects	What to do
<p>Gastrointestinal symptoms:</p> <ul style="list-style-type: none">• nausea and vomiting• loss of appetite• diarrhoea• stomach pains <p>Cold and flu like symptoms:</p> <ul style="list-style-type: none">• enlarged glands• cough	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Common side effects	What to do
<p>Alertness and related effects</p> <ul style="list-style-type: none"> ● headache ● dizziness ● hallucinations ● increased sensitivity to light <p>Other</p> <ul style="list-style-type: none"> ● change in sense of smell or taste ● insomnia ● depression ● ringing in the ears 	

Serious side effects

Serious side effects	What to do
<p>Heart and lung related side effects:</p> <ul style="list-style-type: none"> ● breathlessness ● chest pain ● palpitations <p>Skin related side effects</p> <ul style="list-style-type: none"> ● redness and itchiness of the skin 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● signs of serious skin infections such as rash or mucosal lesions ● dermatitis (dry, itchy skin) <p>Other:</p> <ul style="list-style-type: none"> ● convulsions ● allergic reactions ● swelling of the face ● loss of hair ● signs of liver disease such as yellowing of skin and eyes and dark coloured urine ● severe pain in the loins or pain on urination. <p>Sore throat, fever, pale appearance, rash and yellow skin</p> <p>Tell your doctor immediately. This may mean that you have a serious blood disorder and need urgent medical care.</p> <p>Side effects only seen via blood test include:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> ● blood cell changes ● reversible low sperm count ● swelling of the pancreas ● swelling in the mouth ● impaired folic acid absorption ● peripheral neuropathy and neuritis (which cause tingling, burning or numbness in the hands or feet) ● changes in kidney function and lung complications. 	

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 PYRALIN EN contains

Active ingredient (main ingredient)	500 mg sulfasalazine per tablet
Other ingredients (inactive ingredients)	colloidal anhydrous silica, magnesium stearate, maize starch, povidone, cellacephate, propylene glycol, white beeswax, carnauba wax, glyceryl monostearate, macrogol 20000 and purified talc. PYRALIN EN tablets do not contain lactose, sucrose, or tartrazine.

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

What PYRALIN EN looks like

PYRALIN EN tablets are enteric coated 500mg tablets. They are yellow- orange, elliptical convex tablets, marked with '102' on one side and 'KPh' on the other side.

PYRALIN EN 500mg tablets come in plastic bottles containing 100 tablets (Aust R 58398).

Who distributes PYRALIN EN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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