

Consumer Medicine Information (CMI) summary

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

1. Why am I taking FENAC EC?

FENAC EC contains the active ingredient diclofenac sodium. FENAC EC is used to treat different types of arthritis including rheumatoid arthritis and osteoarthritis; other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow); menstrual cramps (period pain); relieve pain in children after they have had an operation.

For more information, see Section [1. Why am I taking FENAC EC?](#) in the full CMI.

2. What should I know before I take FENAC EC?

Do not take if you have ever had an allergic reaction to FENAC EC 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 FENAC EC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FENAC EC 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 FENAC EC?

- There are different ways to take FENAC EC tablets depending on your condition. Your doctor will tell you exactly how many tablets to take.
- Swallow the tablets whole with a full glass of water or other liquid. Do not chew them.

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

5. What should I know while taking FENAC EC?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or specialist you visit that you are taking FENAC EC.• Tell your doctor immediately if you become pregnant or intend to become pregnant or are breastfeeding.• Tell your doctor immediately if you notice any symptoms such as chest pain, shortness of breath, weakness, slurring of speech
Things you should not do	<ul style="list-style-type: none">• Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.• Do not give FENAC EC to anyone else, even if their condition seems similar to yours.• Do not take it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• FENAC EC may cause vision problems, dizziness, drowsiness, spinning sensation (vertigo), sleepiness or other central nervous system problems in some people. If any of these occur, do not drive, use machine or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep FENAC EC in the original container until it is time to take it.• Keep your tablets below 25°C.

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

6. Are there any side effects?

Common side effects include headache, feeling sick, vomiting, dizziness, indigestion, loss of appetite, problems with vision.

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.

FENAC[®] EC

Active ingredient(s): *diclofenac sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking FENAC EC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking FENAC EC.**

Where to find information in this leaflet:

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

1. Why am I taking FENAC EC?

FENAC EC contains the active ingredient diclofenac sodium. FENAC EC belongs to a group of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness).

FENAC EC is used to treat:

- different types of arthritis including rheumatoid arthritis and osteoarthritis
- other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow)
- menstrual cramps (period pain)

It can relieve the symptoms of pain and inflammation, but it will not cure your condition.

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

Your doctor may have prescribed it for another purpose.

FENAC EC is not addictive.

2. What should I know before I take FENAC EC?

Warnings

Do not take FENAC EC:

- if you are allergic (hypersensitive) to:
 - o diclofenac or any of the other ingredients listed at the end of this leaflet
 - o other medicines containing diclofenac
 - o aspirin
 - o ibuprofen
 - o any other NSAIDIf you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist. Symptoms of an allergic reaction to these medicines may include:

- o shortness of breath
- o wheezing or difficulty breathing
- o swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema)
- o rash, itching or hives on the skin.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.

If you are allergic to aspirin or NSAID medicines and you take FENAC EC, these symptoms may be severe.

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

- if you have had any of the following medical conditions:
 - o a stomach or intestinal ulcer, symptoms include heartburn, feeling sick, vomiting, dull or burning stomach pain, bleeding from the stomach or intestine (symptoms such as blood in your stools or black stools), or any other symptoms such as severe pain in tummy, fever, feeling sick, vomiting.
 - o kidney or liver problems.
 - o severe heart diseases or if you have a history of heart bypass surgery.
 - o a skin rash or skin peeling, blistering and/or mouth sore after taking FENAC EC or other pain medications.
- **during the first 6 months of pregnancy, except on doctor's advice. Do not take this medicine during the last three months of pregnancy.**

Use of this medicine during the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

- after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies, especially if you get skin reactions with redness, itching or rash
- take any medicines for any other condition
- have, or have had, any of the following medical conditions:

- o established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease, or atherosclerotic cardiovascular disease) as treatment with FENAC EC is generally not recommended
- o established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe FENAC EC, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks
- o current or past history of gastrointestinal problems such as stomach or intestinal ulceration, loose and urgent bowel movements, weight loss, bleeding or black stools, and/or stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- o diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis)
- o past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- o liver or kidney problems
- o a rare liver condition called porphyria
- o bleeding disorders or other blood disorders (e.g. anaemia)
- o asthma or any other chronic lung disease that causes difficulty in breathing
- o hay fever (seasonal allergic rhinitis)
- o repeated chest infections
- o polyps in the nose
- o diabetes
- o dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)
- o swollen feet, suffering from leg pain while walking, muscle pain or cramps in the arms or legs or calf
- o smoking if you have history of smoking
- o skin problems, skin rash or any other sign of allergic reactions.
- o Feeling sick, vomiting, pain in stomach, diarrhea, constipation, tiredness or if you have a rare genetic condition called glucose-galactose malabsorption, symptoms include severe diarrhea, which can cause dehydration and weight loss.

Your doctor may want to take special precautions if you have any of the above conditions.

It is generally important to take the lowest dose of FENAC EC that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.

- currently have an infection

If you take FENAC EC while you have an infection, some of the signs of the infection such as pain, fever, swelling and redness may be hidden. You may think,

mistakenly, that you are better or that the infection is not serious.

- are lactose intolerant

FENAC EC tablets contain lactose.

- are planning to give this medicine to a child.

Safety and effectiveness in children have not been established.

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

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

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

Do not use FENAC EC in women who are trying to conceive.

If you are undergoing any treatment for infertility, check with your doctor. Your doctor will discuss with you the risks and benefits involved.

Do not use FENAC EC during pregnancy.

Do not take FENAC EC in the first 6 months of pregnancy, it may increase the risk of miscarriage. Do not take FENAC EC during the last 3 months of pregnancy as it may affect your baby, may cause complications during pregnancy or may delay labour and birth.

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

Do not take FENAC EC if you are breastfeeding or intend to breastfeed.

The active ingredient, diclofenac, passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking FENAC EC when breastfeeding.

Children

There is not enough information to recommend the use of FENAC EC tablets in children.

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 FENAC EC and affect how it works. These include:

- other anti-inflammatory medicines e.g. aspirin, salicylates or ibuprofen
- warfarin, medicines used to prevent blood clotting
- digoxin, a medicine for heart problems
- lithium or selective serotonin-reuptake inhibitors (SSRIs), medicines used to treat some types of depression

- diuretics (furosemide), medicines used to increase the amount of urine
- medicines used to treat high blood pressure, heart problems e.g. beta-blockers (such as propranolol), angiotensin converting enzyme (ACE) inhibitors (such as ramipril), angiotensin II receptor antagonists (such as valsartan)
- medicines used to treat diabetes except insulin, e.g. metformin
- methotrexate, a medicine used to treat arthritis and some cancers
- ciclosporin and tacrolimus, medicines used in organ transplants
- trimethoprim, a medicine used to prevent or treat urinary tract infections
- quinolone antibacterials, medicines used to treat infection
- glucocorticoid, steroids, prednisone, medicines used to provide relief from swelling, arthritis
- sulfinpyrazone, a medicine used to treat gout
- voriconazole, a medicine used to treat fungal infections
- phenytoin, a medicine used to treat seizures
- rifampicin, an antibiotic medicine used to treat bacterial infections)

You may need to take different amounts of your medicines or to take different medicines while you are taking FENAC EC. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start taking FENAC EC.

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

4. How do I take FENAC EC?

How much to take

- Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.
- There are different ways to take FENAC EC tablets depending on your condition. Your doctor will tell you exactly how many tablets to take.
- Do not exceed the recommended dose.

To treat arthritis or other painful conditions:

- The usual starting dose of FENAC EC tablets is 75 mg to 150 mg each day. After the early stages of treatment, it is usually possible to reduce the dose to 75 mg to 100 mg each day.

To treat menstrual cramps (period pain):

- The tablets are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

The usual starting dose of FENAC EC tablets is 50 mg to 100 mg each day, beginning as soon as cramps

begin and continuing until the pain goes away, but for no longer than 3 days.

If necessary, the dose can be raised over several menstrual periods to a maximum of 200 mg each day.

When to take FENAC EC

- It is recommended to take the tablets before meals or on an empty stomach. If they upset your stomach, you can take them with food or immediately after food. They will work more quickly if you take them on an empty stomach, but they will still work if you have to take them with food to prevent stomach upset.

How to take FENAC EC

- FENAC EC tablets are usually taken in 2 or 3 doses during the day.
- Swallow the tablets whole with a full glass of water or other liquid. Do not divide or chew them. The tablets have a special coating to keep them from dissolving until they have passed through the stomach into the bowel. Chewing the tablets would destroy the coating.

How long to take it for

- Do not take FENAC EC for longer than your doctor says.
- If you are taking FENAC EC for arthritis, it will not cure your disease, but it should help to control pain and inflammation. It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine.

If you forget to take FENAC EC

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

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

If you take too much FENAC EC

If you think that you or anyone else has taken too much FENAC EC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, 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.

Symptoms of an overdose may include vomiting, bleeding from the stomach or bowel, diarrhoea, dizziness, ringing in the ears or convulsions (fits).

5. What should I know while taking FENAC EC?

Things you should do

- If you take FENAC EC for more than a few weeks, you should make sure to visit your doctor for regular check-ups to ensure that you are not suffering from unnoticed undesirable effects.
- Be sure to keep all of your doctor's appointments so that your progress can be checked.
- Your doctor will periodically reevaluate whether you should continue treatment with FENAC EC, if you have established heart disease or significant risks for heart disease, especially in case you are treated for more than 4 weeks.

Your doctor may want to check your kidneys, liver and blood from time to time to help prevent unwanted side effects.

If, at any time while taking FENAC EC you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately. These may be signs of cardiovascular toxicity.

- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking FENAC EC.

NSAID medicines can slow down blood clotting and affect kidney function.
- If you get an infection while taking FENAC EC, tell your doctor.

FENAC EC may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FENAC EC.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking FENAC EC.
- Your doctor may do a routine blood checkup during treatment with FENAC EC.

Call your doctor straight away if you:

- become pregnant or intend to become pregnant or if you are breastfeeding while taking this medicine
- notice any symptoms such as chest pain, shortness of breath, weakness, slurring of speech
- have symptoms like feeling sick, tiredness, lethargy, itching, yellowing of your skin, eye pain or pain in the right upper part of the stomach.
- develop any signs of allergic reaction.

Tell any doctor, dentist or pharmacist you visit that you are taking FENAC EC.

Things you should not do

- Do not take any of the following medicines while you are taking FENAC EC without first checking with your doctor or pharmacist:
 - aspirin (also called ASA or acetylsalicylic acid)
 - other salicylates
 - other medicines containing diclofenac
 - ibuprofen
 - any other NSAID medicines.

If you take these medicines together with FENAC EC, they may cause unwanted side effects.

If you need to take something for headache or fever, it is recommended that you take paracetamol. If you are not sure, your doctor or pharmacist can advise you.

- Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.

FENAC EC does not replace exercise or rest programs or the use of heat/cold treatments.
- Do not give FENAC EC to anyone else, even if their condition seems similar to yours.
- Do not take it to treat any other complaints unless your doctor tells you to.

Things to be careful of

- **Elderly patients should take the minimum number of tablets that provides relief of symptoms.**

Elderly patients, especially those with a low body weight, may be more sensitive to the effects of FENAC EC than other adults.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FENAC EC affects you.

FENAC EC may cause vision problems, dizziness, drowsiness, spinning sensation (vertigo), sleepiness or other central nervous system problems in some people. If any of these occur, do not drive, use machine or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- **Keep your medicine in the original container until it is time to take it.**

If you take the tablets out of the blister pack, they may not keep well.
- **Keep your tablets below 25°C.**

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; 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.

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

Getting rid of any unwanted medicine

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

Do not take FENAC EC after the expiry date.

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.

If you are over 65 years of age, you should be especially careful while taking FENAC EC. Report any side effects promptly to your doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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
General problems: <ul style="list-style-type: none">• headache• dizziness, spinning sensation• vision disorders e.g. blurred or double vision• buzzing or ringing in the ears, difficulty hearing• hair loss or thinning• drowsiness, disorientation, forgetfulness• feeling depressed, anxious or irritable• strange or disturbing thoughts or moods• shakiness, sleeplessness, nightmares• tingling or numbness of the hands or feet• feeling of fast or irregular heartbeat• hypertension (high blood pressure)• unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build-up• sore mouth or tongue• altered taste sensation• heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<p>tube that carries food from the throat to the stomach)</p> <p>Stomach problems:</p> <ul style="list-style-type: none">• stomach upset including nausea (feeling sick), vomiting, indigestion, cramps, loss of appetite, wind• stomach or abdominal pain• constipation, diarrhoea• excessive gas in stomach or intestine• worsening of haemorrhoids (piles) <p>Skin problems:</p> <ul style="list-style-type: none">• rashes• application site irritation• itching• swelling• skin inflammation with flaking or peeling• symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth, and/or skin) that happen more quickly than normal <p>Abnormal blood results:</p> <ul style="list-style-type: none">• weakness, shortness of breath, dizziness or light-headedness, pale skin, headache• stomach pain, yellowing of skin or eyes dark urine, tiredness• easy bruising, excessive bleeding after minor injuries, tiredness.	

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak.

Close medical surveillance and caution are recommended when taking FENAC EC after gastrointestinal surgery.

***If symptoms of vision disorders occur during treatment with FENAC EC, contact your doctor as an eye examination may be considered to exclude other causes.**

Serious side effects

Serious side effects	What to do
General problems: <ul style="list-style-type: none">• rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of	Call your doctor straight away, or go straight to the Emergency

Serious side effects	What to do
<p>the body which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)</p> <ul style="list-style-type: none"> wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma) coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome) change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess of protein in the urine (possible kidney disorders) yellowing of the skin and/or eyes (signs of hepatitis/liver failure) persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems) signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits) <p>Skin problems:</p> <ul style="list-style-type: none"> large widespread red and/or dark patches, swelling of the skin, painful red areas, large blisters, itching. Darkening of the skin in affected areas, which might persist after healing, may also occur. peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles and feeling generally unwell (possible serious skin reaction) <p>Heart problems:</p> <ul style="list-style-type: none"> fast or irregular heart beats sudden and oppressive chest pain (which may be a sign of myocardial infarction or a heart attack) 	<p>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"> breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure) <p>Stomach problems:</p> <ul style="list-style-type: none"> severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems) <p>Blood problems:</p> <ul style="list-style-type: none"> red or purple skin (possible signs of blood vessel inflammation) constant "flu-like" symptoms including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy, bleeding or bruising more easily than normal (possible blood problem) 	

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 FENAC EC contains

Active ingredient (main ingredient)	25 mg or 50 mg diclofenac sodium per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> colloidal anhydrous silica microcrystalline cellulose lactose monohydrate magnesium stearate maize starch povidone

	<ul style="list-style-type: none"> • hypromellose • iron oxide yellow • iron oxide red (50 mg tablet only) • titanium dioxide • sodium starch glycollate type A • purified talc • PEG-40 hydrogenated castor oil • methacrylic acid - ethyl acrylate copolymer (1:1) • triethyl citrate
Potential allergens	sugars as lactose

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

What FENAC EC looks like

- **FENAC EC 25 mg:** round, pale yellow, enteric coated tablets plain on both sides (AUST R 272882).

Available in blister packs of 50 tablets.

- **FENAC EC 50 mg:** round, pale brown, enteric coated tablets plain on both sides (AUST R 272871).

Available in blister packs of 50 tablets.

Who distributes FENAC EC

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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FENAC® is a Viatris company trade mark

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