

ANAPROX[®]

contains the active ingredient naproxen sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ANAPROX tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ANAPROX tablets against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ANAPROX is used for

ANAPROX belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

ANAPROX relieves pain and reduces inflammation (swelling, redness and soreness) that may occur

- in different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
- in muscle and bone injuries such as sprains, strains, lower back pain (lumbago), rheumatism and tendonitis, such as tennis elbow
- from swelling and pain after setting broken or dislocated bones
- in menstrual cramps (period pain)
- due to migraine headache
- following surgery
- due to dental pain

Your doctor may have prescribed ANAPROX for another purpose.

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

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

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

ANAPROX is not addictive.

Before you take ANAPROX

When you must not take it

Do not take ANAPROX if you have an allergy to:

- **ANAPROX or any ingredients listed at the end of this leaflet**
- **aspirin or any other NSAID medicine**

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting
- sudden blocked or running nose

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

Do not take ANAPROX if:

- 1. you are vomiting blood or material that looks like coffee grounds**
- 2. you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea**
- 3. you currently have a peptic ulcer (i.e. stomach or duodenal ulcer) or have had one previously**
- 4. you have severe liver disease**
- 5. you have recently had or are about to have heart bypass surgery**
- 6. you are taking other medications which contain naproxen or naproxen sodium (e.g. Naprogesic[®], Naprosyn[®], Crysanal[®] or Inza[®])**
- 7. you have severe heart failure**

Do not give ANAPROX to a child under the age of 2 years.

The safety and effectiveness of ANAPROX in children under 2 years of age has not been established.

Do not take ANAPROX if the package is torn or shows signs of tampering.

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

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

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- any other medicines including aspirin or other NSAID medicines
- any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant

ANAPROX may impair fertility and is not recommended in women attempting to conceive. ANAPROX may affect your developing baby if you take it during pregnancy. If it is necessary for you to take ANAPROX, your doctor will discuss the risks and benefits of taking it during pregnancy.

3. you are breast-feeding or intend to breast-feed

ANAPROX passes into breast milk. The effect on the baby is not known.

4. you have or have had any medical conditions, especially the following:

- heartburn, indigestion, stomach ulcers or other stomach problems

- vomiting blood or bleeding from the back passage
- bowel or intestinal problems such as ulcerative colitis
- kidney or liver disease
- heart failure
- high blood pressure or heart problems
- swelling of the ankles or feet
- a tendency to bleed or other blood problems, such as anaemia

5. you currently have an infection

If you take ANAPROX while you have an infection, the tablets may hide some of the signs of an infection (eg pain, fever). This may make you think, mistakenly, that you are better or that it is not serious.

6. you plan to have surgery

ANAPROX can prolong bleeding.

7. you are on a strict salt (or sodium) restricted diet

ANAPROX contains a small amount of sodium.

If you are not sure if you should be taking ANAPROX, talk to your doctor.

Taking other medicines

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

Some medicines may interfere with ANAPROX. These include:

- antacids, medicines used to treat indigestion and heartburn
- aspirin, salicylates or other NSAID medicines
- diuretics, also called fluid or water tablets
- lithium, a medicine used to treat some types of depression
- probenecid, a medicine used to treat gout
- phenytoin a medicine used to treat epilepsy
- methotrexate, a medicine used to treat arthritis and some cancers
- warfarin, a medicine used to prevent blood clots
- heparin, a medicine used to prevent blood clots
- medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- certain antibiotics called sulphonamides

- some medicines used to treat diabetes
- steroids, medicines used to treat inflammation
- serotonin reuptake inhibitors, also known as SSRIs, medicines used to treat some types of depression
- zidovudine, a medicine used to treat HIV infection
- sodium bicarbonate, a medicine used to treat stomach upset or ulcers

These medicines may be affected by ANAPROX, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ANAPROX.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

Use in Children

There is no specific information available to recommend the use of ANAPROX in children under 5 years.

Use in People Over 65 Years

Older people may be at more risk of developing stomach ulcers and hence your doctor may prescribe a lower dose.

How to take ANAPROX

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

They may differ from the information contained in this leaflet.

How much to take

Take ANAPROX exactly as your doctor has prescribed.

Your doctor will tell you how many ANAPROX tablets to take each day.

The dose your doctor recommends depends on both the type and severity of pain and/or inflammation you have.

Sprains, strains and period pain

The recommended dose is 550 mg (one tablet) given initially, then 275 mg (half-a-tablet) every 6 to 8 hours as needed. The total dose in one day should not be more than 1375 mg (two and a half tablets).

Migraine Headache

The recommended dose is 825 mg (one and a half tablets) taken at the first sign of a migraine. An additional dose of 275 mg (half a tablet) to 550 mg (one tablet) can be taken at least one hour after the initial dose, if required. The total dose in one day should not be more than 1375 mg (two and a half tablets).

Different types of arthritis

The recommended dose is 550 mg (one tablet) to 1100 mg (two tablets) a day (divided in two doses).

Your doctor may recommend lower doses than these, it is always best to use the lowest effective dose for your condition.

How to take it

Swallow ANAPROX tablets whole with a glass of water or milk.

When to take it

Take the tablets during or immediately after food with a full glass of water or milk.

This may help reduce the possibility of an upset stomach.

How long to take it

Do not take ANAPROX for longer than your doctor says.

Depending on your condition, you may need to use ANAPROX, only once, for a few days, a few weeks or for longer periods.

For sprains and strains, ANAPROX is usually only needed for a few days.

As with other NSAID medicines, if you are using ANAPROX for arthritis, it will not cure your condition, but it should help to control pain, swelling and stiffness. If you have arthritis, ANAPROX should be taken every day for as long as your doctor prescribes.

For menstrual cramps (period pain), ANAPROX is usually taken during each period as soon as the cramps begin and continued for a few days until the pain goes away.

Ask your doctor if you are not sure how long to take ANAPROX for.

If you forget to take it

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 it as soon as you remember and then continue taking it as you would normally.

Do not double a dose to make up for one you have missed.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ANAPROX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much ANAPROX you may experience drowsiness, pain or tenderness in the stomach, stomach upset

including nausea (feeling sick), vomiting, heartburn, indigestion or cramps.

While you are taking ANAPROX

Things you must do

If you become pregnant while taking ANAPROX, tell your doctor immediately.

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

Ask your doctor or pharmacist before you start taking any new medicines.

If you are going to have surgery, tell your doctor you are taking ANAPROX.

If you are going to have any laboratory tests, tell your doctor that you are taking ANAPROX.

ANAPROX can affect the results of some of these tests.

If you get an infection while using ANAPROX, tell your doctor.

ANAPROX may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective or change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Things you must not do

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

Do not use ANAPROX to treat other complaints unless your doctor tells you to.

Things to be careful of

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

As with other NSAID medicines, ANAPROX may cause dizziness or light-headedness in some people. Make sure you know how you react to ANAPROX before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side Effects

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

ANAPROX helps most people with pain and inflammation but it may have unwanted side effects in a few 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.

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:

- stomach upset including nausea (feeling sick) and heartburn
- constipation or pain in the stomach
- loss of appetite
- dizziness, light-headedness
- headache, drowsiness
- buzzing or ringing in the ears
- itching or mild skin rashes
- fluid retention or shortness of breath

These are more common side effects of ANAPROX. Mostly these are mild.

Tell your doctor immediately if you notice any of the following:

- bleeding or bruising more easily than normal, reddish-purplish or blue-black blotches under the skin
- eye problems such as blurred vision
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness
- unusual weight gain, swelling of ankles or legs
- yellowing of the skin or eyes

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- vomiting blood or material that look like coffee grounds
- bleeding from back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- severe pain or tenderness in any part of the stomach
- difficulty breathing, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- pain or tightness in chest
- severe dizziness, spinning sensation

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

After taking ANAPROX

Storage

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

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

Keep your tablets protected from light.

Keep ANAPROX in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Keep ANAPROX 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.

Disposal

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

Product Description

What ANAPROX looks like

ANAPROX 550 is a dark blue capsule-shaped tablet with 'NPS 550' on one side.

ANAPROX comes in packs of 50.

Ingredients

Active ingredient:

naproxen sodium

- each ANAPROX 550 tablet contains 550mg of naproxen sodium

Inactive ingredients:

- cellulose
- magnesium stearate [470]
- povidone
- talc
- Opadry YS-1-4216 (contains [171] and [132])

ANAPROX tablets are lactose and gluten free.

Manufacturer

Sponsor

Atnahs Pharma Australia Pty Ltd

Level 10

10 Shelley Street,

SYDNEY, NSW, 2000, Australia

Supplier

ANAPROX is supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Customer enquiries: 1 800 899 005

Please check with your pharmacist for the latest Consumer Medicines Information.

Australian Registration Number:

AUST R 66544.

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