

Consumer Medicine Information

SYNFLEX[®]

Naproxen sodium
275mg and 550mg film-coated tablets

What is in this leaflet

This leaflet answers some common questions about SYNFLEX 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 SYNFLEX tablets against the benefits expected 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 SYNFLEX is used for

SYNFLEX contains the active ingredient naproxen sodium.

SYNFLEX belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). There are many different types of NSAIDs used to treat pain and inflammation.

SYNFLEX is used to relieve pain and reduce inflammation (swelling, redness and heat) associated with:

- ailments of muscles and bones, such as sprains, strains, knocks (direct trauma), back pain, neck pain, tendonitis (eg. tennis elbow), and inflammation of muscles and tendons
- period pain
- pain following the insertion of an IUD (intrauterine device, used for contraception)
- dental pain
- prevention and treatment of migraine headaches
- different types of arthritis including rheumatoid arthritis and osteoarthritis
- arthritis in children (juvenile arthritis)
- gout (inflammation and swelling of the joints, a type of arthritis)
- ankylosing spondylitis (a disease of the joints in the spine)

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

Your doctor may have prescribed SYNFLEX for another purpose.

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

SYNFLEX is not addictive.

This medicine is available only with a prescription.

Before you take SYNFLEX

When you must not take it

Do not take SYNFLEX if:

1. **you have had an allergic reaction to SYNFLEX, or any ingredients listed at the end of this leaflet, or you have had an allergic reaction to aspirin or any other NSAID, including other medicines containing naproxen such as Naprosyn[®], Naxen[®] and Naprogesic[®].**

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 allergic to any of these medicines, ask your doctor or pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma attack, 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

If you are allergic to aspirin or NSAID medicines and take SYNFLEX, you may experience a severe reaction to them.

2. **aspirin or other NSAIDs have triggered an asthma attack or rhinitis (hay fever symptoms such as runny nose, stuffiness, watery eyes, sneezing, itchy nose, throat and eyes) in the past**
3. **you are vomiting blood, or material that looks like coffee grounds**
4. **you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea or you have had in the past**
5. **you have a tendency to spontaneously bleed or bleed when incurring minor accidents (haemorrhagic diathesis)**
6. **you currently have a peptic ulcer (i.e. stomach or duodenal ulcer) or have had one in the past or a history of gastric (stomach) bleeding**
7. **you have liver disease**
8. **you have heart disease**
9. **the package is torn or shows signs of tampering**
10. **the expiry date printed on the pack has passed**

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

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

Do not give SYNFLEX to children under 2 years of age.

Safety and effectiveness in children under 2 have not been established.

SYNFLEX is only recommended for children over 5 years and under 16 years of age as a treatment for juvenile arthritis.

Before you start to take it

Tell your doctor if:

1. you are pregnant or plan to become pregnant

SYNFLEX may make it more difficult to get pregnant and is not recommended in women trying to get pregnant. SYNFLX may affect your developing baby if you take it during pregnancy. SYNFLX is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

SYNFLEX is not recommended during labour or delivery as it may harm you and/or affect the baby.

2. you are breast-feeding or plan to breast-feed

SYNFLEX passes into breast milk, your doctor will discuss the risks and benefits of taking SYNFLX if you are breast-feeding.

3. you have or have had any other health problems, especially the following:

- rhinitis, nasal polyps
- asthma
- heartburn, indigestion, stomach ulcers or other stomach problems
- kidney or liver disease
- heart problems or risk factors for heart disease such as smoking or diabetes
- high blood pressure
- swelling of the hands, ankles or feet (peripheral oedema)
- a tendency to bleed easily
- inflammatory bowel diseases such as ulcerative colitis or Crohn's disease
- you are on a low sodium diet
- you have low salt levels in your blood

4. you currently have an infection

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

5. you plan to have surgery

SYNFLEX can prolong bleeding.

6. you are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, do so before you start taking SYNFLX.

Taking other medicines

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

Some medicines may interfere with SYNFLX. These medicines include:

- aspirin, salicylates or other NSAID medicines
- lithium (Lithicarb[®], Priadel[®]), a medicine used to treat some types of depression
- probenecid, a medicine used to treat gout
- furosemide (Diurin[®], Lasix[®]), a diuretic, a medicine used to treat high blood pressure or fluid (water) retention
- phenytoin (Dilantin[®]) a medicine used to treat epilepsy

- methotrexate (Methoblastin[®], Ledertrexate[®]), a medicine used to treat arthritis, kidney disease and some cancers
- warfarin (Coumadin[®], Marevan[®]), 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 (Trisul[®], Apo-Sulfatrim[®], Salazopyrin[®])
- some medicines used to treat diabetes called sulphonylureas (Diamicron[®], Apo-Gliclazide[®], Minidiab[®], Gliben[®])
- steroids, a group of medicines used to treat inflammation
- a group of medicines known as selective serotonin reuptake inhibitors, also known as SSRIs, medicines used to treat some types of depression

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SYNFLEX.

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

How to take SYNFLEX

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

They may differ from the information contained in this leaflet.

How much to take

Take SYNFLEX exactly as your doctor has prescribed.

Your doctor will tell you how many SYNFLEX tablets you or your child should take each day.

The dose depends on both the type and severity of pain and/or inflammation you have. Your doctor may give you a lower dose if you are older or have certain health problems.

The usual dose for adults is 550mg initially, followed by 275 mg three to four times a day if required. The maximum dose should not exceed 1375mg per day.

The usual dose for children over 5 years of age for juvenile arthritis is 10mg per kg bodyweight per day.

How to take it

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

When to take it

Take SYNFLEX at about the same time each day.

It does not matter whether you take SYNFLEX with food or not. However, if you take SYNFLEX after food this may help reduce the possibility of an upset stomach.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking SYNFLEX until your doctor tells you to stop.

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

If you forget to take SYNFLEX

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 take too much (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much SYNFLEX. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

You may need urgent medical attention.

The following are some symptoms which may or may not occur:

- drowsiness, dizziness
- pain or tenderness in the stomach
- stomach upset including indigestion, nausea (feeling sick), vomiting, heartburn or cramps
- convulsions (fits)
- confusion
- difficulty breathing
- vomiting blood, bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea, or blood in the urine

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

While you are taking SYNFLEX

Things you must do

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

Tell your doctor if you become pregnant while taking SYNFLEX.

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

Tell your doctor you are taking SYNFLEX if you are going to have any laboratory tests.
SYNFLEX can affect the results of some of these tests.

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

SYNFLEX 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 and change your treatment unnecessarily.

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

Be sure to keep all your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking SYNFLEX or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not use SYNFLEX to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

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

SYNFLEX may cause dizziness, light-headedness, drowsiness or a spinning sensation (vertigo) in some people. Make sure you know how you react to SYNFLEX before you drive a car, operate machinery, or do anything else that could be dangerous.

Side Effects

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

SYNFLEX helps most people but it may have unwanted side effects in some 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), heartburn, indigestion
- constipation, diarrhoea, pain in the stomach
- dizziness, light-headedness, drowsiness, difficulty concentrating
- spinning sensation (vertigo)
- headache
-
- sore or dry mouth or tongue, mouth ulcers
- feeling thirsty, swelling/fluid retention
- skin eruptions, rash, itching, sweating
- muscle pain, weakness

These are the more common side effects of NAPROSYN. 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, sore or burning eyes
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness, buzzing, ringing in the ears

- unusual weight gain, swelling of ankles or legs
- yellowing of the skin or eyes (jaundice)
- depression (feelings of deep sadness and unworthiness)
- inability to sleep (insomnia), difficulty concentrating
- sharp abdominal pains (pancreatitis)

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

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

- severe or sharp pain or tenderness in any part of the stomach, vomiting
- vomiting blood, or material that looks like coffee grounds
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea, or blood in the urine
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma attack, wheezing, shortness of breath
- fainting, seizures or fits
- severe or persistent headache, sometimes accompanied by a fever
- chills, general feeling of being unwell
- persistent fever
- red or purple skin rash that spreads
- blisters on your skin and mucous membranes, especially your mouth, nose and eyes
- shedding of your skin

These are serious side effects. You may need urgent medical attention. 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 this list of possible side effects. You may not experience any of them.

After taking SYNFLEX

Storage

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

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

Keep your tablets in a cool, dry place where the temperature stays at or below 25°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 SYNFLEX 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 SYNFLEX, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

Availability

SYNFLEX tablets are available in two strengths, 275mg and 550mg.

Both strengths come in packs of 100 tablets.

What SYNFLEX looks like

SYNFLEX 275mg is a light blue, oval-shaped film-coated tablet engraved with 'NPS 275' on one side.

SYNFLEX 550mg is a dark blue oblong-shaped film-coated tablet with 'NPS 550' on one side, and a break-score on both sides.

Ingredients

Active ingredient - naproxen sodium

- each SYNFLEX 275mg tablet contains 275mg of naproxen sodium.
- each SYNFLEX 550mg tablet contains 550mg of naproxen sodium

Inactive ingredients -

SYNFLEX 275mg tablets also contain microcrystalline cellulose, povidone K29/32, talc, magnesium stearate and purified water. The film coating contains Opadry YS-1-4215.

SYNFLEX 550mg tablets also contain microcrystalline cellulose, povidone K29/32, talc, magnesium stearate and purified water. The film coating contains Opadry YS-1-4216.

Distributor

SYNFLEX is distributed by:

Roche Products (New Zealand) Ltd
P O Box 12492
Penrose
AUCKLAND 1642

Telephone: (09) 633 0700
Toll Free: 0800 656 464

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