

## What is in this leaflet

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## What Synflex is used for

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

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

- after delivery
- after IUD insertion
- acute gout
- following surgery
- following orthopedic surgery
- in soft tissue injuries/inflammation
- in menstrual cramps (period pain)
- due to migraine headache

Your doctor may have prescribed Synflex for another purpose.

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

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

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

Synflex is not addictive.

## How Synflex works

Naproxen is a nonsteroidal anti-inflammatory drug (NSAID). Naproxen works by blocking the production of prostaglandins, substances in the body that play a role in causing pain and inflammation.

## Before you use Synflex

- When you must not use it

Do not take Synflex if you have an allergy to:

- Synflex 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 Synflex, these symptoms may be severe.

Do not take Synflex if:

- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhea
- you currently have a peptic ulcer (i.e. stomach or duodenal ulcer) or have had one previously
- you are taking other medications which contain naproxen or naproxen sodium
- you have severe heart failure

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

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

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

Do not take Synflex 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 use it

Tell your doctor if:

- you have any allergies to:
  - any other medicines including aspirin or other NSAID medicines
  - any other substances, such as foods, preservatives or dyes
- you are pregnant or intend to become pregnant
  - Synflex may impair fertility and is not recommended in women attempting to conceive.
  - Synflex may affect your developing baby if you take it during pregnancy. If it is necessary for you to take Synflex, your doctor will discuss the risks and benefits of taking it during pregnancy.
- you are breast-feeding or intend to breast-feed
  - Synflex passes into breast milk. The effect on the baby is not known.
- 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
  - perforation of the stomach or intestinal wall
  - elderly patient
  - vision problem
  - stroke

- Naproxen may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- you currently have an infection. If you take Synflex 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.
- you plan to have surgery. Synflex can prolong bleeding.
- you are on a strict salt (or sodium) restricted diet. Synflex contains a small amount of sodium.

If you are not sure if you should be taking Synflex, 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 Synflex. 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 Synflex, 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 Synflex.

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 Synflex 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 use Synflex**

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 use

Take Synflex exactly as your doctor has prescribed.

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

**Sprains and strains**

The recommended dose is 550 mg given initially, then 275 mg every 6 to 8 hours

as needed. The total dose in one day should not be more than 1375 mg.

**Acute Gout**

The recommended dose is 825mg followed by 275mg every eight hours as needed.

**Period Pain**

The recommended dose is 825 – 1375mg per day taken in two doses on first day of period. Do not exceed 1100mg after that.

**Migraine Headache**

The recommended dose is 825 mg taken at the first sign of a migraine. An additional dose of 275 mg to 550 mg can be taken throughout the day but not before half an hour after the initial dose. The total dose in one day should not be more than 1375 mg.

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

- When to take it

Synflex may be given orally either in fasting state or with meals and/or antacids.

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

- How long to use it

Do not take Synflex for longer than your doctor says.

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

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

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

For menstrual cramps (period pain),

Synflex 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 Synflex for.

- If you forget to use 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 use too much (overdose)

Immediately telephone your doctor 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 Synflex. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Synflex you may experience drowsiness, pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps

**While you are using it**

- Things you must do

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

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

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 Synflex.

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

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 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 Synflex to anyone else, even if they have the same condition as you.

Do not use Synflex 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 Synflex affects you.

As with other NSAID medicines, Synflex may cause dizziness or light-headedness 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 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 Synflex.

Synflex 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 Synflex. Mostly these are mild.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital 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
- 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
- severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time.
- Skin blistering when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.
- Blood in your water (urine) or kidney problems.

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 do not understand anything in this list.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting).

### Storage and Disposal of Synflex

#### - 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 Synflex in a cool dry place where the temperature stays below 25 degrees 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

#### - What Synflex looks like

Synflex 275 mg: Light blue, oval filmcoated tablet, with marking NPS 275 on one side.

Synflex 550: Dark blue capsule-shaped tablet with NPS 550 on one side.

Synflex comes in packs of 100.

#### - Ingredients

- Active ingredient
  - Naproxen sodium
- Inactive ingredients
  - Cellulose
  - Magnesium stearate [470]
  - Povidone
  - Talc
  - Opadry YS-1-4215

Synflex tablets are lactose and gluten free.

#### - MAL number(s):

Synflex Tablets 275 mg  
(MAL20020896AZ)

Synflex Tablets 550 mg  
(MAL20020897AZ)

### Manufacturer

Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland  
by Roche Farma S.A, Leganes, Spain

### Product Registration Holder

Roche (M) Sdn. Bhd.  
Level 21, The Pinnacle,  
Persiaran Lagoon, Bandar Sunway,  
47500 Subang Jaya,  
Selangor Malaysia.

### Date of Revision

24/08/2015

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