

Package Leaflet: Information for the user

Ipaflex 200 mg mjuka kapslar naproxen

Read all this leaflet carefully before you start taking this medicine - because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

1. What Ipaflex is and what they are used for
2. What you need to know before you take Ipaflex
3. How to take Ipaflex
4. Possible side effects
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1. What Ipaflex are and what they are used for

Ipaflex contains the active substance naproxen sodium. It belongs to a group of medicines called 'Non-Steroidal Anti-Inflammatory Drugs' or 'NSAIDs'.

Ipaflex is used in adults and adolescents over 12 years of age for short-term symptomatic treatment of mild to moderate pain such as back, muscle and joint pain.

2. What you need to know before you take Ipaflex

Do not take Ipaflex if:

- you are allergic to naproxen sodium or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to peanut or soya as this medicine may contain trace amounts of soya lecithin
- you have a severe kidney problem
- you have severe liver problem
- you have or have had internal bleeding after using aspirin, ibuprofen or other pain and non-steroidal anti-inflammatory medicines (known as 'NSAIDs')
- you have, or have had more than 2 episodes of internal bleeding – such as bleeding from your stomach, gut or have had a stroke
- you have, or have had a stomach ulcer, inflamed stomach lining or have stomach pain
- you have ever had an allergic reaction - such as asthma, runny nose or itching - after using aspirin, ibuprofen or other pain and non-steroidal anti-inflammatory medicines (known as 'NSAIDs')
- you tend to bleed easily or if you are being treated with medicines to thin your blood (called 'anti-coagulants')
- you have severe heart failure

- you are under the age of 12
- you are in the last three months of pregnancy

Do not take Ipaflex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ipaflex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ipaflex if:

- you have problems with how your blood clots
- you have an infection
- you have liver problems
- you have kidney problems
- you have just had major surgery
- have ever had asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past
- you develop stomach or gut problems – such as stomach pain or heartburn
- your pain does not get better – also if it comes back often or gets worse (even if it is mild)
- have colitis or Crohn's disease, the symptoms are inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss you have lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked or itchy nose (rhinitis)
- have an autoimmune condition, such as 'systemic lupus erythematosus' that causes joint pain, skin rashes and fever
- you are 65 years and above
- you have chickenpox infection

If you ever had stomach problems you must not use Ipaflex - unless your doctor has prescribed it.

Heart problems

Talk to your doctor or pharmacist before taking this medicine if:

- you have heart problems
- you have had a stroke
- you have high blood pressure
- you have diabetes
- you have high cholesterol levels
- you smoke

Heart attack or stroke risk

Medicines like Ipaflex may be linked with a slightly increased risk of heart attack or stroke. The risk increases with higher doses and the longer you use the medicine. Do not use more than the prescribed recommended dose. Do not use this medicine for longer than 5 days – talk to your doctor if you want to take for longer.

Skin reactions

Very rarely, serious skin reactions with redness and blistering, some of which were fatal, have been reported during NSAID therapy (exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome, and drug reaction with eosinophilia and systemic symptoms (DRESS); see section 4). The risk of such reactions appears to be greatest early in the course of therapy, as these reactions occurred during the first month of treatment in the majority of cases. At the first signs of skin rash, mucous membrane defects or any other signs of a hypersensitivity reaction, you should stop taking Ipaflex and consult your doctor immediately.

Children and adolescents

Do not give this medicine to children under the age of 12 years.

Other medicines and Ipaflex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Ipaflex with the following medicines, as Ipaflex increases the risk of side effects of these medicines:

- methotrexate to treat skin conditions or rheumatoid arthritis
- ACE inhibitor or angiotensin-II antagonist medicines for high blood pressure
- ciclosporine or tacrolimus for autoimmune diseases
- other medicines for pain and inflammation including other non-steroidal anti-inflammatory drugs ('NSAIDs') such as aspirin and ibuprofen.

Taking Ipaflex with the following medicines can increase the risk of gastrointestinal bleeding

- steroids like prednisolone, hydrocortisone or dexamethasone
- clopidogrel and other antiplatelet agents to prevent blood clotting
- selective serotonin reuptake inhibitors for depression

Ipaflex may increase the effect of some medicines. This includes:

- medicines to thin the blood called anticoagulants for example warfarin
- lithium for mental illness

Ipaflex can also reduce the effect of some medicines for high blood pressure. This includes

- diuretics (water tablets)

Probenecid for gout may make Ipaflex stay in your body for longer. Talk to your doctor or pharmacist before taking probenecid.

Talk to your doctor or pharmacist first, if you are taking medicines to prevent blood clots, Aspirin/ acetylsalicylic acid.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking this medicine.

Ipaflex with alcohol

Avoid alcohol, as some side effects may be more likely when alcohol is taken at the same time as Ipaflex.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Ipaflex if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take Ipaflex during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Ipaflex can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing

of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Naproxen, the active ingredient of Ipaflex passes into breast milk. Therefore, Ipaflex should not be used during breast-feeding.

Fertility

This belongs to a group of medicines (NSAIDs) which might reduce fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

Naproxen may make you tired or dizzy, which may affect your concentration. Talk to your doctor if any of these happen to you and do not drive or use any tools or machines.

This medicine contains

- 17.7 mg propylene glycol in each capsule
- 76.8 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- less than 1 mmol sodium (23 mg) in each capsule, that is to say essentially 'Sodium Free'.
- This medicine may contain trace amounts of soya lecithin, if you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Ipaflex

Always take Ipaflex exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Use in adults and children over 12 years of age:

- Take a first dose of 2 capsules.
- Then take 1 capsule 12 hours later if symptoms persist.

Do not take more than 3 capsules in 24 hours.

- One tablet every 8 to 12 hours is generally enough.

People over 65 years of age:

- Do not take more than 2 capsules in 24 hours, taken as two single doses.

Do not use Ipaflex for more than 5 days without talking to your doctor.

Taking this medicine

- Swallow the capsules whole with plenty of fluid
- Take before a meal if possible. However, patients with a sensitive stomach are recommended to take Ipaflex during meals.

If you feel that the effect of the Ipaflex is too weak or too strong, talk to your doctor or pharmacist.

You should always take the lowest dose for the shortest duration necessary to reduce the risk of side effects.

If you take more Ipaflex than you should

If you take more Ipaflex than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen:

- feeling or being sick, pain in the stomach area, diarrhoea
- feeling sleepy or dizzy

If you forget to take Ipaflex

- If you forget to take a dose, take it when you remember.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Ipaflex

If you suddenly stop taking Ipaflex, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ipaflex can cause side effects, although not everybody gets them. Stop taking Ipaflex and immediately contact a doctor if you notice any of the following serious side effects.

- Uncommon reaction causing swelling of the skin, mouth, throat or tongue.
- Very rare reactions: a red/purple rash causing the skin to blister and peel off or a problem with blood formation (anaemia), which may show as fever, sore throat, small wounds in the mouth, flu-like symptoms, fatigue, bleeding from nose or skin.
- Reaction with frequency not known (frequency cannot be estimated from the available data):
 - widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.
 - Reaction with frequency not known: a distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

The following side effects may also be seen following the use of Ipaflex.

Common: may affect up to 1 in 10 people

- stomach pain, heartburn
- feeling sick (nausea), unpleasant feeling in the stomach and headache, feeling dizzy

Uncommon: may affect up to 1 in 100 people

- stomach ulcers, which may bleed causing vomiting blood, black stools or bloody diarrhoea
- visual disturbance
- reduced urine output
- being sick (vomiting), indigestion, diarrhoea, or constipation
- skin rashes, bleeding under the skin, blisters or itching
- sleeplessness, agitation, irritability, tiredness

Rare: may affect up to 1 in 1000 people

- bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds
- sensitivity to light

Very rare: may affect up to 1 in 10,000 people

- Sign of meningitis including fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion. Most likely in people with autoimmune conditions such as ‘systemic lupus erythematosus’
- Skin reactions such as hair loss, sweating
- A fluttering feeling in your heart (palpitation), slow heartbeat or high blood pressure
- Shortness of breath or asthma attack
- Increased liver enzymes, jaundice, liver inflammation, increased potassium level in the blood (shown in tests)
- passing water often, kidney problems, increased creatinine level in the blood (shown in tests)
- Kidney damage, shown by blood or protein in the urine
- Sudden swelling of your throat, hands or feet
- Depression, abnormal dreams or inability to concentrate
- Inability to think straight, convulsions (fitting)
- Discomfort in the gut, from food pipe to large intestine
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.xxx.xx.xx.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ipaflex

Keep this medicine out of the sight and reach of children.

Do not use Ipaflex after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not refrigerate.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ipaflex contains

- The active substance is naproxen. Each capsule contains 220mg naproxen sodium equivalent to 200 mg naproxen. The other ingredients are macrogol, lactic acid, propylene glycol (E 1520), povidone, trace amounts of soya lecithin.
- The capsule shell ingredients are gelatine, sorbitol liquid partially dehydrated (E 420), glycerol, purified water, patent blue V (E131).

What Ipaflex look like and contents of the pack

- Ipaflex are transparent light blue, oval capsules.
- The blister pack is comprised of PVC/PE/PVDC/Alu
- Ipaflex are available in blister packs of 10, and 20 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

< To be completed nationally >

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