Package leaflet: Information for the user

Naproxennatrium Aurobindo 220 mg, zachte capsules
naproxennatrium

Read all of 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 or nurse. 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 3 days in case of fever and 5 days in case of pain.

What is in this leaflet:

1. What Naproxennatrium Aurobindo 220 is and what it is used for

Naproxennatrium Aurobindo 220 contains naproxen which is an anti-inflammatory, pain-relieving and antipyretic medicine. It belongs to a group of medicines named NSAID (non-steroidal anti-inflammatory drugs).

Naproxennatrium Aurobindo 220 is used in adults and children from 12 years of age for short term treatment of pain.

Indications for use
Treatment of minor and moderate pain, such as:
- Headache,
- toothache,
- muscle pain,
- arthralgia,
- back pain,
- painful menstruation,
- minor pain associated with the cold.
- Reducing fever.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days in case of fever and 5 days in case of pain.

2. What you need to know before you take Naproxennatrium Aurobindo 220

Do not take Naproxennatrium Aurobindo 220

- if you are allergic to naproxen or naproxen sodium, or to any of the other ingredients of this medicine (listed in section 6).
- if you ever had an allergic reaction such as asthma, runny nose or itching, when using aspirin, ibuprofen or other analgesic and anti-inflammatory drugs (NSAIDs)
- if you have a history of gastrointestinal bleeding or perforation after using non-steroidal anti-inflammatory medicines (known as 'NSAIDs').
- if you have, or have had recurrent stomach/duodenal ulcers or bleeding (at least two different episodes of proven ulceration or bleeding).
- if you have a stomach or intestinal ulcer, inflammation of the stomach mucosa, or stomach pain.
- if you have an internal bleeding (e.g. stomach, intestine or brain haemorrhage)
- if you have a tendency to bleed or if you are treated with anticoagulants (medicines that thin your blood)
- if you have severe kidney problems.
- if you have severe liver problems.
- if you have severe heart failure.
- if you are in the last three months of pregnancy.

Warnings and precautions

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see gastro-intestinal and cardiovascular risks below).

Talk to your doctor or pharmacist or nurse before taking Naproxennatrium Aurobindo 220

- if pain or fever symptoms persist, recur regularly or worsen, even if these symptoms are mild
- if gastrointestinal problems (such as stomach pain or heartburn) occur during the use of this medicinal product
- if you have high blood pressure or heart diseases
- if you have an infection
- if you are elderly
- if you suffer from liver problems
- if you suffer from kidney problems.

If you have heart problems, previous stroke or think that you might be at risk for these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss this with your doctor or pharmacist before you take this medicine.

Medicines such as Naproxennatrium Aurobindo 220 may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (10 days).

For patients with gastrointestinal problems extra precausions are needed:

Bleeding of the gastrointestinal tract, ulcers and perforation, in some cases fatal, have been reported during treatment with all NSAIDs. Such effects occurred at any time during therapy, with or without warning symptoms or a previous history of serious events in the gastrointestinal tract.

The risk of developing gastrointestinal bleeding, ulcers and perforation is higher with the increasing NSAID doses and is higher in patients with a history of ulcer, especially with complications of bleeding or perforation (see section 2: "DO NOT take <Invented Name>") and in elderly patients. These patients should start treatment at the lowest available dose. For these patients, as well as patients who require additional therapy with low-dose acetylsalicylic acid or other medicines likely to increase gastrointestinal risk, combination treatment with protective active substances (e.g. misoprostol or proton pump inhibitors) should be considered.

If you have a history of side effects affecting the gastrointestinal tract, particularly if you are elderly, you should report all unusual abdominal symptoms (especially gastrointestinal bleeding), especially in the initial stages of therapy.

Caution is advised if you are receiving other medicines that can increase the risk of ulcers or bleeding, such as oral corticosteroids, anticoagulants (blood-thinners) such as warfarin, selective serotonin reuptake inhibitors (used to treat psychiatric disorders including depression) or platelet aggregation inhibitors such as acetylsalicylic acid (see section 2: "Other medicines and <Invented Name>").

Treatment must be stopped and a doctor consulted if you develop gastrointestinal bleeding or ulcers during treatment with <Invented Name>.

NSAIDs should be used with caution in patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease), as their condition may get worse (see section 4).

If you have stomach problems or have had stomach problems you should not use Naproxennatrium Aurobindo 220, unless prescribed by a doctor.

This medicine is not suitable for treatment of the pain due to gastrointestinal discomfort.

You should avoid using <Invented Name> at the same time as other non-steroidal anti-inflammatory drugs, including so-called COX-2 inhibitors (cyclooxygenase-2 inhibitors).

The use of NSAIDs by the elderly has an increased risk of side effects, particularly (sometimes fatal) gastrointestinal bleeding and perforation.

Patients with bleeding disorders should take this medicine only under the supervision of a doctor.

Consult your doctor if any of the above warnings applies to you, or has applied in the past.

Serious skin reactions including (exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with <Invented Name>. 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. Stop using <Invented Name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

This product belongs to the group of medicines (NSAIDs) that can negatively affect female fertility during use. This is reversible by stopping the use of this medicine.

Other medicines and Naproxennatrium Aurobindo 220

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without prescription.
- aspirin/ acetylsalicylic acid to prevent blood clots.

Do not take Naproxennatrium Aurobindo 220 in combination with the following medicines:
Naproxennatrium Aurobindo 220 can enhance the effect of:
- certain anti-coagulants (medicines that thin the blood)
- certain oral anti-diabetes medicines
- certain antibiotics
- certain medicines to treat epilepsy (hydantoins), like phenytoin
- certain sulfonamide medicines, like sulfadoxine
- certain narcotics, like thiopental

Naproxennatrium Aurobindo 220 can decrease the effect of certain medicines to treat high blood pressure (beta blockers and diuretics).

Naproxennatrium Aurobindo 220 can delay the excretion of lithium preparations (used to treat nervous disorders).

Naproxennatrium Aurobindo 220 increases the risk of side effects when using:
- methotrexate (used to treat rheumatism)
- ACE inhibitors (used to treat for instance high blood pressure)
- cyclosporine (used to treat autoimmune diseases)
- other analgesic and anti-inflammatory medicines

When using Naproxennatrium Aurobindo 220 at the same time with probenecid (used to treat gout), the elimination of naproxen can be delayed.

Consult with your doctor also in case you use other medicines which increase the risk of ulceration or bleeding, such as oral corticosteroids (inflammatory inhibitors), anticoagulants (anticoagulants) such as warfarin, selective serotonin reuptake inhibitors (used in depression) and drugs that prevent blood clotting, such as acetylsalicylic acid.

Pregnancy, breast-feeding and fertility

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

Pregnancy
Do not take Naproxennatrium Aurbindo 220 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 Naproxennatrium Aurobindo 220 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, Naproxennnatrium Aurobindo 220 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 Naproxennatrium Aurobindo 220, passes into breast milk. Therefore, Naproxennatrium Aurobindo 220 should not be used during breast-feeding.

Fertility
This product belongs to a group of medicines (NSAIDs) which might impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant however, talk to your doctor before using it if you have problems becoming pregnant.

Driving and using machines
<Invented Name> can cause drowsiness, dizziness and difficulty sleeping as side effects. If you are affected in this way, do not drive or operate machinery.
Naproxennatrium Aurobindo 220 contains sorbitol
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.

Naproxennatrium Aurobindo 220 contains lecithin originating from soya oil
If you are allergic to peanut or soya, do not use this medicinal product.

Naproxennatrium Aurobindo 220 contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Naproxennatrium Aurobindo 220

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

The recommended dose is:

Adults and children from 12 years of age and above:

The recommended dose is one capsule every 8 – 12 hours. The initial dose may be two capsules, **and if the complaints persist** followed by one capsule after 12 hours. Do not take more than 3 capsules a day.
The capsules should be taken with plenty of water or milk, preferably immediately after meals.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days in case of fever and 5 days in case of pain. Do not use longer than 10 consecutive days without medical advice.

Elderly from 65 years old:
Not more than 2 capsules per 24 hours.

Patients with kidney problems
If you have mild kidney problems, you should use the lowest effective dose and your doctor should monitor your kidney function. If you have moderate kidney problems, the use of naproxen should be avoided. Naproxen must not be used if you have severe kidney problems.

Patients with liver problems
If you have problems with the way your liver works, you should use Naproxennatrium Aurobindo 220 with caution. Naproxen Aurobindo 220 mg Capsules, soft should be avoided if you have severe liver problems or cirrhotic liver disease.

Method of administration
The capsules should be taken orally with plenty of water or milk, preferably immediately after meals.

If you take more Naproxennatrium Aurobindo 220 than you should
If you take more Naproxennatrium Aurobindo 220 than you should, immediately contact your doctor or pharmacist. Show the package or the leaflet to your doctor or pharmacist.

Symptoms of overdose may include: nausea, vomiting, stomach pain, drowsiness, dizziness disorientation, diarrhoea, bleeding of the gastrointestinal tract, high levels of sodium in the blood (hypernatremia), convulsions (rarely), transient change in hepatic function, renal dysfunction, respiratory depression and acidification of the blood (metabolic acidosis).

If you forget to take Naproxennatrium Aurobindo 220
In that case you can take a normal dose as soon as you remember. Do not take a double dose to make up for a forgotten capsule.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most commonly observed side effects are gastrointestinal in nature. Stomach/duodenal ulcers (peptic ulcers), perforation or gastrointestinal bleeding, sometimes fatal, may occur (particularly in the elderly). Nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, melaena, haematemesis, inflammation of the mouth lining (ulcerative stomatitis), and worsening of colitis and Crohn's disease have been reported following administration. Less frequently, inflammation of the stomach lining (gastritis) has been observed.

Oedema, high blood pressure and heart failure have been reported in association with NSAID therapy.

Medicines such as <Invented Name> may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Stop taking <Invented Name> 220 and immediately contact a doctor if you notice any of the following side effects:

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.
• 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

Side effects which may occur are:

Very common (may affect more than 1 in 10 people)
- Discomfort in the abdomen

Common (may affect up to 1 in 10 people)
- Headache
- Dizziness
- Drowsiness
- Light-headedness
- Visual disturbances
- Ringing or buzzing in the ears (tinnitus)
- Nausea
- Indigestion
- Heartburn

Uncommon (may affect up to 1 in 100 people)
- Inability to concentrate
- Trouble sleeping (insomnia)
- Inability to concentrate or remember things (cognitive dysfunction)
- Vomiting
- Diarrhoea
- Constipation
- Gastrointestinal bleeding and / or perforations
- Reactions due to exposure to light
- Rash
- Itching

Rare (may affect up to 1 in 1,000 people)
- Allergic reactions to naproxen and naproxen sodium preparations. Allergic reactions usually occur in patients with known allergy to aspirin, other NSAIDs and to Naproxennatrium Aurobindo 220 . However, they can also occur in patients without previous experience with this allergy.
- High levels of potassium in the blood (hyperkalaemia)
- Problems with hearing
- Inflammation of the blood vessels (vasculitis)
- Inflammation of the lung (eosinophilic pneumonitis)
- Mouth ulcers
- Vomiting of blood

Very rare (may affect up to 1 in 10,000 people)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anemia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anemia)
- A reduction in the number of white blood cells (granulocytopenia)
- Decreased platelet count (thrombocytopenia)

- Convulsions
- Non-infectious inflammation of the membranes of the brain (aseptic meningitis)
- Increased heart rate
- Swollen ankles and feet (oedema)
- High blood pressure
- Insufficient pumping strength of the heart (heart failure)
- Shortness of breath
- Asthma
- Inflammation of the colon (colitis)
- Life-threatening inflammation of the liver (fatal hepatitis)
- Jaundice
- Stevens-Johnson syndrome (blistering of hands and feet)
- Redness of the skin (erythema multiforme)
- Peeling skin (toxic epidermal necrolysis)
- Hair loss (alopecia)
- Reactions due to exposure to light such as inflammation of the skin and blistering eruptions (porphyria cutanea tarda or epidermolysis bullosa-like reactions)
- Blood in urine (haematuria)
- Kidney disorders including glomerular or interstitial nephritis (inflammation of the kidney), renal papillary necrosis (death of part of the tissue of your kidneys) and nephrotic syndrome (protein in the urine)

Not known (frequency cannot be estimated from the available data)
- Gout
- Non-peptic gastrointestinal ulceration, peptic ulceration
- Swelling of the neck and face (angioedema)
- Kidney failure
- Impaired female fertility
- Mildly swollen ankles and feet (mild peripheral oedema)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naproxennatrium Aurobindo 220

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

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate.
Store in the original package in order to protect from moisture.

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 Naproxennatrium Aurobindo 220 contains
- The active substance is naproxen sodium. One capsule contains 220 mg naproxen sodium.

- The other ingredients (excipients) are Macrogol, Lactic acid, Propylene glycol, Povidone K-30, Gelatin, Sorbitol, Glycerol, Purified water, Patent blue V (E131), Triglycerine, Isopropyl alcohol, Lecithin.

What Naproxennatrium Aurobindo 220 looks like and the contents of the pack
- Naproxennatrium Aurobindo 220 is a blue transparent, soft gelatin capsule containing 220 mg of naproxen sodium per capsule.
- Naproxennatrium Aurobindo 220 is supplied in a PVDC/PE/PVC//Alu blister. Each pack contains 3, 10, 12, 20 or 24 capsules. Not all pack sizes may be marketed.

Marketing Authorization Holder

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In het register ingeschreven onder:

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RVG 118864 – Naproxennatrium Aurobindo 220 mg, zachte capsules

This medicinal product is authorized in the Member States of the EEA under the following names:

Nederland: Naproxennatrium Aurobindo 220 mg, zachte capsules
Polen: Apo-Napro Fast

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