PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S1

ALEVE®, Naproxen sodium 220 mg (equivalent to 200 mg naproxen), Tablets

Read all of this leaflet carefully because it contains important information for you:

ALEVE® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ALEVE® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALEVE® with any other person.
- Ask your pharmacist if you need more information or advice
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What ALEVE® is and what it is used for
2. What you need to know before you take ALEVE®
3. How to take ALEVE®
4. Possible side effects
5. How to store ALEVE®
6. Contents of the pack and other information

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1. What ALEVE® is and what it is used for

ALEVE® is a medicine indicated to sooth pain, lower fever and reduce inflammation.

ALEVE® can be used to relieve: headache, toothache, muscular ache and pain, backache, pain of menstrual cramps i.e. period pain, minor pain of arthritis, minor aches and pains associated with the common cold and fever.

2. What you need to know before you take ALEVE®

Do not take ALEVE®:

- If you are hypersensitive to ALEVE® or any of the other ingredients of ALEVE®
- If you have a history of asthma, urticaria (hives) or allergic-type reactions after taking aspirin or other non-steroidal-anti-inflammatory drugs (NSAIDs)
- If you have a history of a disease of the stomach or of the intestines (e.g. ulcer)
- If you have severe heart failure
- If you are pregnant or breastfeeding

Warnings and precautions

Take special care with ALEVE®:

- Stomach and intestinal pain should not be treated with ALEVE®
- ALEVE® should not be used with other NSAIDs including cyclooxygenase-2 selective inhibitors (other medication of the same class used for same conditions)
- If you experience any undesirable effects, this may be reduced by taking the lowest effective dose for the shortest duration necessary to control symptoms

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- If you are over 65, a reduction in the daily dosage is recommended and the use of ALEVE® should be under the close supervision of a doctor
- If you have renal (kidney) disorder, stomach, brain or heart disease, a reduction in the daily dosage is recommended and the use of ALEVE® should be under the close supervision of a doctor
- If you experience any allergic reactions to ALEVE® treatment should be stopped with ALEVE®
- If you have severe liver disease
- If you take ALEVE®, it may reduce your ability to become pregnant. This effect will be reversed when you stop taking ALEVE®
- Patients with the following additional medical history should be under adequate and careful supervision of their doctor when taking ALEVE®:
    - Those taking any other painkillers or steroids
    - Those with bleeding disorders or those taking medicines to prevent and stop bleeding
    - Those on water tablets (diuretics)
    - Those with severe kidney, liver or heart impairment (failure)

Other medicines and ALEVE®

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Cyclosporine (immunosuppressive medicine):

Cyclosporine concentrations may increase, increasing the risk for nephrotoxicity.

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Lithium (psychiatric medication):

Lithium levels may increase, which could induce nausea, polydipsia (excessive thirst), polyuria (excessive urine production), tremor (uncontrolled trembling or shaking movements in one or more parts of your body), confusion.

Methotrexate (immune system suppressant) used at doses of 15 mg/week or more:

Elevated concentration of methotrexate, increasing the risk for toxicity to this substance.

Non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin:

Increased risk of ulcers and gastrointestinal bleeding. (See warnings and precautions).

Anticoagulants (blood thinners):

NSAIDs may enhance the effects of anti-coagulants, such as warfarin (See warnings and precautions). Anticoagulants and other drugs influencing hemostasis (prevent or stop bleeding) add to the risk of bleeding and require careful monitoring.

Anti-platelet agents (medication use to stop clots from forming) and selective serotonin reuptake inhibitors (SSRIs) (antidepressant medicine):

Increased risk of gastrointestinal bleeding (See warnings and precautions)

Corticosteroids:

Increased risk of gastro-intestinal ulceration or bleeding (See warnings and precautions)

Diuretics and antihypertensive drugs including ACE Inhibitors (medication for treatment of high blood pressure):

The diuretic and antihypertensive efficacy, particularly in patients with pre-existing nephropathy, may be reduced.

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During short term use of ALEVE® interactions of clinical significance do not seem to be relevant for the following medications:

- Antacids
- Antidiabetic agents
- Hydantoins (anticonvulsants)
- Probenecid (medicine normally used for treatment of gout or hyperuricemia)
- Zidovudine

ALEVE® with food and drink

ALEVE® should preferably be taken prior to having a meal, as ingestion of a meal may delay absorption.

Pregnancy and breastfeeding

ALEVE® is not recommended for patients who are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

- ALEVE® may make you dizzy, drowsy or unable to sleep or stay asleep.
- Do not drive because ALEVE® could interfere with your ability to drive safely.
- Do not operate any tools or machines.

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3. How to take ALEVE®

Do not share medicines prescribed for you with any other person.

Always take ALEVE® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Each dose should be taken orally with a glass of water and can be taken fasting or with meals. Absorption may be delayed with meals.

The usual dose is:

Adults:

- 1 tablet every eight to twelve hours while symptoms persist.
- With experience, some patients may find that an initial dose of 2 tablets followed by 1 tablet 12 hours later, if necessary, will give better relief.
- 3 tablets in 24 hours should not be exceeded unless directed to do so by a doctor.

Elderly (65 and over):

- No more than 2 tablets per day, unless directed to do so by a doctor.

Children:

- Do not give this medicine to children under 12 years, except under the advice and supervision of a doctor.

Dose in severe renal, hepatic or cardiac impairment:

- Dose reduction may be necessary.

- *ALEVE must not be taken for more than 10 days, unless advised to do so by a doctor.*
- *If pain or fever prolongs or if symptoms change, a doctor should be consulted.*

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4. Possible side effects

ALEVE ® can have side effects.

Not all side effects reported for ALEVE® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Nausea
- Vomiting
- Diarrhoea
- Flatulence (excess passing of gas)
- Constipation
- Dyspepsia (heartburn)
- Abdominal pain (belly pain)
- Melena (production of dark sticky faeces contains partly digested blood)
- Hematemesis (vomiting of blood)
- Ulcerative stomatitis
- Exacerbation of colitis (swelling and redness of a large bowel)
- Crohn's disease (chronic inflammatory bowel disease that affects the lining of the digestive tract)

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

Tell your doctor if you notice any of the following:

Body System	**Side Effects**
Immune System disorders	Serious, life-threatening allergic reactions that require immediate medical treatment (e.g. shock with fatal outcome)
Blood and the lymphatic system disorders	Blood disorder (low level of white blood cells, abnormally low level of platelets in the bloodstream, agranulocytosis (acute condition involving lowered white blood cells), aplastic anaemia (a rare condition in which the body stop producing enough new blood cells), eosinophilia (increase in number of eosinophils in the blood), haemolytic anaemia (disorder in which red blood cells are destroyed faster than they can be made)
Psychiatric disorders	psychiatric disorders, depression, dream abnormalities, inability to concentrate
Nervous system disorders	dizziness, headache, light-headedness
	drowsiness, insomnia, somnolence (sleepiness)
	aseptic meningitis, cognitive dysfunction (lack of intellectual functions), convulsions
Eye disorders	visual disturbance*,* corneal opacity, papillitis (inflammation and deterioration of the portion of the optic nerve known as the optic disk), retrobulbar optic neuritis, papilledema (swelling of optic nerve)
Ear & labyrinth disorders	Vertigo (feeling of spinning or whirling)
	hearing impairment, tinnitus (noise in the ears, such as ringing, buzzing), hearing disturbances
Cardiac disorders	congestive heart failure, hypertension, pulmonary oedema (abnormal buildup of fluid in the lungs), palpitations (unpleasant sensation of irregular and/or forceful beating of the heart)
Vascular disorders	vasculitis (Inflammation, swelling and redness) of the blood vessels)
Respiratory disorders	Dyspnea (shortness of breath), asthma, eosinophilic pneumonitis (a lung disease in which an eosinophil, a type of white blood cell, accumulates in the lungs and in bloodstream),
Gastro-intestinal disorders	nausea, heartburn, abdominal pain
	diarrhoea, constipation, vomiting

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Body System	**Side Effects**
	peptic ulcers without or with bleeding or perforation, gastrointestinal bleeding, hematemesis (vomiting of blood), melena
	Pancreatitis (inflammation of the organ lying behind the lower part of the stomach called pancreas), colitis, aphthous ulcers, stomatitis, esophagitis, intestinal ulcerations
Hepatobiliary disorders	hepatitis, (including fatal cases), jaundice
Skin & Subcutaneous Tissue disorders	exanthema (rash), pruritus, urticaria
	angioneurotic edema
	alopecia (usually reversible), photosensitivity, porphyria, exudative erythema multiforme, bullous reactions including Steven's-Johnson syndrome and toxic epidermal necrolysis, erythema nodosum, fixed drug eruption, lichen planus, pustular reaction, skin rashes, Systemic Lupus Erythematosus, photosensitivity reactions including porphyria cutanea tarda ("pseudoporphyria") or epidermolysis bullosa, ecchymoses, purpura, sweating
Renal & Urinary disorders	renal impairment
	interstitial nephritis, renal papillary necrosis, nephrotic syndrome, renal failure, renal disease hematuria, proteinuria
Pregnancy	Induction of labour
Congenital	Closure of ductus arteriosus
Reproductive	Female infertility
General disorders	peripheral edema, particular in patients with hypertension or kidney failure, pyrexia (including chills and fever)
	edema, thirst, malaise
Investigations	raised serum creatinine, abnormal liver function test, hyperkalemia

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA publications: https://www.sahpra.org.za/Publications/Index/8. or you can report the side effects directly to Bayer Pharmacovigilance Department by sending an email to zapv@bayer.com or via the Bayer website (www.bayer.co.za). By reporting side effects, you can help provide more information on the safety of ALEVE®.

5. How to store ALEVE®

Store all medicines out of reach of children.

- ALEVE® should be stored at or below 25 °C
- Protect from light.
- Do not use ALEVE® after the expiry date shown on the blister strip.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What ALEVE® contains

The active substance is: Naproxen 200 mg and 20 mg sodium

The other ingredients are: Magnesium stearate, microcrystalline cellulose, opadry blue YS-1-42I5 CI: 73015, povidone K-30, purified water, talc.

What ALEVE® looks like and contents of the pack

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ALEVE® is presented as a light blue, coated, oval shaped tablet, each containing 220 mg naproxen sodium.

ALEVE is available in blister packs of 12 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.bayer.co.za