1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PANAMOR - 100 SR TABLETS

PANAMOR - 75 SR TABLETS

Diclofenac sodium

Sugar free

Read all of this leaflet carefully before you start taking PANAMOR SR TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PANAMOR SR TABLETS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What PANAMOR SR TABLETS is and what it is used for

PANAMOR SR TABLETS belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

PANAMOR SR TABLETS relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:

- Rheumatoid arthritis, osteoarthritis, (painful inflammation of the joints especially in the feet and hands), ankylosing spondylitis (form of spinal arthritis). Painful musculoskeletal conditions.
- Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures.
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.
- Painful post-operative and post-traumatic inflammation and swelling.
- Pain and inflammation associated with dental surgery.
- Painful period pains.

2. What you need to know before you take PANAMOR SR TABLETS

Do not take PANAMOR SR TABLETS:

- if you are hypersensitive (allergic) to diclofenac sodium or any of the other ingredients of PANAMOR SR TABLETS (listed in section 6).
- if you are allergic to aspirin, ibuprofen or any other NSAID. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- if you experience attacks of asthma after taking, ibuprofen, acetylsalicylic acid or other NSAIDs.

- if you have now, or ever had stomach (gastric) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- if you have had stomach or bowel problems after you have taken other NSAIDs.
- if you have kidney or liver failure.
- if you have heart failure, established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack, stroke, mini-stroke or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria).
- if you are pregnant, do not use NSAIDs at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.
- if you are breastfeeding your baby.
- if the patient is a child (see section titled ‘Children and adolescents’).

Warnings and precautions

Take special care with PANAMOR SR TABLETS:

- if you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn’s disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), angiodysplasia (a small vascular malformation of the gut) as these conditions may be exacerbated.
- if you have or have had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen and report them at once to your doctor. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.

- if you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- if you have any known blood clotting disorder or are on any current blood thinning medicines such as warfarin.
- if you have kidney or liver problems, or if you are elderly.
- if you suffer from anaemia which may occur as a result of water retention or other blood disorders.
- if you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking PANAMOR SR TABLETS.
- if you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.
- if you have an infection since symptoms such as fever and inflammation may be masked. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- if you have heart problems such chest pain, blood clots, or if you had a stroke or you think you might be at risk of these conditions (for example, if you have high blood pressure, high blood sugar levels, high amounts of fat in the blood or are a smoker). There is an increased risk of heart attack or stroke when you are taking PANAMOR SR TABLETS. The risk is higher if you are taking high doses for a long time.
- if you, at any time while taking PANAMOR SR TABLETS, experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.
- if you have serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Rash with Eosinophilia and

Systemic Symptoms (DRESS) and toxic skin degeneration. PANAMOR SR TABLETS should be discontinued immediately at the first appearance of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity (such as Stevens Johnson's syndrome, Toxic Epidermal Necrosis, Drug Reaction with Eosinophilia and Systemic Symptoms). You should also contact your doctor as soon as possible.

- if you have Systemic Lupus Erythematosus (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition.
- if you have any allergic reaction including chest pain, which can be a sign of a potentially serious allergic reaction (Kounis syndrome).
- if you recently had or you are going to have a surgery of the stomach or intestinal tract, as PANAMOR SR TABLETS can sometimes delay wound healing in your gut after surgery.
- if you are pregnant or plan to become pregnant. Taking PANAMOR SR TABLETS at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to use PANAMOR SR TABLETS for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take PANAMOR SR TABLETS around 30 weeks of pregnancy or later.
- The use of PANAMOR SR TABLETS may affect a woman's ability to have a baby.

Children and adolescents

PANAMOR SR TABLETS are not suitable for use in children and adolescents below 14 years of age.

Other medicines and PANAMOR SR TABLETS

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

Tell your doctor if you are taking any of the following:

- Medicines used to treat diabetes.
- Anti-platelets and anticoagulants (blood thinning tablets), such as heparin or warfarin.
- Diuretics (water tablets).
- Lithium (a medicine used to treat depression).
- Methotrexate (a medicine used for the treatment of some inflammatory diseases and some cancers).
- Ciclosporin and tacrolimus (medicines used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibiotics (a medicine for infections).
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).
- Digoxin (a cardiac glycosides), used to treat heart problems.
- Selective serotonin reuptake inhibitors (SSRIs (used to treat depression)).
- Corticosteroids (an anti-inflammatory medicine).
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Sulfinpyrazone or probenecid (medicines used to treat gout).
- Phenytoin (a medicine used to treat seizures).
- Colestipol/cholestyramine (a medicine used to lower cholesterol).

- Hydantoin (a medicine used to treat different types of seizures).
- Pemetrexed (a chemotherapy medicine used to treat some forms of cancer).
- Deferasirox (a medicine used in patients receiving long term blood transfusions).

PANAMOR SR TABLETS with food and drink

PANAMOR SR TABLETS should preferably be taken at mealtimes.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PANAMOR SR TABLETS.

PANAMOR SR TABLETS should not be used while you are pregnant or breastfeeding your baby.

Pregnancy

PANAMOR SR TABLETS may harm your unborn baby and may cause problems during delivery. At around 20 weeks or later in pregnancy PANAMOR SR TABLETS may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn baby's lungs and muscles develop. Complications can occur with low levels of this fluid.

Breastfeeding

You should not take PANAMOR SR TABLETS if you are breastfeeding your baby.

Fertility

Taking PANAMOR SR TABLETS may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines

PANAMOR SR TABLETS may cause drowsiness, dizziness and visual disturbances which may affect your ability to perform skilled tasks. If you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent PANAMOR SR TABLETS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PANAMOR SR TABLETS affects you (see section 4).

3. How to take PANAMOR SR TABLETS

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

Always take PANAMOR SR TABLETS exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults

The usual dose of PANAMOR SR TABLETS: Initial daily dosage is 100 mg to 150 mg administered as one tablet of PANAMOR - 100 SR TABLETS as a single dose, or two tablets of PANAMOR - 75 SR TABLETS taken in two divided doses. In milder cases, as well as for long-term therapy, one tablet of PANAMOR - 75 SR TABLETS is usually sufficient.

PANAMOR SR TABLETS is not suitable for use in children and adolescents below 14 years of age.

PANAMOR SR TABLETS should be swallowed whole with a glass of water.

These tablets should be neither broken nor chewed and should preferably be taken at mealtimes. Where the symptoms are most pronounced during the night or in the morning, PANAMOR - 100 SR TABLETS should be taken in the evening.

If you have the impression that the effect of PANAMOR SR TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more PANAMOR SR TABLETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of an overdose can include headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take PANAMOR SR TABLETS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PANAMOR SR TABLETS can have side effects.

Not all side effects reported for PANAMOR SR TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking PANAMOR SR TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking PANAMOR SR TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), toxic epidermal, necrolysis (TEN) or, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to PANAMOR SR TABLETS. You may need urgent medical attention or hospitalisation.

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

- sudden and crushing chest pain (signs of myocardial infarction, heart attack or Kounis syndrome),
- heart disorders or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time,
- fast or irregular heartbeat (palpitations),
- sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision, sudden difficulty in speaking or ability to understand speech, sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke,
- high blood pressure (hypertension), low blood pressure, symptoms of which may include faintness, giddiness or light headedness (hypotension),

- lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease),
- inflammation of the pancreas (pancreatitis),
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick) as you may be experiencing ischemic colitis,
- diarrhoea with blood in it or bleeding from the back passage (haemorrhagic diarrhoea),
- any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit (haematemesis) or black, tarry faeces (melaena),
- kidney disorders including kidney failure, kidney pain or inflammation of the kidneys,
- liver disorders including liver failure or inflammation of the liver,
- presence of blood or protein in the urine,
- an unexpected change in the amount of urine produced and/or its appearance,
- yellowing of your skin or the whites of your eyes (jaundice),
- wheezing or shortness of breath (bronchospasm),
- breathlessness, coughing and a tightness across the chest (asthma),
- inflammation of the lung (pneumonitis),
- inflammation of blood vessels (vasculitis),
- inflammation of the lining of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (meningitis),
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with PANAMOR SR TABLETS and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain,
- if you notice that you are bruising more easily than usual or have frequent sore throats or infections,

- convulsions (fitting).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- stomach pain, heartburn, nausea, vomiting, diarrhoea, constipation, indigestion, wind, loss of appetite,
- inflammation, irritation or swelling of the stomach lining (gastritis),
- mouth ulcers with swelling and redness inside the mouth or individual painful sores,
- headache, dizziness,
- a feeling of whirling or spinning (vertigo),
- raised levels of liver enzymes in the blood,
- anorexia (eating disorder),
- discomfort of the limbs.

Less frequent side effects:

- tiredness, excess sleepiness (somnolence),
- fluid retention, symptoms of which include swollen ankles (oedema),
- visual disturbances such as blurred or double vision,
- hearing disorders, tinnitus (ringing in the ears),
- sleeplessness, nightmares, depression, anxiety, irritability, mental disorders, disorientation, loss of memory, tremor,
- tingling or numbness in the fingers,
- taste changes,
- inflammation of the tongue (glossitis), inflammation of the inside of the mouth or lips (stomatitis),

- blood disorders (including anaemia),
- photosensitivity (increased sensitivity to sunlight),
- hair loss,
- loss of male sexual ability (impotence).

Side effects with an unknown frequency:

- inflammation of the nerves in the eye (optic neuritis), other ocular reactions,
- drowsiness, nervousness, agitation,
- confusion, hallucinations, malaise (general feeling of discomfort).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of PANAMOR SR TABLETS.

5. How to store PANAMOR SR TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 PANAMOR - 75 SR TABLETS contains

The active substance is 75 mg of diclofenac sodium.

The other ingredients are diethyl phthalate, ethylcellulose, ferric oxide red (C.I. 77491), ferric oxide yellow (C.I. 77492), hypromellose, magnesium stearate, macrogol 4000, povidone, stearic acid, talc, titanium dioxide (C.I. 77891)

Sugar free.

What PANAMOR - 100 SR TABLETS contains

The active substance is 100 mg of diclofenac sodium.

The other ingredients are diethyl phthalate, ethylcellulose, ferric oxide red (C.I. 77491), ferric oxide yellow (C.I. 77492), hypromellose, magnesium stearate, macrogol 4000, povidone, stearic acid, talc, titanium dioxide (C. I. 77891).

Sugar free.

What PANAMOR SR TABLETS looks like and contents of the pack

PANAMOR - 75 SR TABLETS is a pink film-coated, triangular tablet.

PANAMOR - 100 SR TABLETS is a pale red, film-coated, round biconvex tablet.

PANAMOR - 75 SR TABLETS:

30 tablets are packed in a clear polyvinylchloride blister strip sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

PANAMOR - 100 SR TABLETS:

28 tablets are packed in a clear polyvinylchloride blister strip sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200

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Registration numbers

PANAMOR - 75 SR TABLETS:	29/3.1/0121
PANAMOR - 100 SR TABLETS:	29/3.1/0122

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana:	S2
PANAMOR - 75 SR TABLETS	B9322615

Namibia:	NS2
PANAMOR - 75 SR TABLETS	04/3.1/0438
PANAMOR - 100 SR TABLETS	04/3.1/0216

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