1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PANAMOR SUPPOSITORIES-12,5

PANAMOR SUPPOSITORIES-25

PANAMOR SUPPOSITORIES 100 mg

Diclofenac sodium

Read all of this leaflet carefully before you start using PANAMOR SUPPOSITORIES

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

1. What PANAMOR SUPPOSITORIES is and what it is used for

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

PANAMOR SUPPOSITORIES 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 periods.

2. What you need to know before you use PANAMOR SUPPOSITORIES

Do not use PANAMOR SUPPOSITORIES:

- if you are hypersensitive (allergic) to diclofenac sodium or any of the other ingredients of PANAMOR SUPPOSITORIES (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’).
- if you have proctitis (inflammation of the lining of the rectum).

Warnings and precautions

Take special care with PANAMOR SUPPOSITORIES:

- 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 any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are using PANAMOR SUPPOSITORIES.
- if you suffer from anaemia which may occur as a result of water retention or other blood disorders.
- 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 use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- 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 SUPPOSITORIES 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 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 using PANAMOR SUPPOSITORIES. The risk is higher if you are using high doses for a long time.
- if you, at any time while using PANAMOR SUPPOSITORIES, 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 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 SUPPOSITORIES can sometimes delay wound healing in your gut after surgery.
- if you are pregnant or plan to become pregnant. Using PANAMOR SUPPOSITORIES at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to use PANAMOR SUPPOSITORIES 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 SUPPOSITORIES around 30 weeks of pregnancy or later.

- The use of PANAMOR SUPPOSITORIES may affect a woman's ability to have a baby.

Children and adolescents

PANAMOR SUPPOSITORIES-12,5 and PANAMOR SUPPOSITORIES-25 are not suitable for children under 2 years.

PANAMOR SUPPOSITORIES 100 mg is not suitable for children and adolescents below 14 years of age.

Other medicines and PANAMOR SUPPOSITORIES

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 (cardiac glycoside) 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 medicines used to treat some forms of cancer).
- Deferasirox (a medicine used in patients having long term blood transfusions).

PANAMOR SUPPOSITORIES with food and drink

PANAMOR SUPPOSITORIES may be used at any time of the day.

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 using PANAMOR SUPPOSITORIES.

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

Pregnancy

PANAMOR SUPPOSITORIES may harm your unborn baby and may cause problems

during delivery. At around 20 weeks or later in pregnancy PANAMOR SUPPOSITORIES 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 use PANAMOR SUPPOSITORIES if you are breastfeeding your baby.

Fertility

Using PANAMOR SUPPOSITORIES 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 SUPPOSITORIES 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 SUPPOSITORIES 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 SUPPOSITORIES affects you (see section 4).

3. How to use PANAMOR SUPPOSITORIES

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

Always use PANAMOR SUPPOSITORIES 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 is 100 mg each of PANAMOR SUPPOSITORIES each evening.

To relieve pain which appears at night, and morning stiffness, you may use tablets during the day and use PANAMOR SUPPOSIOTRIES at bedtime, up to a maximum dosage of 150 mg daily.

Children

PANAMOR-12,5 mg and PANAMOR-25 mg suppositories:

Children aged 2 years or more should be given 2 mg to 3 mg per kg body mass daily, in two or three fractional doses.

PANAMOR SUPPOSITORIES (100 mg) is not suitable for use in children and adolescents below 14 years of age.

PANAMOR SUPPOSITORIES not to be taken by mouth. Only for rectal use. The suppositories should be inserted well into the rectum. It is recommended to use the suppositories after passing stools.

Suppositories should never be divided for administration as the active substance may be distributed unevenly.

Incorrect storage conditions could also lead to an uneven distribution of active substance in the suppository.

Do not use suppositories deformed by exposure to temperatures above 30 °C.

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

If you use more PANAMOR SUPPOSITORIES 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 use PANAMOR SUPPOSITORIES

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

4. Possible side effects

PANAMOR SUPPOSITORIES can have side effects.

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

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

If any of the following happens, stop using PANAMOR SUPPOSITORIES 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) or 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 SUPPOSITORIES. 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 using 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 SUPPOSITORIES 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), application site irritation,
- 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, fits, 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 SUPPOSITORIES.

5. How to store PANAMOR SUPPOSITORIES

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

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 SUPPOSITORIES-12,5 contains

The active substance is 12,5 mg diclofenac sodium.

The other ingredient is suppocire AM.

What PANAMOR SUPPOSITORIES-25 contains

The active substance is 25 mg diclofenac sodium.

The other ingredient is suppocire AM.

What PANAMOR SUPPOSITORIES contains

The active substance is 100 mg diclofenac sodium.

The other ingredient is suppocire AM.

What PANAMOR SUPPOSITORIES looks like and contents of the pack

PANAMOR SUPPOSITORIES-12,5 is a white, torpedo-shaped suppository.

PANAMOR SUPPOSITORIES-25 is a white, torpedo-shaped suppository.

PANAMOR SUPPOSITORIES is a large, white, torpedo-shaped suppository.

PANAMOR SUPPOSITORIES-12,5:

5 suppositories packed in white opaque polyvinylchloride laminated to polyethylene. One or more strips are packed into an outer cardboard carton together with a leaflet.

PANAMOR SUPPOSITORIES-25:

5 suppositories packed in white opaque polyvinylchloride laminated to polyethylene. One or more strips are packed into an outer cardboard carton together with a leaflet.

PANAMOR SUPPOSITORIES:

5 suppositories packed in white opaque polyvinylchloride laminated to polyethylene. One or more strips are packed into an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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PANAMOR SUPPOSITORIES-12,5:	27/3.1/0121
PANAMOR SUPPOSITORIES-25:	Z/3.1/172
PANAMOR SUPPOSITORIES:	Y/3.1/395

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

Namibia:	NS2
PANAMOR SUPPOSITORIES-12,5	04/3.1/0101
PANAMOR SUPPOSITORIES-25	04/3.1/0450
PANAMOR SUPPOSITORIES	04/3.1/0099

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