SCHEDULING STATUS: S2

PONAC SUSPENSION

Mefenamic acid 50 mg per 5 ml

Preservatives:

Butyl hydroxybenzoate 0,015 % m/v

Methyl hydroxybenzoate 0,03 % m/v

Propyl hydroxybenzoate 0,015 % m/v

Contains sweetener:

Saccharin Sodium 1,000 mg per 5 ml

Sorbitol solution 2,000 ml per 5 ml

Read all of this leaflet carefully before you start taking PONAC SUSPENSION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PONAC SUSPENSION have 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 PONAC SUSPENSION is and what it is used for
2. What you need to know before you take PONAC SUSPENSION
3. How to take PONAC SUSPENSION
4. Possible side effects
5. How to store PONAC SUSPENSION

6. Contents of the pack and other information

1. What PONAC SUSPENSION is and what it is used for

PONAC SUSPENSION contain mefenamic acid. Mefenamic acid belongs to a group of medicinal products called non-steroidal anti-inflammatory medicines (NSAIDs).

PONAC SUSPENSION are used for the relief of acute and mild to moderate pain and can also be used for primary dysmenorrhoea (painful cramps during menstruation).

2. What you need to know before you take PONAC SUSPENSION

Do not take PONAC SUSPENSION

- if you are allergic (hypersensitive) to mefenamic acid or any of the other ingredients of PONAC SUSPENSION (listed in section 6).
- if you have or are taking other non-steroidal anti-inflammatory medicine and have experienced symptoms of bronchospasm (spasmodic contraction of the muscular lining of the bronchi, as in asthma, causing difficulty in breathing), allergic rhinitis (referred to as hay fever, is inflammation of the nasal passages) or urticaria (a skin condition characterised by welts that itch intensely).
- if you have a history of gastrointestinal (stomach) perforation, ulceration or bleeding (PUBs).
- if you have an active or history of recurrent ulcer / haemorrhage (bleeding) / perforations.
- if you have chronic inflammation of either the upper or lower gastrointestinal tract (the path that food follows once it is in the stomach).
- if you suffer from epilepsy (fits or seizures, uncontrolled shaking of the body).
- if you have impaired hepatic (liver) or renal (kidney) function.
- if you have heart failure (a condition in which the heart has lost the ability to pump enough blood to the body's tissues and organs which may result in organ failure).

- if you require treatment for pain after coronary artery bypass graft (CABG) surgery.
- if you are pregnant or breastfeeding your baby.
- if you have an intolerance to certain sweeteners.

Warnings and special precautions

Take special care with PONAC SUSPENSION

- if you are elderly, because you may be more susceptible to gastrointestinal (stomach) perforation, bleeding and ulceration which may be fatal.
- if you suffer from asthma or allergic reactions such as hay fever.
- if you are taking diuretics (also called water pills, which help rid your body of salt (sodium) and water). Your doctor will monitor your condition by taking regular blood tests and may adjust your dose.
- if you are taking warfarin (drug used to thin the blood), because PONAC SUSPENSION may result in your blood becoming too thin.
- if you have a history of high blood pressure, PONAC SUSPENSION may result in oedema (excessive build-up of fluid in the tissues, often causes swelling in the feet and ankles) which may precipitate heart failure.
- if you suffer from heart problems, have had a previous stroke or think that you may be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker), PONAC SUSPENSION may make these conditions worse.
- if you experience gastrointestinal (stomach) perforation, bleeding and ulceration, stop taking PONAC SUSPENSION immediately. If you have a history of gastrointestinal (stomach) perforation ulceration (peptic ulcer), bleeding, inflammation of the bowel, hiatus hernia, acid reflux, bleeding of the rectum (resulting in bloody stools), taking PONAC SUSPENSION may make these conditions worse.

- if you suffer from systemic lupus erythematosus (chronic autoimmune disease that can cause joint pain and severe fatigue) and mixed connective tissue disorders since taking PONAC SUSPENSION may lead to an increased risk of aseptic meningitis (serous inflammation of the linings of the brain which lead to headache, fever, firm neck pain, lack of appetite and the possibility of vomiting).
- if you develop a skin rash or experience any allergic reaction such as mouth ulcers or blisters, stop taking PONAC SUSPENSION immediately as this may develop into a more serious condition which may be fatal.
- if you are dehydrated, PONAC SUSPENSION may result in kidney damage.
- if you take PONAC SUSPENSION at higher than recommended doses or for a long period of time, the potassium levels in your blood can become very low and your kidneys may become damaged which affects their ability to remove acids properly from your blood into the urine (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.
- if you have an intolerance to certain sweeteners.

Other medicines and PONAC SUSPENSION

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The use of PONAC SUSPENSION together with the following medicines may cause undesirable effects:

- NSAIDs (anti-inflammatory medicines used to treat inflammation); you may experience an increase in side effects.
- Corticosteroids (medicines used to treat allergic reactions, skin diseases (psoriasis, hives), breathing problems, certain cancers, blood disorders, eye problems, arthritis,

digestive problems); your risk of experiencing stomach perforation, ulceration and bleeding is increased.

- Anti-coagulants (blood thinners) such as warfarin may result in your blood becoming too thin.
- Anti-platelet medicines (medicines that prevent blood clotting) and selective serotonin reuptake inhibitors (SSRIs) (medicines that treat depression); your risk of experiencing stomach perforation, ulceration and bleeding is increased.
- Lithium (medicine used to treat bi-polar disorder); you are at risk of lithium toxicity (poisoning).

PONAC SUSPENSION with food and drink

PONAC SUSPENSION must be taken with food.

Pregnancy, breastfeeding and fertility

You should not use PONAC SUSPENSION when pregnant or breastfeeding your infant.

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 health care provider for advice before taking this medicine.

PONAC SUSPENSION may affect your ability to fall pregnant. If you are having difficulty falling pregnant or you are undergoing fertility treatment , discuss this with you doctor, pharmacist or other health care professional.

If you regularly use PONAC SUSPENSION or other NSAIDs during the third trimester of your pregnancy, it may result in premature closure of a blood vessel in the developing foetus

while still inside the womb. This may lead to persistent high blood pressure in the blood vessels of the lungs of the new-born baby. The onset of labour may be delayed and the duration thereof increased.

Small amounts of mefenamic acid may be present in breast milk and can be transmitted to the breastfeeding infant. Therefore, PONAC SUSPENSION should not be taken by mothers breastfeeding their infants.

Driving and using machines

PONAC SUSPENSION may affect the mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision since PONAC SUSPENSION may cause adverse reactions such as dizziness, drowsiness, fatigue and visual disturbances.

Do not drive or operate any tools or machines after taking PONAC SUSPENSION until you are certain that PONAC SUSPENSION do not adversely affect your ability to do so safely.

PONAC SUSPENSION contain sorbitol

PONAC SUSPENSION contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take PONAC SUSPENSION.

3. How to take PONAC SUSPENSION

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

Always take PONAC SUSPENSION exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will tell you how long your treatment with PONAC SUSPENSION will last.

PONAC SUSPENSION must be taken with meals.

The usual dose for adults is:

Mild to moderate pain

500 mg three (3) times a day.

Acute pain

500 mg initial dose followed by 250 mg every six (6) hours for a maximum treatment period of five (5) days.

Primary dysmenorrhoea (painful cramps during menstruation)

500 mg three (3) times a day for a maximum treatment period of three (3) days.

Children

25 mg per kg body weight daily in divided doses.

The following dose may be repeated as necessary, up to three (3) times daily:

6 months to 1 year: One (1) measureful (5 ml).

2 years to 4 years: Two (2) measureful (10 ml).

5 years to 8 years: Three (3) measureful (15 ml).

9 years to 12 years: Four (4) measureful (20 ml).

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

If you take more PONAC SUSPENSION than you should

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

PONAC SUSPENSION can cause tonic-clonic convulsions (seizures that involve both stiffening and twitching or jerking of muscles) in overdosage. Dyskinesia (impairment of voluntary movement), acute kidney failure and coma have also been reported.

If you take PONAC SUSPENSION at higher than recommended doses or for a long time, the potassium levels in your blood can become very low and your kidneys may become damaged (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If you forget to take PONAC SUSPENSION

If you forget to take a dose, take it as soon as you remember if within a few hours after missing the dose. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PONAC SUSPENSION can have side effects.

Not all side effects reported for PONAC SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PONAC SUSPENSION, please consult your health care provider for advice.

If any of the following happens, stop taking PONAC SUSPENSION 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

These are all very serious side effects. If you have them, you may have had a serious reaction to PONAC SUSPENSION. 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:

Frequent

- Diarrhoea.
- Nausea with or without vomiting.
- Abdominal pain.

Less frequent

- Anorexia (lack or loss of appetite for food).
- Heartburn.
- Flatulence.
- Enterocolitis (inflammation of the small intestine and colon).
- Colitis (inflammation of the inner lining of the colon).
- Steatorrhoea (abnormal quantities of fat in faeces).
- Cholestatic jaundice (yellowish discolouration of the whites of the eyes, skin and mucous membranes).
- Hepatitis (inflammation of the liver).
- Pancreatitis (inflammation of the pancreas).
- Hepato-renal syndrome (progressive kidney failure seen in people with severe liver damage).
- Mild liver toxicity.
- Constipation.
- Peptic ulceration (open sores that develop on the inside lining of your stomach and the upper potion of your small intestine).

- Perforation with or without gastrointestinal bleeding.
- Haemolytic anaemia (occurs when destruction of red blood cells is faster than the bone marrow's production of these cells).
- Decreased haematocrit (decreased volume percentage of red blood cells in blood, measured as part of a blood test).
- Leukopenia (a reduction in the number of white cells in the blood).
- Eosinophilia (an increase in the number of eosinophils (white blood cells containing granules that are readily stained by eosin) in the blood).
- Thrombocytopenia (deficiency of platelets in the blood) or thrombocytopenic purpura (autoimmune disorder where the immune system destroys platelets and sometimes impair their production).
- Agranulocytosis (a deficiency of granulocytes (white blood cell with secretory granules in its cytoplasm) in the blood, causing increased vulnerability to infection).
- Aplastic anaemia (deficiency of all types of blood cells).
- Bone marrow aplasia (disease in which the red bone marrow disappears and consequently ceases the production of white blood cells, platelets and red blood cells).
- Acute hypersensitivity reactions including urticaria (a skin condition characterised by welts that itch intensely), bronchospasm (spasmodic contraction of the muscular lining of the bronchi, as in asthma, causing difficulty in breathing) and anaphylaxis (acute allergic reaction to an antigen).
- Glucose intolerance in diabetic patients.
- Hyponatraemia (low blood sodium or salt deficiency).
- Nervousness.
- Drowsiness.
- Dizziness.
- Headache.

- Visual disturbances.
- Convulsions (uncontrollable muscle contractions).
- Insomnia (sleeplessness).
- Ear pain.
- Palpitations (noticeably rapid, strong or irregular heartbeat).
- Oedema (excessive build-up of fluid in the tissues, often causes swelling in the feet and ankles).
- Hypertension (high blood pressure).
- Heart failure (a condition in which the heart has lost the ability to pump enough blood to the body's tissues and organs which may result in organ failure).
- Hypotension (low blood pressure).
- Asthma.
- Dyspnoea (difficulty in breathing).
- Angioedema (swelling in the deep layers of the skin).
- Oedema of the larynx (an abnormal accumulation of fluid and swelling in the tissues of the voice box).
- Steven-Johnson syndrome (rare, serious disorder of the skin and mucous membranes causing flu-like symptoms followed by a painful rash that spreads and blisters).
- Lyell's syndrome (toxic epidermal necrolysis)/
- Erythema multiforme (acute, self-limiting skin eruption characterised by a typical target lesion).
- Sweating.
- Severe itching of the skin.
- Facial oedema (swelling of the face due to fluid build-up).
- Kidney failure.

- Papillary necrosis (kidney disorder in which all or part of the renal papillae die. The renal papillae are the areas where the openings of the collecting ducts enter the kidney and where urine flows into the ureter).
- Acute interstitial nephritis (a pattern of kidney injury usually associated with an abrupt deterioration of kidney function) with blood in the urine.
- Painful urination.
- Proteinuria (protein in the urine).
- Allergic glomerulonephritis (acute inflammation of the kidney caused by an immune response).

Frequency unknown

- Hypokalaemia (low levels of potassium in your blood)
- Indigestion.
- Black, tarry stools.
- Vomiting of blood.
- Sore or inflammation inside of the mouth.
- Crohn's disease (inflammation of the digestive tract, which can lead to abdominal pain, fatigue, severe diarrhoea and weight loss).
- Inflammation of the lining of the stomach.
- Bullous reactions (reactions that result in fluid-filled blisters).
- Nephrotic syndrome (kidney disorders that causes the body to pass too much protein in the urine).
- Renal tubular acidosis (the kidneys are damaged and can't remove a waste, called acid, from the blood.)
- Elevation in blood urea.

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's publications: https://www.sahpra.org.za/

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

5. How to store PONAC SUSPENSION

Store all medicines out of reach of children.

- Store in a cool dry place at or below 25 °C.
- Keep in the original container.
- Protect from light / moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.

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 PONAC SUSPENSION contain

- The active substance is mefenamic acid.

Each 5 ml PONAC SUSPENSION contains 50,000 mg mefenamic acid. Preservatives: butyl hydroxybenzoate 0,015 % *m/v*, methyl hydroxybenzoate 0,03 % *m/v* and propyl hydroxybenzoate 0,015 % *m/v*. Contains sweetener: saccharin sodium 1,000 mg per 5 ml and sorbitol solution 2,000 ml per 5 ml.

- The other ingredients are:

Sodium citrate, sodium chloride, sodium cyclamate, disodium edetate, citric acid monohydrate, xanthan gum, guar gum, sodium lauryl sulphate, dye lennon white no. 101 (C.I. no.

77891), simethicone emulsion 30 %, flavour vanilla 75012 – 33, flavour tutti-frutti 60785 – 74, purified water.

What PONAC SUSPENSION look like and contents of the pack

Off-white suspension of pourable consistency with a fruity odour and taste.

Contents of the pack

PONAC SUSPENSION is either packed in amber glass bottles, amber PVC bottles or amber PET bottles. The bottles are packed into outer cardboard carton. Pack size: 100 ml and 200 ml.

Not all packs may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Refer to the SAHPRA website.