PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PARAFENGEN ORAL SUSPENSION 160 mg/48 mg

Paracetamol and ibuprofen

Contains sugar (maltitol 1 250 mg/5 ml) and

sweetener (sucralose 7 mg/5 ml)

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

Keep this leaflet. You may need to read it again.

- Do not share PARAFENGEN ORAL SUSPENSION with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your child's symptoms worsen or do not improve after 2 days.

What is in this leaflet

1. What PARAFENGEN ORAL SUSPENSION is and what it is used for

Paracetamol is used to treat pain and it reduces fever.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness).

PARAFENGEN ORAL SUSPENSION is indicated for the short-term treatment of mild to moderate pain and the reduction of fever in children 2 to 12 years of age.

2. What you need to know before you use PARAFENGEN ORAL SUSPENSION

Do not use PARAFENGEN ORAL SUSPENSION:

- If your child is hypersensitive (allergic) to ibuprofen and paracetamol or any of the other ingredients of PARAFENGEN ORAL SUSPENSION (listed in section 6).
- If your child has severe heart failure or hepatic (liver) failure or liver diseases.
- If your child is (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
- If your child has a peptic ulcer (sore on the lining of the stomach or small intestine), a recent history of one, or have had peptic ulcers before.
- If your child has asthma, urticaria (itchy, raised, red or skin-coloured swellings) or allergic-type reactions after taking aspirin, or other NSAIDs.
- If your child has uncontrolled asthma and tightening of the muscles that line the airways (bronchi) in his/her lungs.
- If your child is under the age of 6 months.
- If your child is treated for pain before coronary artery bypass surgery (CABG).

Warnings and precautions

Take special care with PARAFENGEN ORAL SUSPENSION:

- If your child has a history of high blood pressure and/or heart problems and/or high blood sugar (diabetes) as PARAFENGEN ORAL SUSPENSION might worsen these conditions.
- If your child has a history of gastrointestinal diseases, e.g. peptic ulcers, ulcerative colitis (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the tube connecting your mouth and stomach), as PARAFENGEN ORAL SUSPENSION can cause these conditions can re-occur.
- PARAFENGEN ORAL SUSPENSION can cause severe skin reactions (see section 4 Possible side effects).
- PARAFENGEN ORAL SUSPENSION contains paracetamol. Doses higher than those recommended can results in severe liver damage and even death (see section 3. If you gave more PARAFENGEN ORAL SUSPENSION than you should).

- If your child suffers from liver disease and shows any of the following signs and/or symptoms, nausea, weakness, tiredness, itch skin, jaundice, abdominal tenderness in the right upper quadrant and flu-like symptoms, as the liver function can deteriorate with the use of PARAFENGEN ORAL SUSPENSION.
- If your child bleeds easily and/or is using medicine for blood clots, as PARAFENGEN ORAL SUSPENSION can prolong bleeding time.
- If your child is suffering from asthma or has previously shown signs of asthma with use of aspirin.
- If your child develops visual disturbances during treatment with PARAFENGEN ORAL SUSPENSION, an ophthalmological examination will have to be done.
- If your child suffers from systemic lupus erythematosus (SLE) or other connective tissue disorders, he/she might be more susceptible for aseptic meningitis.

Other medicines and PARAFENGEN ORAL SUSPENSION

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

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

- Other NSAIDs, including aspirin or products containing paracetamol
- Corticosteroids (used to treat many conditions, such as inflamed areas of the body, allergic reactions, itching, e.g. prednisone, cortisone)
- Anti-coagulants, as PARAFENGEN ORAL SUSPENSION may enhance the effects of anti-coagulants such as warfarin
- Selective serotonin reuptake inhibitors (SSRPs) (used to treat depression, e.g. fluoxetine, citalopram, sertraline, paroxetine and escitalopram), as the risk of bleeding in the gut increases.
- Medicines that reduce high blood pressure, e.g. ACE-inhibitors such as captopril, beta-blockers (atenolol medicines), angiotensin-II receptor antagonists (losartan) and diuretics (water tablets, e.g. furosemide and thiazide) as they may cause high blood potassium and damages to the kidneys.
- Digoxin (used for heart conditions) as the combination can result in heart failure.
- Lithium (used to treat some types of depression), as the blood levels can be increased, resulting in a lithium overdose.
- Methotrexate (used to treat arthritis and some types of cancer), as the blood levels can be increased, resulting in a methotrexate overdose.

- Metoclopramide as paracetamol absorption is increased by substances that increase gastric emptying.
- Propantheline, antidepressants with anticholinergic properties, and narcotic analgesics: as paracetamol absorption is decreased by substances that decrease gastric emptying.
- Medicines that can have an effect on the liver, e.g. anticoagulants (blood thinning products), barbiturates (sleeping tablets), isoniazid (tuberculosis medicine), rifampicin (antibiotic), co-trimoxazole (antibiotic combination), zidovudine (HIV medicine), and chronic alcohol use, as the risk of paracetamol damage to the liver is increased.
- Probenecid (used to treat gout), as paracetamol excretion may be affected, and plasma concentrations altered.
- Cholestyramine: Reduces the absorption of paracetamol if given within 1 hour of PARAFENGEN ORAL SUSPENSION

Pregnancy, breastfeeding and fertility

PARAFENGEN ORAL SUSPENSION-should not be used during pregnancy and breastfeeding.

Driving and using machines

It is not always possible to predict to what extent PARAFENGEN ORAL SUSPENSION may interfere with your child's daily activities. You should make sure before your child engage in activities that requires concentration until you are aware how PARAFENGEN ORAL SUSPENSION affects him/her.

PARAFENGEN ORAL SUSPENSION may impair your child's ability to perform difficult tasks as it may make him/her feel dizzy, tired or sleepy or he/she can experience visual disturbances.

PARAFENGEN ORAL SUSPENSION contains maltitol

PARAFENGEN ORAL SUSPENSION contains maltitol and may have a laxative effect.

3. How to use PARAFENGEN ORAL SUSPENSION

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

Always give PARAFENGEN ORAL SUSPENSION to your child exactly as described in this leaflet or as your doctor, pharmacist, or nurse have told you. Check with your doctor, pharmacist, or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE

The usual dose should be given every 4 to 6 hours as necessary, with no more than 4 doses in 24 hours.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. Consult a doctor if the symptoms persist or worsen or if the product is required for more than 2 days.

Age*	Average body weight	Dose (ml)
2 to 3 years	12 - 14 kg	5 ml
3 to 4 years	14 - 16 kg	5 - 6 ml
4 to 5 years	16 - 18 kg	6 - 7 ml
6 to 7 years	18 - 20 kg	7 - 8 ml
7 to 8 years	20 - 22 kg	8 ml
8 to 9 years	22 - 25 kg	8 - 9 ml
9 to 10 years	28 - 32 kg	9 - 11 ml
10 to 11 years	32 - 36 kg	12 - 14 ml
11 to 12 years	36 - 41 kg	14 - 15 ml

* If the child's weight is less than the weight corresponding to their age in the table, select the dose for their weight. Do not exceed a dose of 31 ml, regardless of the weight of the child

Method of administration

The bottle should be shaken well before you use it. Use the syringe supplied in the pack to draw up the correct dose in millilitres.

Directions for using the syringe:

1. Shake the bottle for at least 10 seconds before use.
2. Push the syringe firmly into the plug (hole) in the opening of the bottle.
3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe.
4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
5. Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.
6. If the dosing table above recommends a dose of more than 5 mL, repeat steps 2 to 5 to administer the correct amount of medicine.
7. After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.
8. Wash the syringe in warm water and allow to dry.

If you used more PARAFENGEN ORAL 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.

Prompt medical attention is critical. Even if your child does not show symptoms of an overdose, take your child immediately to your nearest hospital or Poison Centre.

PARAFENGEN ORAL SUSPENSION contains paracetamol and an overdose, can be fatal. PARAFENGEN ORAL SUSPENSION also contains ibuprofen, an NSAID and an overdose can increase the risk of heart attack or stroke.

The symptoms of an overdose can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to use PARAFENGEN ORAL SUSPENSION

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

If it is almost time for the next dose, skip the missed dose and give the next dose when you are meant to. Otherwise, give it as soon as you remember, and then go back to giving PARAFENGEN ORAL SUSPENSION as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

PARAFENGEN ORAL SUSPENSION can have side effects.

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

If any of the following happens, stop taking PARAFENGEN ORAL SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Liver damage: nausea, vomiting, loss of appetite, pale colour of the skin, stomach pain.
- Anaphylactic reaction (sudden allergic reaction) including skin rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble

breathing.

- Serious skin reactions, including widespread redness and scaling of the skin, rash on the body where each mark resembles a bullseye, Stevens-Johnson syndrome a rare, serious disorder of your skin and mucous membranes. Often, it begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters.
- Perforation or gastrointestinal bleeding (vomiting blood or material that looks like coffee ground, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.

These are all very serious side effects, and you need urgent medical attention or hospitalisation. If these effects are not treated, they could be fatal.

Tell your doctor if you notice any of the following:

Frequent

- Dizziness, headache, nervousness
- Noise or ringing in the ears (tinnitus)
- Fluid retention, swelling, high blood pressure, heart failure
- Abdominal pain, diarrhoea, indigestion (dyspepsia), nausea, stomach discomfort, vomiting
- Skin rashes, itching
- Change in liver or kidney function tests (established by blood tests)

Less frequent

- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- Signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- Boys' and men's breasts swell and become larger than normal (gynaecomastia), low blood sugar (hypoglycaemic reaction)
- Low potassium levels in your blood (hypokalaemia), low pH in blood and tissues
- Depression, difficulty to fall and/or stay asleep, confusion, changes in your mood, drowsiness, inflammation of the membranes covering the brain and spinal cord (aseptic meningitis) with fever, coma
- Hallucinations, abnormal dreams
- Tingling of the hands and feet, pain and temporary vision loss in one eye (optic neuritis), somnolence, tremors, convulsions
- Blurred and/or diminished vision and scotomata and/or changes in colour vision (amblyopia)

- Sensation of spinning dizziness (vertigo)
- Thickened mucosa
- Asthma, tightness in the chest bronchospasm, shortness of breath
- Peptic sores (ulcers), bleeding form the ulcers, accumulation of gas, constipation, pain in the abdominal, dark sticky faeces, vomiting of blood, ulcers in the mouth, severe condition of bleeding from the ulcers with 10 or more stools, ballooning of the abdomen and fever, Crohn's disease
- Inflamed pancreas
- Yellowing of the skin and /or eyes, also called jaundice
- Excessive sweating, purple coloured spots on the skin, skin becomes very sensitive to the sun
- Unable to completely or partially empty the bladder
- Kidneys unable to function properly
- Feeling tired, have a lack of energy or feeling sick
- Changes in some laboratory blood tests

Frequency unknown

- Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS). Symptoms of DRESS include skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells);
- PARAFENGEN ORAL SUSPENSION, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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 to Acino Pharma via email on drugsafety_za@acino.swiss OR SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

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

5. How to store PARAFENGEN ORAL SUSPENSION

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original container to protect from light.
- Keep the container tightly closed.
- 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 PARAFENGEN ORAL SUSPENSION contains

- The active substances are ibuprofen 48 mg and paracetamol 160 mg per 5 ml.
- The other ingredients are carmoisine dye C1 14720, E122, citric acid monohydrate, E330, fantasy fruit masking flavour PHL-203715, glycerol, E422, maltitol, E965, polysorbate 80, E433, purified water, sodium benzoate, E211, strawberry flavour PHL-028584, sucralose, sweetie flavour FD-221-141-8, trisodium citrate dihydrate, E331, vanilla cream flavour PHL-203716, vivapur MCG 591P containing: microcrystalline cellulose and carmellose sodium, xanthan gum, E415

Preservative (sodium benzoate 0,1 % *m/v).*

Contains sugar (maltitol 1 250 mg/5 ml) and sweetener (sucralose 7 mg/5 ml)

What PARAFENGEN ORAL SUSPENSION looks like and contents of the pack

Viscous pink suspension, free from foreign matters with characteristic strawberry flavouring.

100 ml and 200 ml amber polyethylene terephthalate bottles with white child-proof caps.

The bottle and a 5 ml syringe are packed into an outer carton with the leaflet.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106, 16th Road

Midrand

1686

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Access to the corresponding Professional Information