PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PARAFENGEN, film-coated tablets

Paracetamol and ibuprofen

Contains sugar (lactose monohydrate) 3,81 mg per tablet

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PARAFENGEN 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 symptoms worsen or do not improve in 10 days.

What is in this leaflet

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

1. What PARAFENGEN 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 is used for the relief of headache, feverishness, muscular, menstrual and dental pain.

2. What you need to know before you take PARAFENGEN

Do not take PARAFENGEN:

- If you are hypersensitive (allergic) to paracetamol, ibuprofen, aspirin or other NSAIDs or any of the other ingredients of PARAFENGEN (listed in section 6).
- If you regularly drink large quantities of alcohol.
- If you have severe heart failure, or hepatic (liver) failure, or liver diseases.
- If you are (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
- If you have a history of gastrointestinal perforation (a hole in the stomach lining), ulceration (a sore in the stomach lining) or bleeding related to pervious use of NSAIDs, including PARAFENGEN.
- If you have active stomach ulcers or a history of recurring stomach ulcers.
- If you have a bleeding disorder.
- If you have asthma, bronchospasm (narrowing of the airways which can make it difficult to breathe), urticaria (itchy, raised, red or skin-coloured swellings) or allergic-type reactions after taking aspirin, or other NSAIDs.
- If you are pregnant or breastfeeding.
- If you already take any other medicines containing paracetamol or ibuprofen.
- If you are undergoing treatment of perioperative pain in setting of coronary artery bypass surgery (CABG).
- If you receive coumarin anticoagulants.

Warnings and precautions

PARAFENGEN contains paracetamol. Doses higher than those recommended can result in severe liver damage and even death (see If you have taken more PARAFENGEN than you should).

Take special care with PARAFENGEN:

- If you suffer from liver disease, and show signs and/or symptoms of nausea, fatigue, lethargy, pruritis, jaundice, abnormal tenderness in the right upper quadrant and flu-like symptoms.
- If you have high blood pressure or heart problems including heart failure, angina (chest pain), or if you have had a heart attack, or bypass surgery.
- If you have diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you are elderly as you might experience more adverse events e.g. rupture of the bowels, open sores on the inside lining of your stomach and intestine and bleeding that can be fatal.
- If you are prone to bleeding problems or are taking medicine to prevent blood clots, like warfarin.
- If you have 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 can cause these events to occur.
- If you suffer from any skin reactions such as Stevens-Johnson syndrome, skin rash or mucosal lesions, as PARAFENGEN can cause severe skin reactions (see POSSIBLE SIDE EFFECTS).
- If you suffer from systemic lupus erythematosus (SLE) or other connective tissue disorders.
- If you develop visual disturbances during treatment with PARAFENGEN you should have

an ophthalmological examination.

- If you have been on prolonged corticosteroid therapy, you should have your therapy tapered slowly rather than discontinued abruptly when PARAFENGEN is added to the treatment program.

Children

Children, younger than 12 years, should not take PARAFENGEN**.**

Other medicines and PARAFENGEN

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 may enhance the effects of anti-coagulants such as warfarin.
- Anti-epileptic medicines, as the toxicity may be increased.
- Selective serotonin reuptake inhibitors (SSRIs) (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.
- Chloramphenicol (antibiotic) as the blood levels can be increased.
- Medicines that can influence 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 and may interact with ibuprofen.
- Cholestyramine: Reduces the absorption of paracetamol if given within 1 hour of PARAFENGEN.

PARAFENGEN with food and drink and alcohol

Tablets must be taken with food or after meals with sufficient water.

The risk of paracetamol toxicity can be increased if you take excessive alcohol.

Pregnancy and breastfeeding

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.

PARAFENGEN should not be taken if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent PARAFENGEN 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 PARAFENGEN affects you.

PARAFENGEN may be associated with dizziness, fatigue and headache. Therefore, you must be cautious when driving or using machines and should not drive or operate machinery if you experience these symptoms.

Important information about some of the ingredients of PARAFENGEN

PARAFENGEN contains lactose.

If you have a rare hereditary condition of lactose/fructose or galactose intolerance you should not take PARAFENGEN. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take PARAFENGEN

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

Always take PARAFENGEN 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

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 10 days.

Tablets must be taken with food or after meals with sufficient water.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The usual dose for adults and children older than 12 years of age is 1 to 2 tablets taken every 6 hours, as required, up to a maximum of 8 tablets in 24 hours.

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

If you take more PARAFENGEN 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 you do not show symptoms of an overdose, go immediately to your nearest hospital or poison centre.

PARAFENGEN contains paracetamol and an overdose, can be fatal.

PARAFENGEN 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 take PARAFENGEN

Do not take / receive a double dose to make up for forgotten individual doses. If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

4. Possible side effects

PARAFENGEN can have side effects.

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

If any of the following happens, stop taking PARAFENGEN 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. If you have them, you may have had a serious reaction to PARAFENGEN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Fluid retention, swelling, high blood pressure, heart failure
- Abdominal pain, diarrhoea, indigestion (dyspepsia), nausea, stomach discomfort, vomiting, flatulence, constipation
- Bullous skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis

Frequency unknown

- Dizziness, headache, nervousness, drowsiness, fatigue
- Skin rashes, itching
- Signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- Change in liver or kidney function tests (established by blood tests)
- Depression
- Blurred vision and other reactions of the eye
- Sensitivity to light
- Heart problems
- Kidney problems
- Insomnia (difficulty falling asleep)
- Aseptic meningitis (inflammation of the brain and spinal cord caused by an infection)
- Ringing or buzzing noise in the ear

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 via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. You can also report side effects to Acino Pharma via email on drugsafety_ZA@acino.swiss.

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

5. How to store PARAFENGEN

Store all medicines out of reach of children.

- Store at or below 30 °C
- Store in the original container to protect from light.
- Do not use after the expiry date stated on the carton.

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 contains

- The active substances are paracetamol 500 mg and ibuprofen 150 mg per film-coated tablet.

  Contains sugar (lactose monohydrate) 3,81 mg per tablet.
- The other ingredients are *Core tablet:* croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, pregelatinised maize starch, talc. *Film-coating: Opadry white OYLS 58900 (ID 3441)* containing HPMC 2910/hypromellose 15 cP (E464), lactose monohydrate, macrogol/PEG 4000, sodium citrate dihydrate (trisodium citrate) (E331),

titanium dioxide (E171)

What PARAFENGEN looks like and contents of the pack

White, capsule shaped, film-coated tablets with break-line on one side and plain on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Available in PVC/Alu blister packs containing 8, 10, 16, 20, 24, 30 tablets in an outer cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106, 16th Road

Midrand

1686

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Access to the corresponding Professional Information

The approved professional information for PARAFENGEN can be accessed by scanning the QR-code below: