# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS: S3**

**Unifen 200** (film-coated tablets)

**Unifen 400** (film-coated tablets)

Ibuprofen

Sugar free

**Read all of this leaflet carefully before you start taking UNIFEN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- UNIFEN 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 UNIFEN is and what it is used for

**Unifen** belongs to a group of medicines called anti-inflammatory pain killers (also called nonsteroidal anti-inflammatory drugs NSAIDs). The active ingredient, ibuprofen, has pain relieving, fever reducing and anti-inflammatory actions.

Your doctor may prescribe Unifen to treat:

- Rheumatoid arthritis (chronic disease of the system, mainly inflammation of joints)
- Idiopathic juvenile arthritis (Still's disease) of children
- Ankylosing spondylitis (immobility of a joint due to disease)
- Osteo-arthritis (a non-inflammatory change to a less active form of joints)
- Arthritis due to gout
- Non-articular (non-joint) rheumatism including fibrositis (inflammation with pain and stiffness)
- Non-rheumatic inflammatory conditions such as frozen shoulder (capsulitis), bursitis (inflammation of sac like cavity filled with a liquid in the tissues), tendonitis (inflammation of the tendons), tenosynovitis (inflammation of the membranes of the tendon) and low back pain.
- Relief of mild to moderate pain such as painful menstruation, dental, after prevention of tearing during delivery and pain after childbirth.
- Soft tissue injuries such as sprains and strains.
- Fever.

## 2. What you need to know before you take UNIFEN

### Do not take Unifen

- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of Unifen.
- if you have heart failure.
- if you have stomach ulcer disease or gastro-intestinal bleeding.
- If you have a history of gastro-intestinal bleeding, ulcers or perforation related to previous anti-inflammatory pain killers (NSAIDs).
- If you are sensitive to aspirin or another nonsteroidal anti-inflammatory medicine.
- If you have a history of severe allergic reaction such as anaphylaxis or angioedema (allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing), induced by aspirin or other NSAIDs.
- If you have aspirin-induced nasal protruding growths associated with bronchospasm.
- If you have asthma which has symptoms of breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest
- If you have or ever had any history of kidney disease which has symptoms of little or no urine, drowsiness, nausea, vomiting, breathlessness (renal failure)

- If you are pregnant, do not use UNIFEN at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because these medicines may cause harm in your unborn baby.

**Warnings and precautions**

Tell your doctor or health care provide before taking UNIFEN:

Take special care with UNIFEN:

- If you have a history of high blood pressure and/or heart failure.
- If you have a history of peptic ulcers and other stomach or bowel disease.
- If you experience any unusual abdominal symptoms (especially bleeding from the stomach or bowel) during treatment with UNIFEN.
- If you are elderly, or suffer from asthma or bronchospasm, bleeding disorders, perforation in the digestive tract, heart disease and in liver or kidney failure.
- If you have a serious skin reaction, after taking UNIFEN.
- UNIFEN should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity.
- If you have an abnormal accumulation of fluid due to heart disease, cirrhosis (liver disease), volume depletion due to water tablets or kidney problems.
- If you are receiving anti-blood clotters (such as warfarin).
- If you experience blurred or diminished vision, or changes in colour vision.

- If you have a disease of the connective tissue, you may be at risk of developing aseptic meningitis (inflammation of the membranes of the brain).
- Mild reactions such as allergic inflammation of the mucous membrane of the brain or skin rash induced by aspirin or other NSAIDs.
- If you have anaemia.
- If you have ulcers, sores, or white spots in mouth.
- If you have systemic lupus erythematosus (SLE).
- If you are pregnant, do not use UNIFEN at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

  Additionally do not use UNIFEN at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.
- If you develop a skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

If you are taking UNIFEN for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include

serious harms to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

**Other medicines and UNIFEN**

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

Tell your doctor if you are already taking any of the following as they may interact with your medicine:

- Medicines that prevent blood from clotting (anti-coagulants or anti-platelet agents) – combination with UNIFEN can enhance the effects of the medication and make you prone to excessive bleeding.
- Alcohol, corticosteroids, clopidogrel, ticlopidine, bisphosphonates, pentoxifylline
- Antidiabetic
- Aminoglycosides - (a type of antibiotic) - UNIFEN may decrease the body's ability to remove aminoglycosides from the body which can lead to a dangerous build-up of aminoglycosides levels.
- Aspirin - concomitant administration of UNIFEN and aspirin is not recommended because of the potential of increased adverse effects.
- Digoxin - UNIFEN may decrease the body's ability to remove digoxin from the body which can lead to a dangerous build-up of digoxin levels.

- Lithium - (used to treat mood disorders) - combination with lithium can disrupt the body's ability to remove lithium from the body which can lead to a dangerous build-up of lithium levels.
- Methotrexate
- Immunosuppressive medicines e.g. ciclosporin– there is a small risk of experiencing kidney damage if you take UNIFEN while also taking ciclosporin
- Medicines for high blood pressure including diuretics (medicine to help you pass water) - combination with UNIFEN may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta-blockers and diuretics.
- Bone marrow depressants
- Corticosteroids - (used in the treatment of inflammatory conditions) – concomitant use with UNIFEN increase the risk of gastrointestinal ulceration or bleeding
- Medicines called selective serotonin reuptake inhibitors (typically used as antidepressants) - combination with a UNIFEN can increase the risk of you experiencing bleeding inside their digestive system.
- Any other non-steroidal anti-inflammatory medicines (NSAIDs) - always better to use one type of NSAID at a time to minimise the risks of side effects.
- Herbal extracts such as Ginkgo biloba - concomitant use with UNIFEN increases the risk of bleeding
- Mifepristone – combination with UNIFEN causes a decrease in the efficacy of mifepristone

- Quinolone antibiotics - taking UNIFEN and a quinolone class of antibiotic may increase the risk of you developing a seizure.

You may need to visit your doctor for more frequent checks if you are taking some of these medicines together with Unifen.

**UNIFEN with food, drink and alcohol**

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, UNIFEN should be given with food or milk.

**Pregnancy and breastfeeding and fertility**

**Pregnancy**

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 UNIFEN.

Do not use UNIFEN at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

Additionally do not use UNIFEN at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.

If taken late in pregnancy, may increase the length of pregnancy, prolong labour, or cause other problems during the delivery.

**Breast-feeding**

You should not use UNIFEN if you are breastfeeding.

**Driving and using machines**

UNIFEN may cause dizziness, drowsiness, fatigue and visual disturbances. If you experience this do not drive or operate any machinery.

**3. How to take UNIFEN**

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

Always take Unifen exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Always use the lowest effective dose for the shortest possible duration of treatment.

**Adults:**

The usual dose of Unifen is 600 mg every 6 to 8 hours.

**Do not take more than 2 400 mg of** Unifen **per day.**

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, UNIFEN should be given with food or milk.

**Children:**

This formulation is not suitable for children under the age of 12 years.

If you have the impression that the effect of Unifen is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Unifen than you should**

If you take an overdose, you may experience gastrointestinal effects such as nausea, vomiting and stomach pain.

Other symptoms include vomiting, dizziness, convulsion, loss of consciousness and depression of the central nervous system and respiratory system. Treatment is symptomatic and supportive.

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

**If you forget to take Unifen**

If you miss a dose of UNIFEN, take it as soon as you remember unless it is almost time for your next dose. If it is, do not take the missed dose at all.

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

**4. Possible side effects**

**Unifen** can have side effects.

***Not all side-effects reported for Unifen are included in this leaflet.***

***Should your general health worsen*** **or if you experience any untoward effects** ***while taking Unifen, please consult your health care*** **provider** ***for advice.***

If any of the following happen, stop taking Unifen and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

**Immune disorders:**

Less frequent: Aseptic meningitis (non-infectious inflammation of the membranes covering the brain), anaphylaxis (a severe, potentially life-threatening allergic reaction to something you're allergic to), fever, exacerbation of asthma and bronchospasm

**Gastrointestinal system disorders:**

Frequent: nausea, vomiting, black stools, vomiting of blood, bleeding from the stomach or bowel, abdominal pain and dizziness.
Less frequent: abdominal discomfort or pain, gastrointestinal ulcers, sometimes with bleeding.

A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

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

- Dizziness,
- tinnitus (ringing sound in the ear).

Less frequent side effects:

- Acute renal failure,
- cystitis (inflammation of the bladder),
- haematuria (blood in urine),
- interstitial nephritis (swelling of the kidney),
- nephrotic syndrome (kidney disorder that causes yourbody to excrete too much protein in your urine)
- Hepatotoxicity (liver damage),
- abnormalities in liver function tests
- low blood cell count (anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis)

Frequency unknown:

- Visual impairment,
- changes in visual colour perception,
- toxic amblyopia (lazy eye syndrome)
- Oedema (swelling), hypertension and cardiac failure

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

Tell your doctor if you notice the following :

Frequent side effects:

- indigestion,
- headache,
- constipation,
- diarrhoea,
- flatulence,
- nervousness,
- drowsiness,
- insomnia,
- depression.

Less frequent side effects:

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

UNIFEN, 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 SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this UNIFEN**.**

**5. How to store UNIFEN**

Unifen 200: Store in well closed containers, below 25 °C, protected from moisture.
Unifen 400: Store in well closed containers, below 25 °C, protected from moisture.
Do not store in bathrooms in order to protect from moisture.
Store all medicines out of reach of children
Do not use the medicine after the expiry date stated on the container.
Return any 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 Unifen Contains

**Unifen 200**

The active substance is Ibuprofen 200 mg per tablet.

The other ingredients are colloidal silicon dioxide, magnesium stearate, maize starch, microcrystalline cellulose, polysorbate-80, sodium starch glycolate and film coating - hydroxypropyl methyl cellulose, polyethylene glycol-400, talc, titanium dioxide and ponceau 4R supra.

**Unifen 400**

The active substance is Ibuprofen 400 mg per tablet.

The other ingredients are colloidal silicon dioxide, magnesium stearate maize starch, microcrystalline cellulose, polysorbate-80, sodium starch glycolate and film coating - hydroxypropyl methyl cellulose, polyethylene glycol-400, talc, titanium dioxide and ponceau 4R supra.

### What UNIFEN looks like and contents of the pack

**Unifen 200**

Peach-red coloured, round biconvex film coated tablets with intact coating.

**Unifen 400**

Peach-red coloured, round, biconvex film coated tablets with intact coating.

**Unifen 200**

White HDPE bottle containing 28, 500 or 1000 tablets.

Silver aluminium patient ready packs of different pack sizes.

**Unifen 400**

White HDPE bottle containing 100 or 1000 tablets.

Silver aluminium patient ready packs of different pack sizes.

**Holder of Certificate of Registration**

Unimed Healthcare (Pty) Ltd

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