

MERSYNOFEN®

Ibuprofen and Paracetamol

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Mersynofen.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Mersynofen is used for

Mersynofen is an analgesic (pain reliever). It works to relieve acute (short term) pain and/or inflammation associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, period pain, sore throat, tennis elbow, rheumatic pain and arthritis, and the aches and pains associated with colds and flu.

It contains ibuprofen and paracetamol.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Paracetamol works to stop the pain messages from getting through to the brain.

Ask your doctor or pharmacist if you have any questions about this medicine.

This medicine is not addictive.

It is only available from your pharmacist.

Before you use it

When you must not take it

Do not take Mersynofen if you have an allergy to:

- any medicine containing ibuprofen, aspirin or other NSAIDs
- any medicine containing paracetamol
- any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- any other medicine for pain relief.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Mersynofen if you have any of the following conditions:

- you have a history of hypersensitivity reactions e.g. wheezing, chronic cough, swelling of the face or throat, red or itchy skin, skin rash or runny or stuffy nose when using aspirin, or other non-steroidal anti-inflammatory drugs or analgesic products.

- liver or kidney disease
- heart problems
- asthma
- a stomach ulcer or duodenal ulcer or if you have had either of these conditions or gastric bleeding or other gastrointestinal diseases in the past.
- recently vomited blood or material that looks like coffee grounds
- recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea
- you have had bleeding episodes which cannot be explained

Do not take Mersynofen if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Mersynofen is not recommended to be used during pregnancy.

Do not use it if you are breast-feeding or planning to breast-feed.

Small amounts of ibuprofen and paracetamol may pass into the breast milk

Do not take it after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you use it after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take if you are aged 65 years or older.

Do not give Mersynofen to children aged under 12 years.

Do not take Mersynofen if you are taking any other product containing paracetamol, ibuprofen or other NSAIDs or if you are taking any other medicine for pain relief.

If you are not sure whether you should start taking Mersynofen, talk to your pharmacist or doctor.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- asthma
- diabetes
- liver or kidney disease
- heart problems
- gastrointestinal Problems
- autoimmune problems
- have recently had major surgery
- suffer from hayfever, nasal polyps or have chronic respiratory disorders. These may increase the risk of an allergic reaction occurring.
- if you have had bleeding episodes which cannot be explained
- severe dehydration after vomiting, diarrhoea, or not drinking enough
- taking any medicines for any other conditions
- have recently had major surgery
- suffer from hayfever, nasal polyps or have chronic respiratory disorders. These may increase the risk of an allergic reaction occurring
- have a metabolic disorder
- have a blood platelet disorder
- consume large amounts of alcohol

If you currently have these conditions, do not take this medicine.

Tell your doctor or pharmacist if you have an infection.

Mersynofen may hide signs of infection such as fever and pain. It is therefore possible that Mersynofen may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in patients with serious lung infections (also called pneumonia) caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your

symptoms of the infection persist or worsen, consult a doctor without delay.

Serious skin reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported in association with ibuprofen treatment. Stop using ibuprofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section Side Effects.

During treatment, you may be at risk of developing certain side effects. It is important to understand these risks and how to monitor for them. Refer to Side Effects.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Mersynofen is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

Small amounts of ibuprofen and paracetamol may pass into the breastmilk.

Use of Mersynofen may cause the baby to have kidney problems leading to a low amount of amniotic fluid inside the uterus and in some cases kidney problems in the newborn.

Use in elderly

Do not take if you are aged 65 years or older.

Use in children

Do not give Mersynofen to children aged under 12 years.

Do not give Mersynofen to dehydrated adolescents.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Mersynofen.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and ibuprofen and paracetamol may interfere with each other, or may affect how well it works. These include:

- other paracetamol containing products, analgesics, other medicines for pain relief
- warfarin, a medicine used to prevent blood clots
- antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs)
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure such as diuretics, ACE inhibitors, beta-receptor blockers and angiotensin II antagonists
- medicines that contain probenecid or sulfapyrazone
- salicylates or non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin
- digoxin, a medicine used to treat irregular heart rhythms
- medicines used to lower cholesterol such as cholestyramine
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure
- corticosteroids such as prednisone, prednisolone and cortisone, which reduces the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits (seizures)

- chloramphenicol an antibiotic used to treat ear and eye infections
- ciclosporin or tacrolimus, medicines used to treat immune system conditions

•alcohol

•CYP2C9 inhibitors such as voriconazole and fluconazole

•uricosurics which may delay the excretion of ibuprofen

Your doctor and pharmacist will have more information on these and other medicines to be careful with or to avoid while using Mersynofen.

How to take it

How much to take

Follow all directions for use written on the medicine's label.

If you do not understand the instructions on the label, ask your pharmacist or doctor for help.

How much to take

Adults under 65 and children from 12 years: Take one or two tablets every 6 to 8 hours with water or other liquid when necessary. Do not divide the tablets.

It is recommended that patients with sensitive stomach take Mersynofen with food. If taken shortly after eating it may take a little longer for Mersynofen to work. Do not take more Mersynofen than recommended until it is time to take the next dose.

Not recommended for adults 65 years of age and over or children under 12 years of age.

Do not take more than 6 tablets in 24 hours.

How long to take it

Only take Mersynofen when required for pain.

Take the lowest dose that helps with your pain for the shortest time necessary to relieve your symptoms.

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen.

Adults: do not take Mersynofen for more than 3 days at a time.

Adolescents (12 to 17 years): do not take Mersynofen for more than 2 days at a time.

Do not take more than the recommended dose on the label or for a longer period of time.

Prolonged use of any type of pain relievers for headaches can make it worse. If this is experienced or suspected, medical advice should be obtained or discontinued. The habit of taking analgesics particularly in combination with other pain-relieving products may lead to permanent kidney problems including kidney failure therefore it should be avoided.

If your symptoms persist, worsen or new symptoms develop, talk to your pharmacist or doctor.

If you take too much (overdose)

If you think that you have taken too much Mersynofen, you may need urgent medical attention. Immediately telephone your doctor, or the Poisons Information Centre (telephone New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much Mersynofen.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

You are at risk of serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood.

Mersynofen when taken at higher than recommended doses (for a short or 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. Signs and symptoms include muscle weakness and light-headedness.

While you are using it

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Mersynofen.

Talk to your doctor or pharmacist if your symptoms do not improve.

Your doctor or pharmacist will assess your condition and decide if you should continue to take this medicine.

If you become pregnant while you are using this medicine, tell your doctor or pharmacist immediately.

If you develop a skin rash, mucosal wounds or any other sign of allergy while you are using this medicine, stop taking this product and tell your doctor or pharmacist immediately.

If you have chest pain, seek immediate medical advice from your doctor or pharmacist.

Things you must not do

Do not take for more than 3 days at a time (2 days for adolescents 12 to 17 years) unless your doctor or pharmacist tells you to.

Do not take more than the recommended dose unless your doctor or pharmacist tells you to.

Things to be aware of

Taking this medicine may increase the risk of you getting

unwanted effects, such as stomach or heart problems.

Driving or using machines

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause tiredness or dizziness in some people.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Do not take Mersynofen to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mersynofen.

It helps most people with the relief of pain, but it may have unwanted side effects in a few people.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

It is rare to get side effects from ibuprofen and paracetamol if taken for a short period of time and in the doses in OTC medicines.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, ingestion, heartburn, or stomach pain, wind or constipation
- loss of appetite
- diarrhoea
- dizziness
- drowsiness
- headache
- nervousness
- skin rashes
- sweating
- low amniotic fluid inside uterus (oligohydramnios)
- kidney problems in newborn baby

The above list includes the more common side effects of your medicine. They are usually mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist immediately if you notice:

- you are getting sunburnt more quickly than usual.
- hypersensitivity reactions with skin rashes and itching as well as asthma attacks (possibly drop in blood pressure)

The above is a list that includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop using this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- eye disorders – visual disturbance
- drug induced reddish scaly, pus filled bumps
- fluid retention
- vomiting blood or bleeding from the back passage
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- flushing of the face
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These

serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis).

- widespread rash, high body temperature (fever > 38°C) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome)
- Round or oval patches of redness and swelling, blistering (hives), itching of the skin (Fixed Drug Eruption)
- increased sensitivity of the skin to sun
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

These are very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your medicine in the original pack until it is time to take.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly. Store in a cool

dry place away from moisture, heat or sunlight.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Mersynofen, or the medicine has passed its expiry date, ask your pharmacist what to do with anything that is left over.

Return any unused medicine to your pharmacist.

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This product does not contain gluten, lactose or sucrose.

Manufacturer/Sponsor

Mersynofen is supplied in New Zealand by:

Sanofi-aventis new zealand limited
Level 8
56 Cawley Street
Ellerslie, Auckland
New Zealand
Tel: 0800 283 684

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Product description

What it looks like

Mersynofen is a white to off white, capsule shaped, film coated tablet with a break bar on one side

They are available in blister packs in a range of sizes up to 30 tablets.

Ingredients

Active Ingredient:

Each Mersynofen tablet contains 200mg of ibuprofen and 500mg of paracetamol.

Inactive Ingredients:

- maize starch
- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch
- croscarmellose sodium
- sodium lauryl sulfate
- purified talc
- opadry QX Quick and Flexible Film Coating System 321A180025 White