

Mersynofen[®]

Active ingredients: *ibuprofen and paracetamol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mersynofen. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mersynofen.**

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1. Why am I using Mersynofen?

Mersynofen contains the active ingredients **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.

Your doctor may have prescribed this medicine for another use.

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.

This medicine is not addictive.

2. What should I know before I use Mersynofen?

Warnings

Do not use Mersynofen if:

- you are allergic to paracetamol, ibuprofen, aspirin or any other medicine for pain relief, or any of the ingredients listed at the end of this leaflet
Always check the ingredients to make sure you can use this medicine.
- 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 a runny or stuffy nose when using aspirin, or other non-steroidal anti-inflammatory drugs or analgesic products.
- you have liver or kidney disease
- you have pre-existing heart problems
- you have asthma

- you have 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.
- you have recently vomited blood or material that looks like coffee grounds
- you have recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea.
- you have had bleeding episodes which cannot be explained
- you are using other paracetamol-containing products
- you are severely dehydrated after having vomited, had diarrhoea or not enough to drink
- if the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering

Check with your doctor or pharmacist if you:

- have a severe and extensive skin rash known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with following reactions such as fever, rash, enlargement of lymph nodes and/or facial swelling, kidney problems, blood disorder, inflammation of the heart, muscle weakness/pain
- have a severe skin reaction with rash and blisters known as Fixed Drug Eruption (FDE) and Generalised Bullous Drug Eruption (GBFDE) with clearly defined dark red or brown patches that may develop into large fluid-filled bumps and sores on the skin.
- have any other medical conditions, especially asthma, diabetes, liver or kidney disease or heart, gastrointestinal or autoimmune problems (where your own immune system mistakenly attacks substances naturally occurring in your body).
- take any medicines for any other condition
- 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

Tell your doctor or pharmacist if you have an infection.

Mersynofen may hide signs of infections 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) and Acute Generalised Exanthematous Pustulosis (AGEP) 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 [6. Are there any side effects?](#)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Use of Mersynofen may cause kidney or heart problems in your unborn baby leading to a low amount of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby.

Check with your doctor or pharmacist about taking Mersynofen if you are breast-feeding or planning to breast-feed.

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

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

Use in the 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.

3. What if I am taking other medicines?

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

Some medicines and Mersynofen may interfere with each other. 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 sulfinpyrazone

- 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

These medicines may be affected by Mersynofen or may affect how well Mersynofen works. You may need different amounts of your medicines, or you may need to take different medicines.

If you have not told your doctor or pharmacist about any of these things, tell him/her before you take any Mersynofen.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mersynofen.

4. How do I use Mersynofen?

How much to take

- The label on your pack of Mersynofen will tell you how to take your medicine and how often.

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

- **The usual dose of Mersynofen is:**

Adults under 65 and children from 12 years:

- 1 tablet.
- This dosage may be repeated every 8 hours if necessary.

You should not take more than 3 tablets in 24 hours.

Do not take more than the recommended dose.

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

How to take Mersynofen

- For oral use only
- Swallow tablets with a little water or other liquid.
- It is recommended that patients with sensitive stomachs 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.

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.

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

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 medicines for pain relief particularly in combination with other pain-relievers may lead to permanent kidney problems including kidney failure therefore it should be avoided.

If you take too much Mersynofen

If you think that you have taken too much Mersynofen, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. 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

5. What should I know while using Mersynofen?

Things you should do

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

Talk to your doctor or pharmacist if your symptoms don't improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the 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 the product and tell your doctor or pharmacist immediately.

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

Things you should 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.

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.

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.

Drinking alcohol

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.

Looking after your medicine

- Store below 30°C.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea • indigestion • heart burn • stomach pain • diarrhoea • loss of appetite • wind or constipation <p>Eye Disorders</p> <ul style="list-style-type: none"> • Visual disturbance <p>Head and neurology related:</p> <ul style="list-style-type: none"> • dizziness • drowsiness • headache • nervousness <p>Skin related:</p> <ul style="list-style-type: none"> • skin rashes • sweating <p>Immune System Disorders</p> <ul style="list-style-type: none"> • Hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure) <p>Pregnancy related:</p> <ul style="list-style-type: none"> • low amniotic fluid inside uterus (oligohydramnios) • kidney problems in newborn baby 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing 	<p>Call your doctor straight away, or go straight to the</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin • flushing of the face <p>Heart related:</p> <ul style="list-style-type: none"> • fluid retention • chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome <p>Breathing related:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing <p>Skin related:</p> <ul style="list-style-type: none"> • getting sunburnt more quickly than usual • increased sensitivity of the skin to sun • drug induced reddish, scaly, pus-filled bumps • 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) • isolated round or oval patches of redness and swelling, blistering (hives), itching of the skin (Fixed Drug Eruption) or covering large area of your body, which may be complicated by blisters (Generalised Bullous Fixed Drug Eruption). <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • vomiting blood or bleeding from the back passage 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available from your pharmacist.

What Mersynofen contains

Active ingredients (main ingredient)	Ibuprofen and paracetamol.
Other ingredients (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, and opadry fx special effects film coating system 63F97546 Silver.

Do not take this medicine if you are allergic to any of these ingredients.

What Mersynofen looks like

Mersynofen is a white to off white, capsule shaped, film coated tablet with a break bar on one side (AUST R 321566).

Mersynofen is available in a range of sizes up to 30 tablets.

Who distributes Mersynofen

Sanofi Consumer Healthcare

87 Yarraman Place

Virginia, QLD 4014, Australia

Toll Free Number (medical information): 1800 818 806

Email: medinfo.australia@sanofi.com

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