

COMBIGESIC®

Ibuprofen and paracetamol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Combigesic.

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

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Combigesic is used for

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

This medicine is not addictive.

It is only available from your pharmacist.

Before you take Combigesic

When you must not take it

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

- 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.

Do not take Combigesic if you are pregnant or plan to become pregnant.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Do not give Combigesic to children aged under 12 years.

Do not take Combigesic 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 Combigesic, talk to your pharmacist or doctor.

Before you start to take it

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

Tell your pharmacist or doctor if you currently have or have had diabetes in the past.

Tell your pharmacist or doctor if you have had any of the following medical conditions in the past:

- asthma
- liver or kidney disease
- heart problems.

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

Ask your pharmacist or doctor about taking this medicine if you are breastfeeding.

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

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

Taking other medicines

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

Some medicines and ibuprofen or paracetamol may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure
- medicines such as prednisone, prednisolone and cortisone, which reduce 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
- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol.

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

How to take Combigesic

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

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

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 tablet every 8 hours with water when necessary.

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

Do not take more than 3 tablets in 24 hours.

How long to take it

Only take Combigesic when required for pain.

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

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

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

Overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Combigesic. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Combigesic

Things you must do

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

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

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 tells you to.

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

Things to be careful of

Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems.

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

This medicine helps most people with relief of pain, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- **nausea, heartburn, or stomach pain**
- **loss of appetite**
- **diarrhoea**
- **dizziness**
- **drowsiness**
- **headache**
- **nervousness.**

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- **get sunburnt more quickly than usual.**

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

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

- **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.**

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

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

Other side effects not listed above may also occur in some people.

After using Combigesic

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.

Do not store Combigesic or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or 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

Ask your pharmacist what to do with any medicine that is left over after the expiry date has passed.

Product description

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

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

It also contains:

- Cellulose - microcrystalline
- Croscarmellose sodium
- Maize starch pre-gelatinised
- Opadry II complete film coating system 85G58923
- Silica - colloidal anhydrous

Combigesic does not contain gluten, lactose or sucrose.

Sponsor

Combigesic is supplied by:

Aspen Pharmacare Pty Ltd
34-36 Chandos St
St Leonards
NSW 2065

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