

Package leaflet: Information for the patient
Combogesic 500 mg/150 mg film-coated tablets

Paracetamol and Ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

This medicine is available without prescription. However, you still need to read this leaflet carefully to get the best results from it.

What is in this leaflet

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

1. What Combogesic is and what it is used for

Combogesic contains paracetamol and ibuprofen. Paracetamol works to stop the pain messages from getting through to the brain. It also acts to reduce 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).

Combogesic is used for temporary relief of pain associated with:

- headache
- migraine
- backache
- period pain
- dental pain
- muscular pain
- cold and flu symptoms
- sore throat
- fever

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

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Combogesic

Do not take Combogesic:

- if you are allergic to the active substance(s) or any of the other ingredients of this medicine (listed in section 6);
- if you are (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea;
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before;
- with any other medicines containing paracetamol or ibuprofen
- if you regularly drink large quantities of alcohol
- if you have severe heart failure, hepatic failure or renal failure
- if you have cerebrovascular or other active bleeding
- if you have blood-formation disturbances, i.e. reduced numbers of platelets in the blood
- if you have asthma, urticaria or allergic-type reactions after taking aspirin, or other NSAIDs
- during the last three months of pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before taking Combogesic

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Combogesic if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- have liver disease, hepatitis, kidney disease or difficulty urinating;
- are a heavy drinker or drug user;
- have allergies to any other medicines containing aspirin, or other NSAID medicines or any other substances listed at the end of this leaflet;
- are pregnant or intend to become pregnant;
- are breast-feeding or plan to breast-feed;

- currently have an infection;
- plan to have surgery;
- have or have had other medical conditions including:
 - heartburn, indigestion, stomach ulcer or any other stomach problems;
 - vomiting blood or bleeding from back passage;
 - severe skin reactions such as Stevens-Johnson syndrome;
 - asthma;
 - vision problems;
 - tendency to bleed or other blood problems;
 - bowel or intestinal problems such as ulcerative colitis or Crohn's Disease
 - swelling of ankles or feet;
 - diarrhoea;
 - inherited genetic or acquired disorder of certain enzymes that manifest with either neurological complications or skin problems or occasionally both i.e. porphyria;
 - smallpox;
 - autoimmune disease such as Lupus erythematosus.

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Combogesic may lead to liver damage.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Taking Combogesic may interfere with the results from the urine analysis test for 5-hydroxyindoleacetic acid (5HIAA), causing false-positive results. To avoid false results do not take Combogesic or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children and adolescents

This product is not recommended for children under 18 years.

Other medicines and Combogesic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Combogesic may affect or be affected by some other medicines. For example:-

- medicines that are anti-coagulants (i.e. thin blood/ prevent clotting e.g. aspirin, warfarin, ticlopidine)
- medicines to treat epilepsy or fits such as phenytoin
- chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout
- zidovudine, a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)
- medicines used to treat tuberculosis such as isoniazid
- aspirin, salicylates or other NSAID medicines
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines for other heart conditions such as digoxin
- diuretics, also called fluid tablets
- lithium, a medicine used to treat some types of depression
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- metoclopramide, propantheline
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics)

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

Some other medicines may also affect or be affected by the treatment with Combogesic. You should therefore always seek the advice of your doctor or pharmacist before you use Combogesic with other medicines.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine during the last 3 months of your pregnancy. Take special care if you are in the first 6 months of pregnancy.

This product may impair female fertility and is not recommended in women attempting to conceive.

Driving and using machines

Be careful driving or operating machines until you know how Combogesic affects you.

Combogesic contains Lactose Monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Combogesic

Always take this medicine exactly as your doctor or pharmacist has told you. These directions may differ from the information contained in this leaflet. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: The usual dosage is one to two tablets taken every six hours, as required up to a maximum of six in 24 hours.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. The patient should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

Do not take more than 6 tablets in a 24 hour period.

If your doctor prescribes a different dose, follow directions given by your doctor.

Take Combogesic tablets with a full glass of water. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Use in children under 18 years

Combogesic is not recommended for children under 18 years.

If you take more Combogesic than you should

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much Paracetamol can cause delayed, serious liver damage.

Taking too many Combogesic tablets can also lead to serious kidney problems. You may need urgent medical attention.

If you take too much Combogesic you may:

- feel sick or vomit
- have stomach pain
- have convulsions
- feel dizzy or even become unconscious

If you forget to take Combogesic

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.

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor or pharmacist. Side effects may occur with certain frequencies, which are defined as follows:

The following rare serious side effects were reported:

If any of these serious side effects happen, stop taking Combogesic and tell your doctor immediately or go to the emergency room at your nearest hospital:

- vomiting blood or material that looks like coffee grounds;
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea;
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
- asthma, wheezing, shortness of breath;
- sudden or severe itching, skin rash, hives;
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.

The following includes the more common side effects:

- nausea or vomiting
- loss of appetite
- heartburn or pain in the upper part of your stomach
- cramps, wind, constipation or diarrhoea
- skin rashes
- headache
- dizziness
- sleeplessness
- change in mood, for example depression, confusion, nervousness

The following side effects have also been reported rarely:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- yellowing of the skin and /or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- tingling of the hands and feet
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.

- severe or persistent headache
- fast or irregular heartbeats, also called palpitations.

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.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Combogesic

Keep this medicine out of the sight and reach of children.

Store below 30°C. Store in the original packaging to protect from light.

Do not use this medicine after the expiry date which is stated on the carton label and on the blister after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice packaging is torn or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Combogesic contains

The active substances are paracetamol and ibuprofen.

The other ingredients are: maize starch, pregelatinised maize starch, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, talc, hypromellose (E464), lactose monohydrate, titanium dioxide (E171), macrogol/ PEG- 4000 and sodium citrate dihydrate (E331).

What Combogesic looks like and contents of the pack

Combogesic film-coated tablets are white coloured, capsule shaped 19 mm in length 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.

Each blister pack contains 8, 10, 16, 20, 24, 30 and 32, film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Thornton & Ross Ltd, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer

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This leaflet was last revised in June 2016.

PL 00240/0383

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THRLT003-1