

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.
- You should not take this product for longer than 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.

If you are taking Combogesic 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 stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

During treatment with Combogesic, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Talk to your doctor or pharmacist if you have an infection - please see heading “Infections” below.

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.

Skin reactions

Serious skin reactions have been reported in association with Combogesic treatment. You should stop taking Combogesic and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See Section 4.

Infections

Combogesic may hide signs of infections such as fever and pain. It is therefore possible that Combogesic may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in 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.

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;
 - 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)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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 as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take Combogesic during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you

are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken more than a few days from 20 weeks of pregnancy onward, Combogesic can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

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.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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. **Do not take for more than 3 days.**

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

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

If you have taken more Combogesic than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. Do this even if there are no signs of discomfort or poisoning.

Taking too many Combogesic tablets can lead to delayed, serious liver and renal damage. You may need urgent medical attention

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

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.

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;
- very rare cases of serious skin reactions have been reported including sudden or severe itching, skin rash, hives;
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome)
- 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).
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.

Combogesic, 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.

Other side effects:

Common (may affect up to 1 in 10 people):

- fluid retention, swelling
- ringing in the ears (tinnitus)
- nausea or vomiting

- loss of appetite
- heartburn or pain in the upper part of your stomach
- diarrhoea
- skin rashes
- headache
- dizziness
- change in liver or kidney function (established by blood tests)

Uncommon (may affect up to 1 in 100 people):

- reduction in red blood cell numbers, bleeding episodes such as nosebleeds, abnormal or prolonged bleeding during menstrual periods, increased number of platelets
- eye problems such as blurred or diminished vision, changes to the appearance of colours
- wind and constipation.
- increased sensitivity to allergic reactions, angioedema (symptoms may include itchy, sore red eyes)
- breast enlargement (in males)
- abnormally low blood sugar (hypoglycaemia)
- change in mood, for example, depression, confusion, excessive emotional reactions
- change in the desire to sleep (sleepiness or sleeplessness)
- difficulty urinating
- thickening of respiratory secretions (mucous)

Rare (may affect up to 1 in 1,000 people):

- hallucinations and increased nightmare occurrence
- numbness or abnormal skin sensations (e.g. burning, tingling or pricking) in the hands and feet

Very rare (may affect up to 1 in 10,000 people):

- severe pain or tenderness in the stomach
- 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
- vertigo
- yellowing of the skin and /or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs, decreased urine output
- involuntary muscle movements/spasms, tremors and convulsions, slowing of physical and emotional reactions
- temporary vision loss, pain during eye movements
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- fast or irregular heartbeats, also called palpitations
- increased sweating

Frequency not known (cannot be estimated from available data)

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Combogesic if you develop these symptoms and seek medical attention immediately. See also Section 2.

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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 or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. 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 filmcoated 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

AFT Pharma UK Limited, Milner House, 14 Manchester Square, London, W1U 3PP, United Kingdom

Manufacturer

QP-Services UK Ltd., 46 High Street, Yatton, Bristol, BS49 4HJ, UK

or

Elara Pharmservices Ltd., Iron Farm, 7 Grimesgate, Diseworth, Derby, DE74 2QD, UK.

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