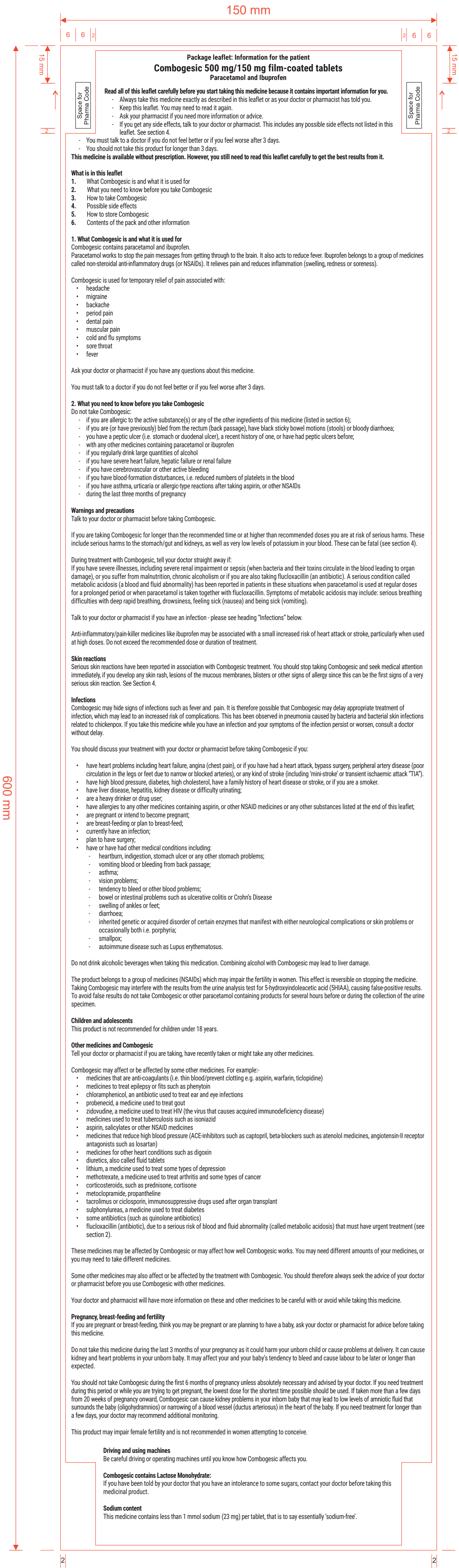


Front



Package Insert Cutterguide  
Size : 600(L) x 150(W) mm  
Rajesh Kadam  
Date : 29 Sept 2020  
Version No. 1

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 by 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](http://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**

Ceuta Healthcare Ltd, Hill House, 41 Richmond Hill, Bournemouth, Dorset, BH2 6HS, UK.

**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.

**This leaflet was last revised in December 2024.**

**PL 16243/0004**

XXXXXXXXXX

Space for Artwork Code

Space for Pharma Code

Space for Pharma Code