PACKAGE LEAFLET

Package leaflet: Information for the patient

Paracetamol/Ibuprofen 500 mg/150 mg powder for oral solution in sachet
paracetamol/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 should not take this product for longer than 3 days**.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Paracetamol/Ibuprofen is and what it is used for

Paracetamol/Ibuprofen contains paracetamol and ibuprofen (as lysine).
Paracetamol works to stop the pain messages from getting through to the brain.
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).

Paracetamol/Ibuprofen is used in adults for short-term symptomatic treatment of mild to moderate pain. This product is especially suitable for pain which has not been relieved by ibuprofen or paracetamol alone.
Ask your doctor or pharmacist if you have any questions about this medicine.

Do not take for more than 3 days. 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 Paracetamol/Ibuprofen

Do not take Paracetamol/Ibuprofen:
- if you are allergic to paracetamol or ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if you have ever had an allergic reaction such as bronchospasm (tightening of the muscles in the lungs that may cause shortness of breath), asthma, runny, itchy and inflamed nose with sneezing, urticaria (an itchy rash), or angioedema (swelling under the skin) when taking acetylsalicylic acid or other NSAIDs
- if you have an active or have ever had a recurrent ulcer or bleeding in your stomach or duodenum (small bowel) (at least two distinct episodes of confirmed bleeding or an ulcer)
- if you have a history of gastrointestinal ulceration/perforation or bleeding related to previous treatment with NSAIDs
- if you are already taking any other medicines containing paracetamol, or ibuprofen, acetylsalicylic acid (above 75 mg per day), salicylates, or other non-steroidal anti-inflammatory drugs (NSAIDs)
- 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
- during the last three months of pregnancy

- if you suffer from severe dehydration.

Warnings and precautions
Talk to your doctor or pharmacist before taking Paracetamol/Ibuprofen

Caution: Ingestion of more than the recommended dose carries a risk of severe liver damage. Therefore, the maximum daily dose of paracetamol should **not** be exceeded. Check that you are not taking any other medicines containing paracetamol, including those obtained without a prescription. Do not combine them so as not to exceed the recommended daily dose (see section 3 "How to take Paracetamol/Ibuprofen" and "If you take more Paracetamol/Ibuprofen than you should").

You should also check that you are not taking any other medicines containing ibuprofen.
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 Paracetamol/Ibuprofen 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.

Take special care with Paracetamol/Ibuprofen

During treatment with Paracetamol/Ibuprofen, 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).

Tell your doctor or pharmacist if:
- you have liver disease (including Gilbert's syndrome), hepatitis, kidney disease or difficulty urinating
- you are dehydrated or you have a poor nutritional status, for example due to excessive alcohol intake, anorexia or poor diet
- you are heavy drinker or drug user
- you suffer from a haemolytic anaemia (abnormal destruction of red cells)
- you suffer from a deficiency in a certain enzyme called glucose-6-phosphate dehydrogenase
- you have allergies to any other medicines contain acetylsalicylic acid or other NSAID medicines or any other substances listed at the end of this leaflet
- you are pregnant or intend to become pregnant
- you are breast-feeding or plan to breast-feed
- you have an infection - please see heading "Infections" below
- you plan to have surgery
- you 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

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Paracetamol/Ibuprofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections
Paracetamol/Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Paracetamol/Ibuprofen 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.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Paracetamol/Ibuprofen and contact immediately your doctor or medical emergencies if you notice any of these signs.

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Paracetamol/Ibuprofen 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.
The prolonged use of analgesics can result in headache which must not be treated by increasing the dose of the medicine.

Taking this medicine 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 this medicine or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children and adolescents
This product is not intended for children and adolescents under 18 years.

Other medicines and Paracetamol/Ibuprofen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Paracetamol/Ibuprofen 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/acetylsalicylic acid, warfarin, ticlopidine)
- medicines to treat epilepsy or fits
- 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
- acetylsalicylic acid, 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)
- 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, domperidone, propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics)
- cardiac glycosides, medicines to strengthen the heart
- 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 Paracetamol/Ibuprofen or may affect how well Paracetamol/Ibuprofen 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 of Paracetamol/Ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use Paracetamol/Ibuprofen 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.

Paracetamol/Ibuprofen with alcohol
If you consume a lot of alcohol or if you drink regularly large quantities of alcohol, do not use this medication (see section 2. “What you need to know before you take Paracetamol/Ibuprofen”).

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.

Pregnancy
Do not take Paracetamol/Ibuprofen if you are in the last 3 months of 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 Paracetamol/Ibuprofen 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 for more than a few days from 20 weeks of pregnancy onward, Paracetamol/Ibuprofen 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.

Breast-feeding
Only small amounts of paracetamol and ibuprofen pass into breast milk. This medicine may be given during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

Fertility
This product may impair female fertility and is not recommended in women attempting to conceive. This effect is reversible on stopping the medicine.

Driving and using machines
Be careful driving or operating machines until you know how Paracetamol/Ibuprofen affects you. Paracetamol/Ibuprofen may cause undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances. If you experience any of these side effects, you should not drive or operate machinery.
Paracetamol/Ibuprofen contains aspartame, sucrose, and sodium.

This medicine contains 62.5 mg aspartame in each dosage unit which is equivalent to 0.0625 g/2.5g sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains sucrose:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Paracetamol/Ibuprofen

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.
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 pain) persist or worsen (see section 2). You should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

The recommended dose is:
Adults (body weight greater than 50kg):
The usual dosage is one to two sachets taken every six hours, as required, up to a maximum of six sachets in 24 hours. The interval between single doses should be at least six hours.
Do not take more than 6 sachets in a 24-hour period.

Do not take more than 4 sachets in 24 hours in the following situations unless directed by a doctor
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition

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

The contents of the sachet should be completely dissolved in a glass of hot water. Take Paracetamol/Ibuprofen with or straight after food.

In case of kidney failure:
- If you suffer from severe kidney failure, do not use Paracetamol/Ibuprofen.
- If you suffer mild to moderate kidney impairment, tell your doctor or pharmacist before taking Paracetamol/Ibuprofen.
- You can use the usual dose of this medication, however the lowest dose should be used for the shortest duration.

In case of liver impairment:
- If you suffer from severe liver failure, do not use Paracetamol/Ibuprofen.
- If you suffer from reduced liver function (including Gilbert's syndrome), tell your doctor or pharmacist before taking Paracetamol/Ibuprofen.
- You can use the usual dose of this medication, however the lowest dose should be used for the shortest duration.

CONTAINS PARACETAMOL.
Do not take any other paracetamol-containing products.
Do not exceed the stated dose. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage.

Use in children under 18 years
Paracetamol/Ibuprofen is not recommended for children under 18 years.

If you take more Paracetamol/Ibuprofen than you should
Immediately telephone your doctor 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 Paracetamol/Ibuprofen. Do this even if there are no signs of discomfort or poisoning.

If you have taken more Paracetamol/Ibuprofen 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.
The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

Taking too much Paracetamol/Ibuprofen can lead to delayed, serious liver and kidney damage. You may need urgent medical attention.

If you forget to take Paracetamol/Ibuprofen
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 sachet 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 Paracetamol/Ibuprofen 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 (Steven Johnson Syndrome).
- fever, generally feeling unwell, nausea, stomach-ache, headache and stiff neck.

Other side effects:

Common (may affect up to 1 in 10 people):
- oedema, fluid retention
- ringing in the ears (tinnitus)
- abdominal pain
- nausea, vomiting, diarrhoea
- discomfort, heartburn or pain in the upper part of your stomach
- skin rashes (including maculopapular type), and pruritus
- headache, dizziness, nervousness

- alteration of blood tests indicating change in liver or kidney function (Alanine aminotransferase increased, gamma-glutamyltransferase increased and liver function tests abnormal, blood creatinine increased and blood urea increased).

Uncommon (may affect up to 1 in 100 people):
- reduction in red blood cell numbers, haemoglobin reduction, bleeding episodes such as nosebleeds, abnormal or prolonged bleeding during menstrual periods, increased number of platelets
- alteration of blood tests (Aspartate aminotransferase increased, blood alkaline phosphatase increased, blood creatine phosphokinase increased)
- eye problems such as blurred or diminished vision, scotoma (blind spot), changes to the appearance of colours
- wind and constipation.
- peptic ulcer, perforation or gastrointestinal bleeding with blood in the stool (melena), vomiting blood (haematemesis)
- lesions inside the mouth (ulcerative stomatitis)
- worsening of inflammatory bowel diseases (ulcerative colitis and Crohn's disease)
- inflammation of the stomach (gastritis) and pancreas (pancreatitis)
- increased sensitivity to allergic reactions, angioedema (symptoms may include itchy, sore red eye, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing), serum sickness (reaction similar to an allergy)
- lupus erythematosus syndrome (chronic autoimmune disease)
- Henoch-Schönlein purpura (an inflammation of the small blood vessels)
- breast enlargement (in males)
- abnormally low blood sugar (hypoglycaemia)
- change in mood, for example, depression, confusion, excessive emotional lability
- change in the desire to sleep (sleepiness or sleeplessness)
- inflammation of the meninges (aseptic meningitis) with fever and coma
- 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)

Very rare (may affect up to 1 in 10,000 people):
- haematopoietic disorders: 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 (purpura), signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- abnormal liver function, hepatitis and yellowing of the skin and /or eyes, also called jaundice
- vertigo
- metabolic acidosis, hypokalaemia
- paraesthesia, paradoxical stimulation, optic neuritis, somnolence, psychomotor impairment
- involuntary muscle movements/spasms, tremors and convulsions, slowing of physical and emotional reactions
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- fast or irregular heartbeats, also called tachycardia or palpitations, arrhythmia and other cardiac dysrhythmias
- oedema, hypertension and cardiac failure
- increased sweating
- 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 [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis]
- fatigue and malaise

- hypersensitivity reactions including skin rash
- nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome, and acute and chronic renal failure
- acute tubular necrosis usually occurs in conjunction with liver failure
- respiratory reactivity including: asthma, exacerbation of asthma, bronchospasm and dyspnoea.

Not known (frequency cannot be estimated from the available data):
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Paracetamol/Ibuprofen if you develop these symptoms and seek medical attention immediately. See also section 2
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provided more information on the safety of this medicine.

5. How to store Paracetamol/Ibuprofen

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

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and on the sachet 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 Paracetamol/Ibuprofen contains

The active substances are paracetamol and ibuprofen. Each sachet of Paracetamol/Ibuprofen contains Paracetamol 500 mg and Ibuprofen (as lysine) 150 mg. The other ingredients are: aspartame (E 951), Turmeric Extract 95%, lemon flavour, sodium citrate, and sucrose

What Paracetamol/Ibuprofen looks like and contents of the pack

Paracetamol/Ibuprofen is a light yellow to yellow-coloured powder, supplied in thermo-sealed sachet made from two multi-layer foils, in cartons containing 10, 16, or 20. Not all pack sizes may be marketed. Paracetamol/Ibuprofen forms a yellow solution when dissolved in hot water.

Marketing Authorisation Holder

Vale Pharmaceuticals Limited
Dungarvan Enterprise Centre,
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X35 FX45,
Ireland

Manufacturer

E-Pharma Trento S.P.A
Frazione Ravina
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Paracetamol/Ibuprofen 500 mg/150 mg powder for oral solution in sachet
Belgium:	Combophen 500mg/150mg poudre pour solution buvable en sachet
Luxembourg:	Combophen 500mg/150mg poudre pour solution buvable en sachet

This leaflet was last revised in August 2025.