

Package leaflet: Information for the patient

Paracetamol Medical Valley 500 mg film-coated tablets **Paracetamol Medical Valley 1000 mg film-coated tablets**

paracetamol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1. What Paracetamol Medical Valley is and what it is used for

Paracetamol Medical Valley contains paracetamol which belongs to the group of medicines called analgesics and antipyretics.

Paracetamol Medical Valley is used to relieve headache, toothache, menstrual pain, muscle and joint pain, rheumatic pain, fever during cold and hyperpyrexia.

Paracetamol Medical Valley 500 mg is indicated in adults and children over 3 years (above 15 kg body weight).

Paracetamol Medical Valley 1000 mg is indicated in adults and adolescents weighing more than 40 kg (over 12 years).

2. What you need to know before you take Paracetamol Medical Valley

Do not take Paracetamol Medical Valley

- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver insufficiency.

Warnings and precautions

Do not take Paracetamol Medical Valley without a doctor's prescription if you have alcohol problems or liver damage and, also do not take Paracetamol Medical Valley with alcohol. The intoxicating effect of alcohol does not increase through the use of Paracetamol Medical Valley.

If you take other analgesics containing paracetamol, do not take Paracetamol Medical Valley without first consulting a doctor or pharmacist.

Never take more Paracetamol Medical Valley than what is stated in the dosing instructions. *Higher doses than recommended will not lead to better pain relief, but the risk of very severe liver damage increases.* The symptoms of liver damage usually appear after a few days. It is therefore important that you contact a doctor as soon as possible if you have taken too much, even if you feel well. See also section 3 “If you take more Paracetamol Medical Valley than you should”.

Talk to your doctor or pharmacist before taking Paracetamol Medical Valley:

- if you have kidney or liver problems (including Gilbert’s syndrome and hepatitis)
- if you use any other medicines affecting the liver function
- if you have a deficiency of a certain enzyme called glucose-6-phosphatedehydrogenase
- if you have glutathione deficiency, since the use of paracetamol increases the risk of metabolic acidosis
- if you are dehydrated or malnourished
- if you have abnormal breakdown of red blood cells (haemolytic anaemia)
- if you are using pain relieving medicines frequently for a long period of time, as prolonged use may cause more severe or more frequent headache. You should not increase your dose of the pain relieving medicine but contact your doctor for advice
- if you have asthma and at the same time are sensitive to acetylsalicylic acid

You should not take Paracetamol Medical Valley for long periods or at high doses without talking to your doctor.

During treatment with Paracetamol Medical Valley, 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).

Children and adolescents

Paracetamol Medical Valley is not recommended for children aged under 3 years or below 15 kg body weight.

Other medicines and Paracetamol Medical Valley

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is especially important in case of:

- Chloramphenicol (to treat bacterial infections)
- Zidovudine (to treat HIV infection)
- Rifampicin (to treat tuberculosis)
- Cimetidine (to treat heartburn)
- Metoclopramide or domperidone (to treat nausea and vomiting)
- Cholestyramine (to lower cholesterol)
- Probenecid (used for gout)
- Warfarin (used to thin the blood)
- Phenytoin or carbamazepine (used to treat epilepsy)
- St. John’s Wort extract (included in some herbal remedy)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see “What you need to know before you take Paracetamol Medical Valley”).

In order to avoid overdose, it should be checked that other drugs used simultaneously with Paracetamol Medical Valley do not contain paracetamol.

Paracetamol Medical Valley with food, drink and alcohol

You can use Paracetamol Medical Valley independently of food.

Do not drink alcohol when taking paracetamol, see “Warnings and precautions”. The dosage must be reduced in patients who consume large quantities of alcohol (see “How to take Paracetamol Medical Valley”).

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.

If necessary, Paracetamol Medical Valley can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Recommended doses of paracetamol may be used during breast-feeding.

Driving and using machines

Paracetamol Medical Valley does not influence your ability to drive or use machines.

3. How to take Paracetamol Medical Valley

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for use

Swallow the tablet with a glass of water.

The tablet can be divided into equal doses.

Dosage

Do not exceed the stated dose. *Doses higher than those recommended may involve serious risks.*

Use the lowest possible dose, for shortest time possible to relieve the pain.

The recommended dose is:

500 mg tablets: Adults and adolescents weighing more than 40 kg (over 12 years)

1-2 tablets (500 mg to 1000 mg) every 4 to 6 hours as required.

The maximum daily dose is 8 tablets (4 gram) in 24 hours.

500 mg tablets: Children and adolescents weighing from 15 kg to less than 40 kg (3 to 12 years)

Dosage for children and adolescents should be based on body weight, see table below for details:

Body weight	Age	Dose of the 500 mg tablet
15-25 kg	3-7 years	Half tablet (250 mg) every 4 to 6 hours, as required. Maximum four times daily (1 gram)
25-40 kg	7-12 years	Half to one tablet (250 mg to 500 mg) every 4 to 6 hours, as required. Maximum four times daily (2 gram).

1000 mg tablets: Adults and adolescents weighing more than 40 kg (over 12 years)

Half to one tablet (500 mg to 1000 mg) every 4 to 6 hours as required.

The maximum daily dose is 4 tablets (4 gram) in 24 hours.

Paracetamol Medical Valley 1000 mg is not recommended for use in children below 12 years or below 40 kg body weight.

Body weight	Age	Dose of the 1000 mg tablet
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over 40 kg	over 12 years	Half to one tablet (500 mg to 1000 mg) paracetamol every 4 to 6 hours, maximum 4 tablets daily. The maximum daily dose is 4 g.
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Children and adolescents with a low body weight (<15 kg)

Paracetamol Medical Valley is not recommended for use in children below 3 years or below 15 kg body weight. Other more appropriate dosage strengths and/or formulations are available for children with a low body weight or for children who cannot swallow a tablet.

Special groups of patients

Elderly

There is no need for dosage reduction in the elderly.

Impaired kidney or liver function or alcohol dependency

For patients with impaired hepatic or kidney function or with Gilbert's syndrome, the doctor will adjust the dose.

If you take more Paracetamol Medical Valley than you should

Seek immediate medical help if you take too much, or if a child or adolescent take too much of the medicine, even if you or the child feels well. This is because too much paracetamol can cause delayed, serious liver damage. In order to avoid liver damage, it is essential to get medical treatment **as early as possible**. The shorter the interval between intake and initiation of treatment with the antidote (as few hours as possible), the greater the likelihood that liver injury can be prevented.

If you forget to take Paracetamol Medical Valley

Do not take a double dose to make up for a forgotten dose and never exceed the maximum daily dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Paracetamol Medical Valley and contact a doctor or go to the nearest hospital immediately if you get any of these very rare severe side effects (may affect up to 1 in 10,000 people):

- Angioedema, a severe allergic reaction
 - swollen face, tongue or throat
 - difficulty swallowing,
 - hives and difficulty in breathing
- Anaphylactic reaction, a severe allergic reaction or hypersensitivity reaction with fever, rash, swelling and sometimes fall in blood pressure
- Serious skin reactions have been reported (toxic epidermal necrolysis and Stevens-Johnson's syndrome)

Other possible side effects:

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

- Impaired liver function, liver failure, jaundice (with symptoms like yellowing of the skin and eyes).
- Itchy white or red lumps on the skin (urticaria).
- Widespread rash that is usually accompanied by systemic symptoms such as fever, malaise and headache (exanthema).

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

- Reduced number of platelets, red blood cells and white blood cells (leukocytes, granulocytes and neutrophils) in the blood, haemolytic anaemia (abnormal breakdown of red blood cells).
- Trouble breathing, shortness of breath, coughing (bronchospasm).

- Hepatotoxicity (damage caused to the liver due to chemicals).
- Kidney disorders (severe kidney impairment, blood in the urine, inability to urinate) have been reported following long-term use.

Not known (frequency cannot be estimated from the available data)

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (See “What you need to know before you take Paracetamol Medical Valley”).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Medical Valley

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

This medicine does not require any special storage conditions.

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

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 Medical Valley contains

The active substance is paracetamol.

- Each 500 mg film-coated tablet contains 500 mg paracetamol.
- Each 1000 mg film-coated tablet contains 1000 mg paracetamol.

The other excipients: *tablet core*: pregelatinised starch, magnesium stearate (E 470 b); *film-coating*: hypromellose (E 464), macrogol, propylene glycol (E 1520), titanium dioxide (E 171), talc (E553 b)

What Paracetamol Medical Valley looks like and contents of the pack

Paracetamol Film Coated Tablets 500 mg are white to off white, (approximately 17 mm x 8mm) capsule shaped film coated tablet with score line on one side and plain on other side.

The tablets can be divided into equal doses.

Paracetamol Film Coated Tablets 1000 mg are white to off white, (approximately 21 mm x 10 mm) capsule shaped film coated tablets with score line on one side and plain on other side. The tablets can be divided into equal doses.

500 mg:

Bottles (HDPE) with screw cap (PP): 56, 105, 120, 300, 330, 336, 375 film-coated tablets.
Clear PVC/Aluminium blister containing 100 film-coated tablets

1000 mg:

Bottles (HDPE) with screw cap (PP): 105 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>
{Name and address}

Manufacturer

Laboratorios Liconsa, S.A.
Avda. Miralcampo, N°7, Pol. Ind. Miralcampo
19200 Azuqueca de Henares (Guadalajara)
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

IS	Paracetamol Medical Valley 500 mg; 1000 mg töflur
DK	Paracetamol Medical Valley
SE	Paracetamol Medical Valley 500 mg; 1000 mg tabletter

This leaflet was last revised in 28 February 2025
[To be completed nationally]