

Package leaflet: Information for the user

Paralief 500 mg film-coated tablets

paracetamol

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 or nurse 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 or nurse. 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 5 days in case of pain and 3 days in case of fever.

What is in this leaflet

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

1. What Paralief is and what it is used for

Paralief contains active substance paracetamol which belongs to a group of medicines called analgesics (painkillers).

Paralief are used to relieve pain and help reduce fever. The tablets can treat over a short time mild to moderate pain and/or fever.

Paralief may be used in adults and adolescents but is not suitable for use in children below 6 years.

2. What you need to know before you take Paralief

Do not take Paralief

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Paralief.

- if you are taking other paracetamol containing medicines, as it may severely damage the liver.
- if you have kidney or liver disease (including Gilbert's syndrome or acute hepatitis).
- if you have a deficiency of a certain enzyme called glucose-6-phosphatase.
- if you have haemolytic anaemia (abnormal breakdown of red blood cells).
- if you regularly take large amounts of alcohol. Never take more than 4 tablets a day.
- if you are asthmatic sensitive to acetylsalicylic acid.
- if you have a low bodyweight (less than <50 kg).
- in case of a lack of fluid in the body (dehydration), e.g. due to low drinking quantity, diarrhoea or vomiting or chronic malnutrition.
- 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).

In cases of high fever, signs of a secondary infection, or persistence of your symptoms for more than three days, consult your doctor or pharmacist.

Headaches caused by overuse of analgesics should not be handled by increasing the dose. In those cases, the use of analgesics should be taken after consulting a doctor.

In general, habitual use of analgesics, especially when combined with several analgesic agents, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Simultaneous use of this product with other paracetamol-containing medicines, such as flu and cold medicines, should be avoided as high doses can lead to liver damage. Do not use more than one medicine containing paracetamol without consulting your doctor.

Do not take more medicine than recommended in section 3. How to take Paralief.

A single intake of the total daily dose in excess of the recommended dose can lead to life-threatening poisoning. In this case, if an overdose is suspected, consult a doctor immediately as referred in Section 3 'If you take more Paralief than you should'.

Children and adolescents

Paralief should not be given to children under 6 years. Other paracetamol containing dosage forms or strengths should be used in children under 6 years of age.

Other medicines and Paralief

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

DO NOT use Paralief in combination with other paracetamol-containing medicines.

Please talk to your doctor before you take paracetamol in case you use one of the following medicines:

- cholestyramine (used to lower your cholesterol)
- warfarin and other coumarin derivatives (medicines to thin the blood), particularly in case you need to take paracetamol on a daily basis over a long period of time. Long-term use of paracetamol in patients treated with anticoagulants should only be done under medical supervision.
- salicylamide (a painkiller)
- probenecid (a medicine used to treat gout). The dose may need to be reduced because the degradation of paracetamol may be slowed down.
- isoniazid or rifampicin (a medicine used to treat tuberculosis) that may damage the liver. Under certain circumstances, liver damage may occur if taken at the same time as paracetamol.
- lamotrigine or phenytoin (a medicine used to treat epilepsy)
- barbiturates or carbamazepines (medicines that cause relaxation and sleepiness)
- St. John's Wort (a medicine used to treat depression)
- chloramphenicol (an antibiotic)
- zidovudine (a medicine used to treat AIDS). Zidovudine should only be taken/used at the same time as paracetamol on the advice of a doctor.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- anti-nausea agents (metoclopramide and domperidone): These may cause an acceleration of the absorption and onset of action of Paralief.
- In the case of simultaneous use of agents that lead to a slowing down of gastric emptying, the absorption and onset of action of paracetamol may be delayed.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking this medicine as it could affect the results of these tests. Paracetamol alters blood determinations of glucose and uric acid.

Paralief with food and drink and alcohol

It is advised not to drink large amounts of alcohol when taking Paralief.

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

If necessary, Paralief can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your 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.

Breast-feeding

Although paracetamol is excreted in the breast milk in small amounts it has no unwanted effects on the child that is breast fed. Paracetamol may be used by breast-feeding women as long as the recommended dosage is not exceeded. In case of long-term use caution should be exercised.

Fertility

No detrimental effects on fertility upon normal use of paracetamol are known.

Driving and using machines

Paralief is not expected to impair your ability to drive or to operate machinery.

Paralief contains sodium

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

3. How to take Paralief

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

The tablet can be divided into two equal doses.

The recommended dose is:

Adults and Adolescents over 15 years (> 55 kg body weight):

1 to 2 tablets (500-1000 mg) at a time, up to 6 tablets (3000 mg) per 24 hours. At least 4 hours should be left between doses.

The simultaneous intake of two tablets should be recommended only if there is insufficient relief with one tablet, or there is higher requirement due to more intense pain.

Use in children and adolescents

Children aged 6 to 9 years (22-30 kg body weight):

Half tablet (250 mg) at a time, every 4-6 hours when necessary to a maximum of 4 doses in 24 hours (corresponding to 1000 mg Paracetamol) in exceptional cases, up to 6 x ½ dosage form daily, in a dosage interval of at least 4 hours, i.e. up to 1500 mg paracetamol daily.

Children aged 9 to 12 years (30-40 kg body weight):

One tablet (500 mg) at a time, every 4-6 hours when necessary to a maximum of 4 doses in 24 hours (corresponding to 1500-2000 mg Paracetamol).

Children aged 12 to 15 years (40-55 kg body weight):

One tablet (500 mg) at a time, every 4-6 hours when necessary to a maximum of 4 doses in 24 hours (corresponding to 2000 mg Paracetamol) in exceptional cases, in a dosage interval of at least 4 hours, i.e. up to 3000 mg paracetamol daily.

The lower dosing frequency is intended for children in the lower limit of the relevant weight and/or age group.

Method of administration

The tablet should be swallowed whole with plenty of water. Optionally, place the tablet into a large amount of water to disintegrate, stir well and drink.

Directions for use

For children under 6 years, other formulations and dosage strengths are available, which may be more appropriate.

Do not use in combination with other paracetamol-containing preparations.

The use of high daily doses of paracetamol should be avoided for prolonged periods of time since it increases the risk of suffering adverse effects such as liver damage. Treatment should be as short as possible.

If the pain persists for more than 5 days or the fever lasts for more than 3 days or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

The effective daily dose should not exceed 60 mg / kg / day (up to 2 g / day) in the following situations:

- adults weighing less than 50 kg
- dehydration
- chronic malnutrition

Follow these instructions unless your doctor has given you different advice.

If you feel that Paralief too strong or too weak, talk to your doctor or pharmacist.

Special patient groups

Hepatic impairment and mild renal impairment

In patients with hepatic or renal impairment and Gilbert's syndrome, the dose must be reduced or the interval between doses prolonged.

A total daily dose of 2g must not be exceeded without medical advice.

Severe renal insufficiency

Unless otherwise prescribed, a dose reduction is recommended in patients with renal insufficiency. Ask your doctor about the adjusted dosage interval between individual dosages.

If you take more Paralief than you should

SEEK IMMEDIATE MEDICAL ADVICE IN THE EVENT OF AN OVERDOSE, EVEN IF YOU FEEL WELL, because of the risk of **delayed, serious liver damage**. Symptoms of paracetamol overdose are nausea, vomiting and reduced appetite. Unconsciousness does not usually occur.

If you forget to take Paralief

Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

If you stop taking Paralief

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.

Possible side effects are listed below and classified as:

Rare side effects (affects 1 to 10 users in 10,000):

- Several blood disorders including agranulocytosis, thrombocytopenia, thrombocytopenic purpura, hemolytic anemia, leukopenia, platelet disorders (clotting disorders) and stem cell disorders (disorders of the blood forming cells in bone marrow).
- Allergic reactions.
- Depression, confusion, hallucinations.
- Tremor, headache.
- Disturbed vision.
- Oedema (abnormal accumulation of fluid under the skin).
- Abdominal pain, stomach or intestinal bleeding, diarrhoea, nausea, vomiting.
- Abnormal liver function, liver failure, jaundice (with symptoms like yellowing of the skin and eyes), hepatic necrosis (death of liver cells).
- Rash, itching, sweating, hives, red patches on skin, angioedema with symptoms like swollen face, lips, throat or tongue.
- Dizziness, generally feeling unwell (malaise), fever, sedation, interactions with medicines.
- Overdose and poisoning.

Very rare side effects (affects less than 1 user in 10,000):

- Pancytopenia (reduction in the number of blood cells).
- Allergic reactions where treatment should be stopped, including angioedema, difficulty breathing, sweating, nausea, hypotension, shock, and anaphylaxis.
- Low level of blood glucose in the blood.
- Hepatotoxicity (damage caused to the liver due to chemicals).
- Cloudy urine and kidney disorders.
- Bronchospasm (difficulty in breathing) in patients sensitive to aspirin and other anti-inflammatory medicines.
- Haematuria (blood in urine).
- Anuresis (inability to urinate).

Not Known (frequency cannot be estimated from the available data):

- Acute generalised exanthemateus pustulosis (drug eruption characterized by numerous small, primarily non-follicular, sterile pustules).
- Severe skin rash or peeling of the skin.
- Stevens-Johnson syndrome (a severe life-threatening skin disorder).
- Reddening of skin, blisters or rash due to intake of paracetamol.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Once you stop taking the medicine these side effects should go away. If any of the side effects gets serious, please tell your doctor or pharmacist.

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 provide more information on the safety of this medicine.

5. How to store Paralief

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or the bottle or the blister after 'EXP'. The expiry date refers to the last day of that month.

- Do not use this medicine if you notice chipping, discolouration or any other signs of the visible signs of deterioration.
- This medicinal product does not require any special storage conditions.
- 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 Paralief contains

The active substance is paracetamol.

Each film-coated tablet contains 500 mg paracetamol.

The other ingredients are povidone K-30, pregelatinised maize starch, sodium maize starch glycolate type-a, stearic acid (E570), hypromellose (E464) and macrogol 400 (E1521).

What Paralief looks like and contents of the pack

White to off-white coloured, caplet shaped film-coated tablets with flat-edges debossed with "PARA500" on one side and score line on the other side. Approximately, the tablet dimensions are 17.5 mm X 7.3 mm.

The tablets are packaged in blister (PVC/Aluminium or PVC/PVdC/ Aluminium) packs containing 10, 12, 20 and 24 film-coated tablets or high density polyethylene (HDPE) bottle packs with polypropylene closure containing 24, 100, 300, 500 and 1000 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Pharmazet Group s.r.o., Třtinová 260/1, Prague 9, 19600, Czech Republic

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Germany (DE):	Paracetamol Pharmaclan 500 mg Filmtabletten
Hungary (HU):	Paracetamol Pxxgpharma 500 mg filmtableta
Spain (ES):	Paracetamol Pharmaclan 500 mg comprimidos recubiertos con película EFG
The Netherlands (NL):	Paracetamol Pharmaclan 500 mg Filmomhulde tabletten
Ireland (IE):	Paralief 500 mg film-coated tablets

This leaflet was last revised in

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Paralief 500 mg film-coated tablets

paracetamol

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- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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Warnings and precautions

Talk to your doctor or pharmacist before taking Paralief.

- if you are taking other paracetamol containing medicines, as it may severely damage the liver.
- if you have kidney or liver disease (including Gilbert's syndrome or acute hepatitis).
- if you have a deficiency of a certain enzyme called glucose-6-phosphatase.
- if you have haemolytic anaemia (abnormal breakdown of red blood cells).
- if you regularly take large amounts of alcohol. Never take more than 4 tablets a day.
- if you are asthmatic sensitive to acetylsalicylic acid.
- if you have a low body weight (less than <50 kg).
- in case of a lack of fluid in the body (dehydration), e.g. due to low drinking quantity, diarrhoea or vomiting or chronic malnutrition.
- 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).

In cases of high fever, signs of a secondary infection, or persistence of your symptoms for more than three days, consult your doctor or pharmacist.

Headaches caused by overuse of analgesics should not be handled by increasing the dose. In those cases, the use of analgesics should be taken after consulting a doctor.

In general, habitual use of analgesics, especially when combined with several analgesic agents, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Simultaneous use of this product with other paracetamol-containing medicines, such as flu and cold medicines, should be avoided as high doses can lead to liver damage. Do not use more than one medicine containing paracetamol without consulting your doctor.

Do not take more medicine than recommended in section 3. How to take Paralief.

A single intake of the total daily dose in excess of the recommended dose can lead to life-threatening poisoning. In this case, if an overdose is suspected, consult a doctor immediately as referred in Section 3 'If you take more Paralief than you should'.

Children and adolescents

Paralief should not be given to children under 6 years. Other paracetamol containing dosage forms or strengths should be used in children under 6 years of age.

Other medicines and Paralief

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

DO NOT use Paralief in combination with other paracetamol-containing medicines.

Please talk to your doctor before you take paracetamol in case you use one of the following medicines:

- cholestyramine (used to lower your cholesterol)
- warfarin and other coumarin derivatives (medicines to thin the blood), particularly in case you need to take paracetamol on a daily basis over a long period of time. Long-term use of paracetamol in patients treated with anticoagulants should only be done under medical supervision.
- salicylamide (a painkiller)
- probenecid (a medicine used to treat gout). The dose may need to be reduced because the degradation of paracetamol may be slowed down.
- isoniazid or rifampicin (a medicine used to treat tuberculosis) that may damage the liver. Under certain circumstances, liver damage may occur if taken at the same time as paracetamol.
- lamotrigine or phenytoin (a medicine used to treat epilepsy)
- barbiturates or carbamazepines (medicines that cause relaxation and sleepiness)
- St. John's Wort (a medicine used to treat depression)
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- zidovudine (a medicine used to treat AIDS). Zidovudine should only be taken/used at the same time as paracetamol on the advice of a doctor.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- anti-nausea agents (metoclopramide and domperidone): These may cause an acceleration of the absorption and onset of action of Paralief.
- In the case of simultaneous use of agents that lead to a slowing down of gastric emptying, the absorption and onset of action of paracetamol may be delayed.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking this medicine as it could affect the results of these tests. Paracetamol alters blood determinations of glucose and uric acid.

Paralief with food and drink and alcohol

It is advised not to drink large amounts of alcohol when taking Paralief.

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

If necessary, Paralief can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your 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.

Breast-feeding

Although paracetamol is excreted in the breast milk in small amounts it has no unwanted effects on the child that is breast fed. Paracetamol may be used by breast-feeding women as long as the recommended dosage is not exceeded. In case of long-term use caution should be exercised.

Fertility

No detrimental effects on fertility upon normal use of paracetamol are known.

Driving and using machines

Paralief is not expected to impair your ability to drive or to operate machinery.

Paralief contains sodium

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

3. How to take Paralief

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

The tablet can be divided into two equal doses.

The recommended dose is:

Adults and Adolescents over 15 years (> 55 kg body weight):

1 to 2 tablets (500-1000 mg) at a time, up to 6 tablets (3000 mg) per 24 hours. At least 4 hours should be left between doses. The simultaneous intake of two tablets should be recommended only if there is insufficient relief with one tablet, or there is higher requirement due to more intense pain.

Use in children and adolescents

Children aged 6 to 9 years (22-30 kg body weight):

Half tablet (250 mg) at a time, every 4-6 hours when necessary to a maximum of 4 doses in 24 hours (corresponding to 1000 mg Paracetamol) in exceptional cases, up to 6 x ½ dosage form daily, in a dosage interval of at least 4 hours, i.e. up to 1500 mg paracetamol daily.

Children aged 9 to 12 years (30-40 kg body weight):

One tablet (500 mg) at a time, every 4-6 hours when necessary to a maximum of 4 doses in 24 hours (corresponding to 1500-2000 mg Paracetamol).

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The lower dosing frequency is intended for children in the lower limit of the relevant weight and/or age group.

Method of administration

The tablet should be swallowed whole with plenty of water. Optionally, place the tablet into a large amount of water to disintegrate, stir well and drink.

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For children under 6 years, other formulations and dosage strengths are available, which may be more appropriate.

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The effective daily dose should not exceed 60 mg / kg / day (up to 2 g / day) in the following situations:

- adults weighing less than 50 kg
- dehydration
- chronic malnutrition

Follow these instructions unless your doctor has given you different advice.

If you feel that Paralief is too strong or too weak, talk to your doctor or pharmacist.

Special patient groups

Hepatic impairment and mild renal impairment

In patients with hepatic or renal impairment and Gilbert's syndrome, the dose must be reduced or the interval between doses prolonged.

A total daily dose of 2g must not be exceeded without medical advice.

Severe renal insufficiency

Unless otherwise prescribed, a dose reduction is recommended in patients with renal insufficiency. Ask your doctor about the adjusted dosage interval between individual dosages.

If you take more Paralief than you should

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Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

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

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Rare side effects (affects 1 to 10 users in 10,000):

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- Abdominal pain, stomach or intestinal bleeding, diarrhoea, nausea, vomiting.
- Abnormal liver function, liver failure, jaundice (with symptoms like yellowing of the skin and eyes), hepatic necrosis (death of liver cells).
- Rash, itching, sweating, hives, red patches on skin, angioedema with symptoms like swollen face, lips, throat or tongue.
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- Overdose and poisoning.

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- Low level of blood glucose in the blood.
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- Cloudy urine and kidney disorders.
- Bronchospasm (difficulty in breathing) in patients sensitive to aspirin and other anti-inflammatory medicines.
- Haematuria (blood in urine).
- Anuresis (inability to urinate).

Not Known (frequency cannot be estimated from the available data):

- Acute generalised exanthemateus pustulosis (drug eruption characterized by numerous small, primarily non-follicular, sterile pustules).
- Severe skin rash or peeling of the skin.
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Reporting of side effects

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5. How to store Paralief

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or the bottle or the blister after 'EXP'. The expiry date refers to the last day of that month.

- Do not use this medicine if you notice chipping, discolouration or any other signs of the visible signs of deterioration.
- This medicinal product does not require any special storage conditions.
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6. Contents of the pack and other information

What Paralief contains

The active substance is paracetamol.

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The other ingredients are povidone K-30, pregelatinised maize starch, sodium maize starch glycolate type-a, stearic acid (E570), hypromellose (E464) and macrogol 400 (E1521).

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