

PACKAGE LEAFLET

Package leaflet: Information for the user

Padolieve 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, pharmacist or nurse have 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- 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 Padolieve is and what it is used for
2. What you need to know before you take Padolieve
3. How to take Padolieve
4. Possible side effects
5. How to store Padolieve
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1. What Padolieve is and what it is used for

Padolieve contains paracetamol.

Paracetamol is a pain relieving, fever reducing medicinal product (analgesic and antipyretic). Paracetamol is used for symptomatic treatment of mild to moderate pain and/or fever.

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 Padolieve

Do NOT take Padolieve:

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

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Padolieve if;

- you have kidney or liver disease
- you regularly consume excess amounts of alcohol
- you suffer from a condition known as Gilberts syndrome
- you are in a poor nutritional state e.g. due to eating disorders, cystic fibrosis, HIV infection, starvation
- you have severe haemolytic anaemia (abnormal breakdown of red blood cells).

Never take more paracetamol than recommended. A higher dose does not increase pain relief; instead it can cause serious liver damage. The symptoms of liver damage occur first after a few days. It is therefore very important that you contact your doctor **immediately** if you have taken more paracetamol than recommended in this leaflet.

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage.

To avoid overdose, make sure that other medicines that you are taking concurrently do not contain paracetamol.

The lowest effective dose should be used for the shortest duration necessary.

Caution is advised in the administration of paracetamol to patients with poor kidney or liver function.

You should not use paracetamol frequently for a long period of time, as prolonged use may cause liver problems. Discuss with your doctor or pharmacist if you intend taking paracetamol for a longer period of time.

Do not use paracetamol unless prescribed by a doctor if you have an addiction to alcohol or liver damage. Do not use paracetamol together with alcohol. Paracetamol does not increase the effect of alcohol.

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Caution should be exercised in cases of chronic alcoholism. The daily dose should not exceed 2 g in such cases.

Paracetamol should be used with caution if you are dehydrated or very malnourished.

In long-term, high dose, incorrect use of painkillers, particularly a combination of several analgesic substances, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Sudden stopping use of paracetamol following long term use may lead to headaches, fatigue, muscle pain, nervousness, dizziness or fainting. These symptoms resolve within a few days. Until this time, avoid further use of painkillers and do not restart them without medical advice.

You should not take Padolieve for long periods or at high doses without talking to your doctor or dentist.

Children and adolescents

Padolieve is not recommended for use in children under 8 years of age as the dosage strength is not suitable for this age group. However, there are appropriate dosage strengths and/or formulations available for this age.

Other medicines and Padolieve

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.. This is especially important in case of:

- chloramphenicol (to treat infections)
- zidovudine (to treat AIDs)
- rifampicin (to treat infections)
- cimetidine (to treat hearburn)
- metoclopramide or domperidone (used to treat nausea or vomiting)
- colestyramine (used to lower blood cholesterol)
- anticoagulants (drugs to thin the blood e.g. warfarin), in case you need to take a pain relieving product on a daily basis over a long period
- probenecid (used to treat gout)
- Substances that induce liver enzymes e.g. barbiturates, isoniazid, rifampicin, carbamazepine, primidone, St. John's Wort
- Lamotrigine or phenytoin (used to treat epilepsy)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to

organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Do not take with any other paracetamol-containing products.

Padolieve with food and drink

Padolieve can be taken with or without food. Swallow the tablets with a glass of water.

Pregnancy and breast-feeding

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, Padolieve 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Therapeutic doses of paracetamol may be used during pregnancy or breast-feeding.

Driving and using machines

Padolieve should not affect your ability to drive or use machines.

Laboratory tests

Tell your doctor that you are taking Padolieve if you are having blood tests for uric acid or blood sugar as paracetamol may affect the results.

3. How to take Padolieve

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

Do **not** exceed the stated dose.

The recommended dose is:

Adults (including the elderly) and adolescents aged 15 years and over

1-2 tablets (500 mg to 1000 mg) every 4 hours as needed. Do not take more than 6 tablets in any 24 hour period.

Adolescents 12-15 years

1 tablet every 4 hours as needed, up to a maximum of 4 tablets in any 24 hour period.

Children 11-12 years

1 tablet every 6 hours as needed, up to a maximum of 4 tablets in any 24 hour period,

Children 8-11 years

½ tablet every 4 hours **or** 1 tablet every 6 hours, up to a maximum of 3 tablets in any 24 hour period.

Use in children under 8 years

Padolieve are not suitable for children under 8 years of age as the dosage strength is not suitable for this age group. However, there are appropriate dosage strengths and/or formulations available for this age.

The lowest effective dose should be used for the shortest duration necessary. Stop taking paracetamol when you do not need it any more.

If your symptoms worsen or do not improve after 3 days, or if you have high fever you must contact a doctor.

Special groups of patients

Patients with impaired liver or kidney function

In patients with impaired liver or kidney function, the dose must be reduced or the dosing interval prolonged. Ask your doctor or pharmacist for advice.

Method of administration

Swallow the tablets with a drink of water.

Do not exceed the stated dose.

If you take more Padolieve than you should

Immediate medical advice should be sought in the event of overdosage, **even if you feel well**, because of the risk of delayed, irreversible, serious liver damage.

If you forget to take Padolieve

If you forget to take a dose, take it when you remember it and wait at least four hours before taking the next dose. **Do not** take a double dose to make up for a forgotten dose.

Do not exceed the maximum daily dose.

If you stop taking Padolieve

This product should only be used when necessary.

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

4. Possible side effects

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

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

Hives (urticaria); increased liver enzymes, increased creatinine in serum, itching (pruritis), sweating, small haemorrhages in the skin (purpura).

Blood disorders (reduction in platelets, white blood cells and neutrophils in the blood, haemolytic anaemia), narrowing of the airways in predisposed patients; allergic reaction (hypersensitivity reactions inclusive of skin rash and angioedema with symptoms of swollen face, lips, throat or tongue); stomach pain, diarrhoea, nausea (feeling sick), vomiting, bleeding (haemorrhage), yellowing of the eyes (jaundice), swelling of the ankles (oedema).

Liver, kidney and urinary problems as well as inflammation of the pancreas (pancreatitis).

In long term treatment, the possibility of kidney damage cannot be ruled out.

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

- breathing difficulties in patients with sensitivity to acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatories.
- severe skin rash or peeling of the skin which may be accompanied by mouth ulcers (Stevens Johnson syndrome).

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Padolieve

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

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the blister, carton or bottle label after the expiry date ('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 any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Padolieve contains

- The active substance is paracetamol. Each film-coated tablet contains 500 mg paracetamol.
- The other ingredients are starch pregelatinised, maize starch, povidone K-30, stearic acid, talc and opadry white (Y-I-7000) which includes titanium dioxide (E171), macrogol 400 and hypromellose 5cP.

What Padolieve looks like and contents of the pack

White caplet shaped, film-coated tablets with 'P', a bisect breakline and '500' on one side and plain on the other side.

The film-coated tablets can be divided into equal halves.

The film-coated tablets are available in the following pack sizes:
10, 12, 20, 24, 30, 50, 60 and 100 film-coated tablets for blisters
30 and 100 film-coated tablets for HDPE bottles

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Alter Pharma N.V.
Square Marie Curie 50
1070 Anderlecht
Belgium

Manufacturer:

SANTA S.A.

Str. Panselilor nr. 25, nr. 27, nr. 29,
Brasov, jud. Brasov, 500419,
Romania

Apotex Nederland B.V.
Archimedesweg 2
2333 CN Leiden
The Netherlands

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

Portugal: Padolieve

This leaflet was last revised in