

FRONT
LEADING EDGE

94.6
210.0
82.5
140.0

PHARMA CODE REF. IS: XXXX

Patient Information Leaflet

HALEON

Panadol

Advance

Film coated tablets (Analgesic/Antipyretic)

Description

Each tablet contains:
Active ingredient: Paracetamol 500mg
Other ingredients: Pregelatinised starch, Calcium Carbonate, Alginate Acid, Croscopolone, Povidone (K-25), Magnesium Stearate, Silica Colloidal Anhydrous, Purified water, Carnauba wax, Opadry White (YS-1-7003)
Film-coating: Titanium Dioxide(E171), Hypromellose 2910 3CP, Hypromellose 2910 6CP, Macrogol 400, Polysorbate 80

What is Panadol Advance and what is it used for?

Panadol Advance is film coated tablets that contain Paracetamol which is mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of headaches, musculoskeletal disorders, menstrual pains, toothache and for symptoms of common colds and flu. Panadol may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis, as diagnosed by a doctor.

How to take Panadol Advance?

For oral administration only.

Adults (including the elderly) and children aged 16 years and over:
One or two tablets up to four times daily as required.

Children aged 10-15 years:
One tablet up to four times daily as required. Children should not be given Panadol 500mg Tablets for more than 3 days without consulting a doctor. Not recommended for children under 10 years of age. These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period. The lowest dose necessary to achieve efficacy should be used.

Before you take Panadol Advance:

a. Do not take Panadol Advance in case of:
- Known or previous hypersensitivity to Paracetamol or any other ingredients in this product.

b. Take special care with Panadol Advance:

- Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.
- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol.
- Caution in patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.
- Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.
- Do not exceed the stated dose.
- If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful.
- This product should only be used when clearly necessary.
- Keep out of the sight and reach of children.

c. Taking other medicines:
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Please inform your doctor or pharmacist if you are taking:
- 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.

d. Pregnancy & breast feeding:
Pregnancy
There is epidemiological evidence of the safety of paracetamol in human pregnancy. Paracetamol is the mild analgesic of choice during pregnancy. However as with all drugs, caution should be exercised in its use during the first trimester. If clinically needed, paracetamol can be used during pregnancy however

It should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Lactation
Paracetamol is excreted in breast milk. However, the level of paracetamol present is not considered to be harmful.

e. Driving and using machines:
Unlikely to cause an effect on ability to drive and use machines.

Possible adverse events:
Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data). Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Body System	Undesirable Effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune System disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, including, among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis. Very rare cases of serious skin reactions have been reported	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

Overdose
Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity. There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases. Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic. Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may cause coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration. Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue. Some patients may be at increased risk of liver damage from paracetamol toxicity. Risk factors include: If the patient;
• Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
• Regularly consumes ethanol in excess of recommended amounts.
• Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Emergency Procedure:
Immediate transfer to hospital. Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion. Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour. The antidote N-acetylcysteine should be administered as soon as possible in accordance with National treatment guidelines. Symptomatic treatment should be implemented.

How to store Panadol Advance?
Store below 30°C.
Store in original container.
This product is protected in a sealed blister. Do not use if blister is broken. Do not use this medicine after the expiry date, which is stated on the carton. Blister: The expiry date refers to the last day of that month.
Pack sizes: 24 Tablets (12 Tablets X 2 strips), 48 Tablets (12 Tablets X 4 strips), 72 Tablets (12 Tablets X 6 strips) & 96 Tablets (12 Tablets x 8 Strips), not all pack sizes might be available in all markets.

THIS IS A MEDICINE
- Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and pharmacist are experts in the use of medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
KEEP MEDICINE OUT OF REACH OF CHILDREN
Council of Arab Health Ministers
Union of Arab Pharmacists

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Manufactured by GlaxoSmithKline Durganvar Ltd, Knockbrack, Durganvar, Co. Waterford, Ireland
MAH: HALEON Ireland Limited, Ireland
Updated based on GDS V7, Date of Revision: October 2023 as per the Country of origin SmPC dated April 2023
NPA013221

TECHNICAL INFORMATION	
	TEXT FREE MARGINS
	PHARMACODE AREA PHARMACODE TO BE PRINTED IN DARKEST COLOUR ON ARTWORK. THICK BAR: 1.5 THIN BAR: 0.5 GAP BETWEEN BARS: 1.0 BAR HEIGHT: 8.0 CODE LENGTH: VARIABLE
	R-BAR LENGTH 8.0 HEIGHT 2.0
NOTE: GENERIC SPECIFICATION REFERENCE: OTC.LT.SPEC002	
AMENDMENTS	
FIRST ISSUE: CO-0070836.	
ADDED GENERIC SPECIFICATION REFERENCE TO THE TECHNICAL INFORMATION PANEL: CO-0080843.	
DRAWING OWNER (SITE)	Durganvar
Leaflet 140 x 210mm M6GSK - Solid Dose Template 2	
PACKAGING MATERIAL DRAWING REGIONAL SERVICE CENTRE, BARNARD CASTLE	DRAWING No. VERSION OTC.LT.002 2.0
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SCALE: 1:1	GENERAL DRAWING TOLERANCE UNLESS STATED OTHERWISE N/A
ALL DIMS. IN MILLIMETRES	

V1 30 - OCT - 2023		Artwork Information Panel				HALEON	
Non Production Artwork <input checked="" type="checkbox"/>		Production Artwork <input type="checkbox"/>				Component No: NPA013221	AWP No: 7497267
Total Number of Colours including Varnish & Foils: 1						Manufacturing Site:	
						(Note: North American Artwork will have N/A in this field)	
1. Black						Approving Market: United Arab Emirates-ARE	
2.						Technical Drawing No: OTC.LT.002 (2)	
3.						Material Spec No: NA	
4.						(Note: North American Artwork will have N/A in this field)	
5.						Body Text Size: 5.0pt	
6.						Smallest Text Size: 5.0pt	
7.						(Note: For North American Artwork, see Regulatory Spec box for this information)	
8.						Electronic Verification Code:	
9.						Printer and User notes:	
10.							
11.							
12.							
Total Special Finishes: 0							

AIP_CHAMPS_2023_HALEON

BACK LEADING EDGE

Technical drawing of a medicine box for HALEON BANADOL. The drawing shows the back and leading edge of the box with dimensions 210.0mm height and 140.0mm width. It includes Arabic text describing the product, usage instructions, and safety information. A logo for BANADOL is prominently displayed.

Technical information and specifications for the medicine box. It includes a table for 'PHARMACODE AREA' with dimensions for thick and thin bars. It also contains a table for 'AMENDMENTS' and 'FIRST ISSUE' details. A drawing owner box identifies 'Dungarvan' as the owner.

Artwork Information Panel for HALEON V1. This panel contains production details such as 'Non Production Artwork' vs 'Production Artwork', 'Total Number of Colours including Varnish & Foils: 1', and 'Total Special Finishes: 0'. It also includes a color calibration chart and a table for 'Total Special Finishes'.