



TECHNICAL INFORMATION	
	TEXT FREE MARGINS
	<b>PHARMACODE AREA</b> 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
	<b>R-BAR</b> LENGTH 8.0 HEIGHT 2.0

**NOTE:**  
GENERIC SPECIFICATION REFERENCE: OTC.LT.SPEC002

AMENDMENTS	
1.0	FIRST ISSUE. CO-0070836.
2.0	ADDED GENERIC SPECIFICATION REFERENCE TO THE TECHNICAL INFORMATION PANEL. CO-0080843.

DRAWING OWNER (SITE) **Dungarvan**

## Leaflet 140 x 210mm M6GSK - Solid Dose Template 2

PACKAGING MATERIAL DRAWING REGIONAL SERVICE CENTRE, BARNARD CASTLE		DRAWING No. <b>OTC.LT.002</b>	VERSION <b>2.0</b>
COPYRIGHT AND DESIGN RIGHT IS THE PROPERTY OF THE GLAXOSMITHKLINE GROUP OF COMPANIES		SCALE: 1:1 GENERAL DRAWING TOLERANCE UNLESS STATED OTHERWISE ALL DIMS. IN MILLIMETRES	
		N/A	

V1 Artwork Information Panel		HALEON	
08 - May - 2026			
Non Production Artwork <input type="checkbox"/>	Production Artwork <input checked="" type="checkbox"/>	Component No: AWP No: 6200000224169 TR4010315/A	Manufacturing Site: Dungarvan
Total Number of Colours including Varnish & Foils: 1		Approving Market: Bahrain / Iraq / Kuwait / Lebanon / Oman / Qatar / UAE	Technical Drawing No: OTC.LT.002
<b>Black</b>		Material Spec No: OTC.LT.SPEC.002	Body Text Size: 4.5pt
<b>1.</b>		Smallest Text Size: 4.5pt	Electronic Verification Code: 285
Total Special Finishes: 0		Printer and User notes: N/A	
Studio Location: Europe			

**DUNGARVAN**  
Site Additional Artwork Information Panel

Varnish type: N/A  
Reel unwind: 5 inside, 1 outside

BARCODE INFO	
Barcode Type	Pharmacode Standard
Barcode Number	285
Magnification	100
BWR	0 Micrometre

BARCODE INFO	
Barcode Type	Pharmacode Standard
Barcode Number	285
Magnification	100
BWR	0 Micrometre

**HALEON**

**Panadol Cold & Flu Day Caplet**

**PRODUCT INFORMATION**

**PEEL HERE TO REVEAL PRODUCT INFORMATION**

**Description**  
Each caplet contains:  
Paracetamol 500mg  
Caffeine 25mg  
Phenylephrine Hydrochloride 5mg

**Other Ingredients:**  
Tablet core: Pregelatinised starch, maize starch, povidone, potassium sorbate, sodium lauryl sulphate, sunset yellow (E110), stearic acid, talc, microcrystalline cellulose.  
Film coat: Hypromellose, Macrogol 400, titanium dioxide, sunset yellow Aluminium Lake (E110) and Quinoline Yellow Lake (E104)  
Excipients with known effects:  
Sodium 0.06 mg (as Sodium Laurylsulfate)  
Sunset Yellow G4 mg (E110)

**What is Panadol Cold & Flu Day and what is it used for?**  
Panadol Cold & Flu Day caplet are film coated tablets that contain Paracetamol which is an analgesic and antipyretic. Caffeine acts as an analgesic adjuvant which enhances the efficacy of Paracetamol. Phenylephrine Hydrochloride which is a nasal decongestant. Panadol Cold & Flu Day is recommended for the relief of sinus pain and the symptoms of colds and influenza, including fatigue and drowsiness.

**How to take Panadol Cold & Flu Day?**  
Panadol Cold & Flu Day are Tablet for oral administration only.  
Adults (including elderly) and children aged 16 years and over  
2 Tablet every 4 to 6 hours as required.  
Do not take more than 8 Tablet (4000mg paracetamol /200mg caffeine/40mg phenylephrine hydrochloride) in 24 hours.  
These doses should not be repeated more frequently than every four hours.  
Do not use for longer than 7 days without asking your physician.  
Do not exceed the stated dose.  
Use the lowest amount needed to achieve benefit for the shortest duration of treatment.  
Not recommended for children under the age of 16 years.

**Before you take Panadol Cold & Flu Day**

**Don't take Panadol Cold & Flu Day in case of:**

- Known or previous history of hypersensitivity to paracetamol, caffeine or phenylephrine hydrochloride or any other ingredient in the product.
- Concomitant use of other sympathomimetic decongestants
- Phaeochromocytoma
- Closed angle glaucoma
- Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, and heart disease.
- Patients taking tricyclic antidepressants, or beta-blocking drugs and those who are taking or who have taken within the last two weeks monoamine oxidase inhibitors (including moflobemide)

**Take special care with Panadol Cold & Flu Day in case of:**

- You should consult your doctor before taking this product if:
  - You have been diagnosed with liver or kidney impairment (Because Paracetamol is metabolised in the liver and excreted by the kidney in urine).
  - 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.
  - The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Underlying liver disease increases the risk of Paracetamol liver damage.

Medical advice should be sought before using this product in patients with these conditions:

- An enlargement of the prostate gland
- Occlusive vascular disease (e.g. Raynaud's phenomenon)
- glutathione depletion due to metabolic deficiencies
- cardiovascular disease

If symptoms persist consult your doctor.  
Don't exceed the stated dose.  
This product contains paracetamol do not take with any other product containing paracetamol or with medicines for the relief of colds and flu, congestion or blocked nose.  
Consult your doctor if you are taking warfarin.  
This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) (see interactions).  
Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.  
Panadol Cold & Flu Day caplet contains Sunset Yellow (E110), which may cause allergic reactions. Keep out of reach of children.

**Special label warning:**  
Contains paracetamol. Do not take with other flu, cold or decongestant products. Do not take anything else containing paracetamol while taking this medicine. Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. seek immediate medical advice if you take too much of this medicine even if you feel well, because of the risk of delayed, serious liver damage.

**Take other medicines:**  
Medical consultation should be sought before taking Panadol Cold & Flu Day Tablet if you are:  
Enzyme-inducing drugs may increase hepatic damage, as does excessive intake of alcohol. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by ceftriaxime. These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed. 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.

- Taking beta-adrenergic blocking agents and other antihypertensives including delmadipine, guanethidine, reserpine, methyldopa. Phenylephrine may reduce the efficacy of beta blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
- Taking tricyclic antidepressants, e.g. amitriptyline which may increase the risk of cardiovascular side effects with phenylephrine.
- Patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants). Concomitant use of phenylephrine with sympathomimetic amines can increase the risk of cardiovascular side effects.
- Taking Digoxin and cardiac glycosides: Concomitant use of phenylephrine with digoxin or cardiac glycosides may increase the risk of irregular heartbeat or heart attack.
- Taking Warfarin and other coumarins: 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.
- ergotamine and methylecergide will increase risk of ergotism.
- Taking Monoamine oxidase inhibitors: Concomitant use of phenylephrine with other Sympathomimetic amines can increase the risk of cardiovascular side effects.
- caffeine can increase the elimination of Lithium from the body, if taken concomitantly, it is recommended to reduce or moderate the intake of caffeine.

**d. Fertility, Pregnancy & breast feeding:**  
This product is not recommended for use in pregnancy due to the phenylephrine and caffeine content. There is a potential increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption during pregnancy.  
This product should not be used while breast-feeding without medical advice. Avoid the use of the product during lactation, unless the benefits to the mother outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered. Paracetamol is excreted in breast milk but not a clinically significant amount at recommended dosages.  
Caffeine in breast milk may have a stimulating effect on breast-fed infants. But significant toxicity has not been observed. Phenylephrine may be excreted in breast milk.

**e. Driving and using machines:**  
Patients should be advised not to drive or operate machinery if affected by dizziness.

**Possible side effects**

**Paracetamol**  
Stop using this product and consult your doctor immediately if:  
Blood and lymphatic system disorders: Thrombocytopenia, Agranulocytosis These are not necessarily causally related to paracetamol.  
Immune system disorders: Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angioedema, very rare cases of serious skin reactions have been reported.  
Respiratory, thoracic and mediastinal disorders: breathing problems or bronchospasm, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.  
Hepatobiliary disorders: Hepatic dysfunction.  
Phenylephrine  
Adverse events have been observed in clinical trials as common with phenylephrine: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting. The reaction frequency of adverse events reported is unknown but likely to be rare as mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. hypersensitivity, urticaria, and allergic dermatitis), dysuria, and urinary retention. (This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

**Caffeine**  
Adverse reactions identified through post-marketing use with caffeine: Nervousness, Excitability and Dizziness. The frequency of these reactions are unknown.  
When the recommended dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations. If any of the side effects get serious or if you notice any side effects listed or not listed in this leaflet, please stop using this product and tell your doctor.

**Overdose**  
Paracetamol overdose may cause liver failure, which may require liver transplant or lead to death. liver damage is possible in adults who have taken 10g or more of paracetamol.  
Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

**Risk factors**  
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.  
Or  
- Regularly consumes ethanol in excess of recommended amounts.  
Or  
- Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

**Symptoms of Paracetamol**  
Symptoms of Paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. liver damage may become apparent 12 to 48 hours after ingestion and have peaked 4-6 days. abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop in the absence of severe liver damage; cardiac arrhythmias and pancreatitis have been reported. Immediate treatment is essential in the management of paracetamol overdose. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour.  
Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post ingestion, if vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital.

**Caffeine**  
Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions). It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity.  
There is no specific antidote available, but supportive measures such as beta adrenergic antagonist to reverse the cardio-toxic effects may be used.

**Phenylephrine**  
Overdose of Phenylephrine is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include: irritability, restlessness, hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However, the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.  
Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking drug such as Phentolamine.

**How to store Panadol Cold & Flu Day?**  
Store below 30°C. Store in the original container.  
This product is protected in a sealed blister. Do not use if blister or foil is broken.  
Pack size: 24's (8 caplet x 3 blister)  
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.

**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 doctors' 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 prescribe 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

Trade marks are owned by or licensed to the HALEON group of companies.  
Manufactured by: HALEON Ireland/Dungarvan Limited, Ireland.  
MAH: HALEON UK Trading limited, UK.  
Revision Date: December 2025  
Version: 3rd February 2025/ GV 7

6200000224169

