188mm

PRODUCT INFORMATION
PANADEINE TABLETS
Paracetamol BP 500 mg and Codeine Phosphate USP 8 mg

COMPOSITION
Each tablet contains paracetamol, BP 500 mg and codeine phosphate, USP, 8 mg.

ACTIONS
The analgesic and antipyretic actions of paracetamol are similar to those of salicylates. Analgesia mediated peripherally and also centrally, whereas antipyresis is produced by central action on the hypothalamic regulatory centre. Panadeine also contains a small amount of codeine, a mild opiate with analgesic and anti-tussive actions, to provide additional pain relief.

INDICATIONS
Contains paracetamol which is an analgesic and antipyretic and codeine which is an analgesic. Paracetamol-codeine combinations are especially suitable for pain that requires stronger analgesia than single ingredient analgesics alone. Treatment of acute moderate pain, and relief of pain associated with fever, including: Headache, Migraine, Muscle ache, Dysmenorrhoea, Sore throat, Musculoskeletal pain, Sciatica, pain associated with Sinusitis, Neuralgia, pain after dental procedures/ tooth extraction & pain of Osteoarthritis.

DOSAGE AND ADMINISTRATION
Oral administration only. Always read and follow the label.
Dosage:
Adults aged 18 years and over (including the elderly)-500 mg paracetamol/8 mg codeine to 1000 mg paracetamol/16 mg codeine (1 to 2 tablets) every 4 to 6 hours as required.
Maximum daily dose: 8 tablets
Minimum dosing interval: 4 hours.
The lowest dose necessary to achieve efficacy should be used.
Do not exceed the stated dose or take for more than 3 days without consulting your doctor. If symptoms persist or worsen medical advice must be sought.

CONTRAINDICATIONS
This product is contraindicated in patients:
- With a previous history of hypersensitivity to paracetamol, codeine, opioid analgesics, or excipients.
- Under the age of 18 years because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine.
- Who are breastfeeding
- Who are known to be CYP2D6 ultra-rapid metabolisers. If the patient is an extensive or ultra-rapid

CYP2D6 metaboliser there is an increased risk of developing symptoms of opioid toxicity, even at commonly prescribed doses.

WARNINGS AND PRECAUTIONS
Contains paracetamol. Do not use with any other paracetamol or codeine 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. If symptoms persist or worsen, medical advice must be sought. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking paracetamol. **Underlying liver disease increases the risk of paracetamol-related liver damage.** 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.**
Do not take for more than 3 days unless told to do so by your doctor. Prolonged or excessive consumption of codeine can result in dependence.
Check with your doctor before use if you:
- have a severe infection as this may increase metabolic acidosis.
- have bowel problems including blockage of your bowel.
- had an operation to remove your gallbladder.

Patients taking the following medications should consult a physician prior to taking this product
- **Metoclopramide**
- **Domperidone**
- Central nervous system depressants, including alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressant and phenothiazine
- Monoamine oxidase inhibitors (MAOI) Warfarin and other coumarins

Keep out of sight and reach of children.

DRUG INTERACTIONS.
Paracetamol
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.
Codeine
Codeine may antagonize the effects of metoclopramide and domperidone on gastrointestinal motility.

Codeine potentiates the central depressive effects of central nervous system depressants, including alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants and phenothiazines. Opiate analgesics may interact with monoamine oxidase inhibitors (MAOI) and result in serotonin syndrome.

PREGNANCY
Use during pregnancy should be avoided, unless advised by a physician. This includes maternal use during labor because of the potential for respiratory depression in the neonate. The safety of paracetamol -codeine during pregnancy has not been established relative to the possible adverse effects on foetal development.

LACTATION
Codeine-containing products must not be used while breastfeeding (see Contraindications). In nursing mothers, who are ultra-rapid metabolisers of codeine, higher than expected serum and breast milk morphine levels can occur. Morphine toxicity in babies can cause excessive somnolence, hypotonia and difficulty breastfeeding or breathing. In severe cases of respiratory depression, death can occur.

ABILITY TO PERFORM TASKS THAT REQUIRE JUDGEMENT, MOTOR OR COGNETIVE SKILLS
Patients should be advised not to drive or operate machinery if affected by dizziness or drowsiness.

ADVERSE REACTIONS
Some of the reported adverse reactions are
For Paracetamol, although rare: Thrombocytopaenia, Anaphylaxis, Cutaneous hypersensitivity reactions including skin rashes, angiodema, and Stevens Johnson syndrome, Bronchospasm in patients sensitive to aspirin and other NSAID, Hepatic dysfunction
For Codeine: Drug dependency can occur after prolonged use of codeine at higher doses, Constipation, nausea, vomiting, dyspepsia, dry mouth, acute pancreatitis in patients with a history of cholecystectomy, Dizziness, worsening of headache with prolonged use, Drowsiness, Pruritus, sweating.
Stop taking this medicine and tell your doctor immediately if:
- you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting
- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling, or mouth ulcers.
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.
- you experience unexplained bruising or bleeding.

These reactions are rare.

OVERDOSAGE
If you take more of the medicine than you should:
seek medical advice immediately even if you do not have any symptoms because of the risk of liver failure and breathing problems.

HOW SUPPLIED
Cartons of 120 tablets.

STORAGE CONDITION
Store below 30° C.

PRECAUTION
Keep this and all medicines out of the reach of children.

FURTHER INFORMATION
Panadeine does not cause the gastrointestinal side effects often seen after standard doses of Aspirin.

Manufactured by:
SmithKline Beecham (Pvt). Ltd.,
121, Galle Road, Kaldemulla, Moratuwa, Sri Lanka.

Marketed by:
SmithKline Beecham (Pvt). Ltd.,
Level 34, West Tower, World Trade Centre,
Colombo 01, Sri Lanka.

94 114 790 490
contact.srilanka@gsk.com
SmithKline Beecham (Pvt.) Ltd.,
P.O. Box 1744, Colombo.

Revised on 1st May 2022 as per
GDSv5.0 (21st August 2015)

62000000200597

188mm

112mm

112mm

Attention
KLD and Dimensions are only for reference and are not to be printed.

V1
07 - SEP - 2022

champs Consumer Healthcare Artwork Management & Performance Solution

Artwork Information Panel

gsk

D2A ☐		**Non Production** ☐		**Production** X	
Total Number of Colours including Varnish & Foils: 1					
1. PANTONE 485 C	2.	3.	4.	5.	6.
7.	8.	9.	10.	11.	12.
Total Special Finishes: 0					

SGS No: 7039092	**CHAMPS No:** 0000014001
Manufacturing Site: Mt Lavinia	**Site Component No:** 62000000200597
Approving Market: Sri Lanka-LKA	**Site Change Control No:**
Product Market Trade Name: PANADEINE PANADEINE	**Component Type:** Leaflet
Technical Drawing No: 62000000054677	**Material Spec No:**
Print Process: Offset	**Pharma Code No:**
Barcode No:	**Bar Width Reduction:**
Formulation Code:	**Body Text Size:** 6.5pt **Leading:** 7.6pt
Micro Text: N	**Horizontal Scale:** 90% **Smallest Text Size:** 6.5pt

Studio Location: Coimbatore, IN

AIP_CHAMPS_2019_Version 1