

### Abbreviated Prescribing Information.

**Zapain 30mg/500mg Tablets (codeine phosphate and paracetamol).** **Presentation:** Each tablet contains codeine phosphate 30mg and paracetamol 500mg. **Indication:** For the relief of severe pain. Codeine is indicated in patients older than 12 years of age for the treatment of acute moderate pain which is not considered to be relieved by other analgesics such as paracetamol or ibuprofen (alone). **Dosage and administration:** *Method of administration:* Oral. *Adults:* One to two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24-hour period. Maximum daily dose should not exceed 8 tablets in a day. Codeine should be used at the lowest effective dose for the shortest period of time. This dose may be taken, up to 4 times a day at intervals of not less than 6 hours. Maximum daily dose should not exceed 240 mg. The duration of treatment should be limited to 3 days. *Elderly:* Reduced dosage may be necessary. *Children:* Not recommended below the age of 12 years. *Children aged 12 – 15 years:* one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours. *Children aged 16-18 years:* one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours. Dosage needs to be adjusted according to the severity of pain and the response of the patient. Doses of Codeine above 60mg are associated with an increase in unwanted effects. **Contraindications:** Hypersensitivity to either paracetamol or codeine, or any of the excipients. Moderate to severe renal or hepatic impairment. Children under 12 years of age. In conditions where opiate medications are contraindicated e.g. acute asthma, obstructive airway disease, respiratory depression, acute alcoholism, head injuries, raised intracranial pressure, after biliary tract surgery or diarrhoea of any cause. In all paediatric patients (0-18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions. In patients who have taken Monoamine oxidase (MAO) inhibitors within 14 days. In patients for whom it is known they are CYP2D6 ultra-rapid metabolisers and in women during breast-feeding. **Precautions and warnings:** Caution in patients with increased intracranial pressure, acute abdominal conditions, the elderly, the debilitated, impaired hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy, urethral stricture and in children with compromised respiratory function. Patients should be closely monitored for signs of drug dependence, tolerance, misuse, abuse, addiction and withdrawal syndrome. Concomitant use of Zapain tablets and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Caution is advised in patients who are CYP2D6 ultra-rapid metabolisers as there is increased risk of developing side-effects of opioid toxicity even at commonly prescribed doses. Symptoms include confusion, shallow breathing, small pupils, nausea, vomiting, constipation, lack of appetite and somnolence. In severe cases this may include symptoms of circulatory and respiratory depression which may be life threatening and very rarely fatal. Other products containing paracetamol or opiate derivatives should not be taken while on Zapain. Codeine may impair mental or physical abilities required in the performance of potentially hazardous tasks. The cough suppressant effect of codeine may be undesirable in patients with some respiratory conditions. Overdosage in patients with non-cirrhotic alcoholic liver disease can be hazardous. *Patients should not drive, operate machinery or perform hazardous tasks if Zapain causes dizziness or sedation.* **Interactions:** Antihypertensive agents, diuretics, mexilitine, cimetidine, CNS depressants (anxiolytics, hypnotics, antidepressants, antipsychotics, alcohol), MAOIs or tricyclic antidepressants, anti-cholinergics, benzodiazepines, anti-diarrhoeal agents, metoclopramide, domperidone, cholestyramine, warfarin and other coumarins (with long term use of paracetamol), quinine, and quinidine. Codeine may interfere with the results of plasma amylase, lipase, bilirubin, ALP, LDH, AST, and ALT tests. The effects of codeine on the gut may interfere with diagnostic tests of gastro-intestinal functions. **Pregnancy and lactation:** Not recommended. **Undesirable effects:** *Serious:* Respiratory depression particularly in overdosage and in patients with compromised respiratory function, liver damage (in association with therapeutic use of paracetamol and in conjunction with chronic alcohol abuse), thrombocytopenia and agranulocytosis. *Common:* Nausea, vomiting, light headedness, dizziness, sedation, shortness of breath and constipation. Regular prolonged use of codeine/DHC is known to lead to addiction and symptoms of restlessness and irritability may result when treatment is then stopped. Prolonged use of a pain killer for headaches can make them worse. *Please refer to the Summary of Product Characteristics for detailed information.* **Overdose:** *Paracetamol:* Symptoms of overdosage include pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage is possible in adults who have taken 10g or more of paracetamol. Early treatment of paracetamol overdose with agents which facilitate glutathione synthesis, for example N-acetylcysteine and methionine. *Codeine:* Central nervous system depression, including respiratory depression, may develop but is unlikely to be severe unless other sedative agents have been co-ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely. Management includes general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Activated charcoal is to be considered if an adult presents within one hour of ingestion of more than 350mg or a child more than 5mg/kg. Give naloxone if coma or respiratory depression is present. **Legal Category:** POM. **Basic NHS Price:** £1.56 per pack of 50 tablets. **Marketing Authorisation Number:** PL 12762/0034. **Marketing Authorisation Holder:** Mercury Pharmaceuticals Limited (a member of the Advanz Pharma group of companies), Capital House, 1st Floor, 85 King William Street, London EC4N 7BL, UK. **Text last revised:** February 2023. Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to **ADVANS PHARMA Medical Information** via telephone on +44 (0) 208 588 9131 or via e-mail at [medicalinformation@advanzpharma.com](mailto:medicalinformation@advanzpharma.com) **Date of Preparation:** Oct 2024 [UK/ZAP/PM/0018]

Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk), also report using the Yellow Card app. The app is available to download from the Apple App Store, or Google Play Store and you can use your Yellow Card website account details on the app to report. Adverse events should also be reported to **ADVANS PHARMA Medical Information** via telephone on **+44 (0) 208 588 9131** via e-mail at [medicalinformation@advanzpharma.com](mailto:medicalinformation@advanzpharma.com)