# Paracetamol tablets, suspension and suppositories

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| **Legal status** (GSL, P or POM on exemption list, or PGD) | **Tablet 500mg: GSL** - up to 16 tablets; **P** - 17-32 tablets and **POM** >32 tablets (PGD required) ie legal status depend on pack size<br>**Suspension 250mg in 5ml: GSL-** up to 160ml; **P** - > 160ml<br>**Suppository 500mg and 1g: P**<br><br>Midwife Exemptions - midwife can supply up to 32 tablets 500mg (GSL or P), suspension 250mg/ml >160ml or up to 10x500mg or 10 X 1g suppositories |
| **Patient group** | Antenatal women and postnatal women and until discharge from midwifery care with a maximum of 32 tablets. |
| **Clinical indication** | Mild to severe pain alone or in combination with other analgesics where appropriate. |
| **Pharmacology**<br>(Onset and duration of action where appropriate) | Paracetamol is a mild analgesic with antipyretic activity. The mechanism of analgesic action is not known. It may act mainly by inhibiting prostaglandin synthesis in the central nervous system and to a lesser extent through a peripheral action by blocking pain-impulse generation.<br><br>Onset of action within 30 minutes to 2 hours and analgesic effects lasts 4-6 hours. Opiates can delay the onset of action. |
| **Pharmaceutical form, strength, route of administration** | Tablets (standard or dispersible) contain 500mg<br>Suspension contains 250mg in 5ml<br>For oral administration.<br><br>Suppository contains paracetamol 500mg or 1g.<br>For rectal administration. |
| **Dose, frequency and maximum number of doses or period of time for administration or supply** | **Oral or rectal**<br>1g every 4-6 hours as required or 6 hourly regularly<br><br>The minimum interval between each dose must be at least 4 hours.<br><br>Only use rectally if oral route is not possible.<br>Give orally as soon as a woman is able to take anything by oral route.<br><br>**Maximum dosage:**<br>**≥50kg and no additional risk factors for hepatotoxicity –** 4g/day.<br>**≥50kg with additional risk factors for hepatotoxicity -** 3g/day (see "Cautions" for risk factors - refer to an authorised prescriber or doctor).<br>**<50 kg** – 3g/day but review pain relief as dose can be increased to 4g/day if no additional risk factors and pain control is poor.<br><br>**Note** the duration of pain relief is 4-6 hours so if prescribed 8 hourly then it would be advisable to stagger doses of other analgesics.<br><br>**It is dangerous in over-dosage therefore do not administer within 4 hours of other products containing paracetamol including by parenteral route and do not exceed maximum dose.**<br><br>Continue until discharged from midwifery care. Midwives can supply a maximum of 32 tablets 500mg (or 500ml of suspension) at discharge. |

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| **Writing of medicines by midwives: examples** | **Write in "once only" section of Medicine Chart.**<br>**"Regular" and "as required" doses can only be written for women who are self administering medicines"**<br><br>**1 Inpatient - Paracetamol tablets**<br><br>**Medicine (Approved Name):** PARACETAMOL<br>**Dose:** 1g<br>**Route:** ORAL<br>**Frequency: Regular:** 06:00, 12:00, 18:00, 22:00 or<br>**As required:** 4 – 6 hourly. Max 4g in 24 hours<br>**Notes:** For pain<br>**Initial supply:** ≤ 32 500mg tablets<br><br>**1.1 At discharge (TRAK IDL) - Paracetamol tablets**<br><br>**Discharge Medication:** PARACETAMOL Tablets<br>**Dose:** 1g<br>**Frequency:** Every four to six hours as required.<br>Max 4 doses in 24 hours.<br>**Additional info:** Supply ≤ 32<br><br>**2 Inpatient - Paracetamol S/F suspension**<br><br>**Medicine (Approved Name):** PARACETAMOL S/F suspension<br>**Dose:** 1g (20ml)<br>**Route:** ORAL<br>**Frequency: Regular:** 06:00, 12:00, 18:00, 22:00 or<br>**As required:** 4 – 6 hourly. Max 4g in 24 hours<br>**Notes:** 250mg/5ml. For pain.<br>**Initial supply:** 500ml<br><br>**2.1 At discharge (TRAK IDL) - Paracetamol S/F suspension**<br><br>**Discharge Medication:** PARACETAMOL S/F Suspension<br>**Dose:** 1g<br>**Frequency:** Every four to six hours as required.<br>Max 4 doses in 24 hours.<br>**Additional info:** 250mg/5ml. Supply 500ml. **Supply at discharge only if it has been prescribed on Medicine Chart and ordered on an Individual Patient Supply request.** Order item on TRAK as the sugar free (S/F) suspension<br><br>**3 Inpatient - Paracetamol suppositories**<br>**(Write in "once only" section of Medicine Chart)**<br><br>**Medicine (Approved Name):** PARACETAMOL<br>**Dose:** 1g<br>**Route:** PR<br><br>**SIGN and PRINT NAME followed by (MW)** |
| **Contra-indications/exclusion criteria** | ▪ Known hypersensitivity to paracetamol or its components.<br>▪ Severe renal and or liver disease.<br>▪ Known chronic alcoholics.<br>▪ Given paracetamol-containing products within the last 4 hours. |

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| **Cautions and action that will be taken if a caution applies** | ▪ Moderate to severe renal impairment or history of hepatic impairment (especially non-cirrhotic alcoholic liver disease), G6PD deficiency, acute hepatitis, haemolytic anaemia, alcohol abuse, dehydration and those who are likely to be glutathione depleted such as with chronic malnutrition, eating disorders, cystic fibrosis, HIV, starvation, cachexia.<br>▪ Some paracetamol brands contain sorbital so caution with use in known hereditary fructose intolerance.<br>▪ Some products contain sodium so check brand if this will pose a clinical problem.<br>▪ Check and document any allergies.<br>▪ Check and document past medical and drug history and current medication intake to ascertain potential for overdose.<br>▪ If a caution applies consult with an authorised prescriber/ doctor before administration or supply.<br>▪ Document consultation in woman's maternity record. |
| **Medicine interactions and action that will be taken if a patient is taking a medicine that may interact** | ▪ **Alcohol (chronic):** increased risk of hepatotoxicity.<br>▪ **Anticonvulsants:** (carbamazepine, phenobarbitone, phenytoin or other drugs that induce liver enzymes): – risk of hepatotoxicity<br>▪ **Metoclopramide :** increases rate of absorption.<br>▪ **Warfarin:** with 4 g of paracetamol per day for at least 4 days may enhance INR and increase risk of bleeding.<br>▪ **Medicines unlikely to be used during pregnancy and immediate postnatal period:** probenecid, salicylamide, domperidone, colestyramine, isoniazid<br><br>▪ Refer to current BNF for latest information on interactions.<br>▪ If there is a drug interaction, consult with an authorised prescriber/ doctor and pharmacist before supply.<br>▪ Document consultation in woman's maternity record. |
| **Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected** | ▪ **On labour** Nil<br>▪ **On the neonate** Nil<br>▪ **On breast feeding** Nil<br><br>▪ **Cardiovascular**: hypotension.<br>▪ **Immune system disorders:** Very rarely allergic reactions including anaphylactic shock. Cutaneous hypersensitivity reactions include skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis.<br>▪ **Haematological:** Isolated cases of thrombocytopenia, agranulocytosis, leucopenia, and neutropenia.<br>▪ **Liver:** abnormal hepatic function, liver damage following overdose.<br>▪ **Respiratory:** bronchospasm more likely in asthmatics who are sensitive to NSAIDs or aspirin.<br>▪ **Skin:** Rashes. Redness of the mucous membranes of the rectum and minor local vascular changes after rectal route.<br><br>*Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at*: http://www.mhra.gov.uk/yellowcard |

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| **Overdose** | Liver damage is possible in adults who have taken 10g (20 tablets of 500mg) or more but 5g or more may lead to liver damage if the woman has other risk factors such as liver dysfunction, known alcoholism, chronic malnutrition (see Caution).<br><br>Symptoms of 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. 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 even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis may occur.<br><br>• Immediate assessment/treatment is essential even in the absence of above symptoms - refer to doctor.<br>• Manage in accordance with established treatment guidelines or see BNF overdose section.<br>• For further advice contact National Poisons Centre 0844 892 0111 |
| **Action if patient declines** | • Refer to authorised prescriber or doctor.<br>• Document in woman's maternity record. |
| **Additional advice and information** | • Advise woman to contact authorised prescriber/doctor/ midwife if condition worsens or symptoms persist.<br>• Give the manufacturer's Patient Information Leaflet to the woman. |
| **Patient monitoring arrangements during and after treatment and follow-up required** | ▪ Monitor pain scores regularly for at least 24 hours for moderate to severe pain. Follow up depends on the prescribing condition<br>▪ Refer to doctor if response is inadequate after regular dosing as part of triple or duo combination analgesics regimen.<br>▪ Antenatally if 1g dose is ineffective after 2 hours refer to an authorised prescriber or doctor.<br>▪ For mild transient pain, if response is inadequate about 2 hours after 1g dose refer to an authorised prescriber or doctor.<br>▪ For after pains, if response is inadequate about 2 hours after 1g dose, add or use ibuprofen alone depending on severity of pain.<br>▪ Refer to an authorised prescriber or doctor if response is inadequate after regular dose as part of triple or duo combination analgesics regimen. |
| **Particular storage requirements** | - |

**References**

1 Summary of Product Characteristics (GlaxoSmithKline Consumer Healthcare - oral) last updated on eMC 19/07/2017 and (Actavis)- parenteral) last updated on the eMC 05.07.2017. http://www.medicines.org.uk , accessed on 13.08.2017
2 British National Formulary http://www.bnf.org, accessed 13.08.2017

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