Brand Name : AGOMOL SUSPENSION **Generic Name :** Paracetamol Oral Suspension BP 125 mg / 5 ml	2023
Module 1: Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

Paracetamol 120 mg/5 ml Oral Suspension

1.1 (Trade) name of product

AGOMOL SUSPENSION

1.2 Strength

Each 5 ml contains: Paracetamol BP 125 mg

1.3 Pharmaceutical Dosage Form

Suspension

2. Qualitative and Quantitative Composition:

2.1 Qualitative Declaration

Each 5 ml contains: Paracetamol BP 125 mg

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2.2 Quantitative Declaration

Ingredients	Specification	Label Claim / 5 ml	Qty. / 5 ml
ACTIVE			
Paracetamol	BP 2019	125 mg	125.00 mg
NON ACTIVE			
Sucrose	BP 2019	-	2500.00 mg
Sodium Benzoate	BP 2019	-	10.00 mg
Sodium Methyl Paraben	BP 2019	-	5.00 mg
Sodium Propyl Paraben	BP 2019	-	2.50 mg
Sodium Saccharin	BP 2019	-	2.50 mg
Glycerin	BP 2019	-	125.0 mg
Sodium Citrate	BP 2019	-	12.50 mg
Xanthan Gum	BP 2019	-	15.00 mg
Citric Acid Monohydrate	BP 2019	-	5.000 mg
Polysorbate (Tween – 80)	BP 2019	-	5.000 mg
Disodium EDTA	BP 2019	-	5.000 mg
Propylene Glycol	BP 2019	-	1181.25 mg
Colour Tartrazine Supra	Inhouse	-	0.05 mg
Essence Pineapple No.1	Inhouse	-	0.01 mg

BP 2019 = British Pharmacopoeia 2019.

3. Pharmaceutical form:

Yellow coloured uniform suspension on shaking.

4. Clinical particulars:

4.1 Therapeutic indications

For the treatment of mild to moderate pain and as an anti-pyretic. Used for the relief of pain and feverishness associated with teething, toothache, headache, colds, flu and post-immunisation pyrexia.

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4.2 Posology

Refer the below table for dosage:

Child's Age	How Much	How Often (in 24 hours)
3 – 6 months	2.5 ml	4 times
6 – 24 months	5.0 ml	4 times
2 – 4 years	7.5 ml (5.0 ml + 2.05 ml)	4 times
4 – 8 years	10 .0 ml (5.0 ml + 5.0 ml)	4 times
8 – 10 years	15.0 ml (5.0 ml + 5.0 ml + 5.0 ml)	4 times
10 – 12 years	20.0 ml (5.0 ml + 5.0 ml + 5.0 ml + 5.0 ml)	4 times

- Do not give more than 4 doses in any 24 hour period
- Leave at least 4 hours between doses
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

Babies over 2 months in age

For the relief of fever after vaccination at 2, 3 and 4 months 2.5 ml. This dose may be given up to 4 times a day at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

It is important to shake the bottle for at least 10 seconds before use.

4.3 Method of administration: Oral

4.4 Contraindications

Hypersensitivity to Paracetamol or any of the other constituents.

4.5 Special warnings and precautions for use

Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.

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.

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The label should contain the following statements:

• Contains paracetamol.

• Do not give this medicine with any other paracetamol-containing product.

• For oral use only.

• Never give more medicine than shown in the table.

• Do not overfill the spoon.

• Always use the spoon supplied with the pack.

• Do not give more than 4 doses in any 24 hour period.

• Leave at least 4 hours between doses.

• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

• If your baby still needs this medicine two days after receiving the vaccine talk to you doctor or pharmacist (Leaflet).

• As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.

• Do not store above 25°C. Store in the original package.

• Keep all medicines out of the sight and reach of children

• Talk to a doctor at once if your child takes too much of this medicine, even if they seem well (label).

• Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage. (leaflet)

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.6 Interaction with other medicinal products and other forms of interaction

Drugs which induce hepatic microsomal enzymes such as alcohol. Concomitant barbiturates and tricyclic antidepressants may increase the hepatoxicity of Paracetamol particularly after overdose. Anti-convulsant or oral steroid contraceptives have the ability to reduce serum levels of Paracetamol by liver enzyme induction. The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

4.7 Pregnancy and lactation

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Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. 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.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast-feeding.

4.8 Effects on ability to drive and use machines

None.

4.9 Undesirable effects

Very rare cases of serious skin reactions have been reported. Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causually related to Paracetamol. With prolonged use or overdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.10 Overdose

Liver damage is possible in adults who have taken 10 g or more of Paracetamol. Ingestion of 5 g or more of Paracetamol may lead to liver damage if the patient has risk factors.

Risk Factors

If the patient:

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a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes.

Or

b) Regularly consumes ethanol in excess of recommended amounts.

Or

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage 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 have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one 1 hour. Plasma Paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). 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. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPIS or a liver unit.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

Pharmacodynamic effects

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The resultant in vivo effect is a sequential depression of Factors VII, IX, X and II activities. Vitamin K is an essential cofactor for the post ribosomal synthesis of the vitamin K dependent clotting factors. The vitamin promotes the biosynthesis of γ-carboxyglutamic acid residues in the proteins which are essential for biological activity. Warfarin is thought to interfere with clotting factor synthesis by inhibition of the regeneration of vitamin K1 epoxide. The degree of depression is dependent upon the dosage administered. Therapeutic doses of warfarin decrease the total amount of the active form of each vitamin K dependent clotting factor made by the liver by approximately 30% to 50%.

Clinical efficacy and safety

An anticoagulation effect generally occurs within 24 hours after drug administration.

However, peak anticoagulant effect may be delayed 72 to 96 hours. The duration of action of a single dose of racemic warfarin is 2 to 5 days. The effects of warfarin sodium may become more pronounced as effects of daily maintenance doses overlap.

Anticoagulants have no direct effect on an established thrombus, nor do they reverse ischemic tissue damage. However, once a thrombus has occurred, the goal of anticoagulant treatment is to prevent further extension of the formed clot and prevent secondary thromboembolic complications which may result in serious and possibly fatal sequelae.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC. Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP	60.000mg
Micro Crystalline cellulose powder	BP	20.000mg
Pre Gelatinised Starch	BP	8.630mg
Methyl Paraben Sodium	BP	0.100mg
Propyl Paraben Sodium	BP	0.050mg
Maize Starch	BP	10.000mg
Lubrication		
Talcum	BP	2.000mg
Magnesium sterate	BP	1.000mg
Sodium Starch Glycolate	BP	3.000mg
Sodium Lauryal Sulphate	BP	1.000mg
Colloidal Silicon Dioxide	BP	1.000mg
Cross carmellose Sodium	BP	3.000mg
Polyplasdone XL-10 (Cross Povidone)	BP	1.000mg

6.2 Incompatibilities:
None reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Do not store above 30°C. Protect from light.

6.5 Nature and Contents of Container:
28 tablets are packed in a poly bag and such poly bag is packed in a jar.

6.6 Special precautions for disposal:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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7. Registrant:
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8. Manufacturer:
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9. Date of revision of the text: 09/03/2023.