1.3 Product information

1.3.1 Summary of Product Characteristics

1.0 NAME OF THE MEDICINAL PRODUCT :

1.1 Product Name:

Brand Name: - ORPAR-125

Generic Name: Paracetamol Pediatric Oral Suspension B.P.

1.2 Dosage Strength : 125mg /5 ml

1.3 Dosage Form : Suspension

2.0 QUALITY AND QUANTITATIVE COMPOSITION:

2.1 Qualitative Declaration

Composition:

Paracetamol BP

Flavoured Syrup Base

Colour: Carmoisine

2.2 Quantitative Declaration

Composition:

Paracetamol BP…….. 125 mg

Flavoured Syrup Base……. Q.S.

Colour: Carmoisine

3.0 PHARMACEUTICAL FORM

Oral Suspension

Pink coloured Suspension

4.0 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.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

10 - 15 mg/kg of body weight /dose, 3- 4 times a day or as directed by the physician.

Dose may be repeated every 4 hours at the most, up to maximum 60 mg/kg/day of 24 Hours.

15 mg/kg could mean:-

Age	Avg.Wt	Dose	Age	Avg.Wt	Dose
6 Months	6.4 Kg	4 ml	5 Years	18 Kg	11 ml
1 Year	9 Kg	6 ml	7 Years	21 Kg	13 ml
2 Years	12 Kg	8 ml	10 Years	30 Kg	18 ml
3 Years	15 Kg	9 ml	12 Years	36 Kg	22 ml

4.3 SPECIAL WARNING 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.

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.

4.4 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

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.

4.5 PREGNANCY AND LACTATION

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.

4.6 EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

None

4.7 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.

4.8 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 Factor

If the patient:

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

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.

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.

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

01	Acrysol
02	Glycerin
03	Sucrose (Sugar granulated)
04	Sodium benzoate
05	Sodium methay paraben
06	Sodium Propyl paraben
07	Sodium sacharin
08	Aspartum
09	Sod. Metabisulphate
10	Di sodium EDTA
11	Carmosine
12	Citric acid monohydrate
13	Purified Water

6.2 SHELF LIFE:

2 years

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store at room temperature 25°C

7.0 MARKETING AUTHORIZATION HOLDER AND MANUFACTURER

M/s Orbit Pharmaceuticals

Register Office Address:

22/A, 22/B, Meldi estate,

Near Gota Railway Crossing, Gota,

Ahmedabad-382481