SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Brand Name : ACEFORCE SP

1.2 Generic Name : Aceclofenac, Paracetamol & Serratiopeptidase Tablets

1.3 Strength : 100mg + 325mg + 15mg

1.4 Pharmaceutical Form: Tablet

2. QUALITY AND QUANTITATIVE COMPOSITION

Aceclofenac BP	100 mg
Paracetamol BP	325 mg
Serratiopeptidase	15 mg

(As enteric coated granules eq. to 30000 enzyme activity unit of Serratiopeptidase)

Colours: Sunset Yellow FCF & Titanium Dioxide BP

3. PHARMACEUTICAL FORM VISUAL DESCRIPTION:

Orange colored, elongated, biconvex, scored on one side, plain on another side & film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, symptomatic relief of rheumatic aches and pains and of influenza, feverishness and feverish colds.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults, the elderly and young persons over 12 years:

2 tablets every 4 hours to a maximum of 8 tablets in 24 hours.

Children 6 – 12 years:

½ to 1 tablet every 4 hours to a maximum of 4 tablets in 24 hours.
Do not give to children aged under 6 years.

4.3 CONTRAINDICATIONS

Hypersensitivity to Paracetamol or any of the constituents.

4.4 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.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Contains Paracetamol.

Do not take anything else containing paracetamol while taking this medicine.

Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Patients should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as skin reddening, blisters, or rash occurs, they should stop use and seek medical assistance right away.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.

Warfarin: The anticoagulant 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.

Chloramphenicol: Increased plasma concentration of chloramphenicol.

4.6 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 the doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known.

4.8 UNDESIRABLE EFFECTS

Adverse effects of paracetamol are rare. Very rare cases of serious skin reactions have been reported. There have been reports of blood dyscrasias including thrombocytopenia purpura, methaemoglobinaemia and agranulocytosis, but these were not necessarily causality related to paracetamol.

4.9 OVERDOSE

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

Risk Factors

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.

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 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.

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 hours from ingestion should be discussed with the NPIS or a liver unit.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanisms of Action/Effect

Analgesic – the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain-impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic – paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Absorption and Fate

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

5.3 PRECLINICAL SAFETY DATA

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Maize Starch
Microcrystalline Cellulose
Lactose
Purified Water
Sodium Benzoate
Povidone (K-30)
Magnesium Stearate
Sodium Starch Glycolate (Type-A)
Purified Talc
Colloidal Anhydrous Silica
Sodium Lauryl Sulfate
Hypromellose (E-15)
Colour Sunset Yellow FCF Lake
Castor Oil
Titanium Dioxide
Isopropyl Alcohol
Dichloromethane

6.2 INCOMPATIBILITIES

Not applicable

6.3 SHELF LIFE

24 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C, protected from light and moisture

6.5 NATURE AND CONTENTS OF CONTAINER

Blister Pack of 10 x 10 tablets

6.6 SPECIAL PRECAUTION FOR DISPOSAL

None

7. MARKETING AUTHORIZATION HOLDER

Name	:	**UNOSOURCE PHARMA LTD**
Address	:	Unit : 503-504, 5th floor Hubtown Solaris
		N.S. Phadke Marg, Andheri (East) Mumbai – 400 069
Phone	:	+91-22-61056105
Fax	:	+91-22-61056106
E-mail	:	haseeb@unosourcepharma.com

8. MARKETING AUTHORIZATION NUMBERS

Not Applicable

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

Not applicable

11. NAME AND ADDRESS OF THE MANUFACTURER

Name	:	AKUMS DRUGS & PHARMACEUTICALS LTD.
Address	:	Plant I, Plot No. 19, 20, 21, Sector 6-A, IIE, Sidcul, Ranipur, District: Haridwar, Uttarakhand.
Phone	:	91-0133-4325982
Fax	:	91-0133-4239219
E-mail	:	works@akums.in