SUMMARY OF PRODUCTS CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Name of the medicinal product

Product name: Asmol

Generic name: Paracetamol Tablets BP 500 mg

1.2 Strength

500 mg

1.3 Pharmaceutical form

Uncoated tablets

2. Qualitative and quantitative composition

Name of Ingredients
Paracetamol
Maize starch
Pregelatinized starch
Maize starch
Povidone K-30
Purified water
Maize starch
Purified talc
Magnesium stearate
Average Weigh

3. Pharmaceutical form

Dosage Form: Tablet

Description: White, uncoated, round tablet with bevelled edges and breakline on one side and scoring with “PARA” and “500” on same side.

4. Clinical particulars

4.1 Therapeutic indications

Paracetamol has analgesic and antipyretic action. It is used for the relief of mild to moderate pain and febrile conditions, eg headache, toothache, colds, influenza, neuralgia, rheumatic pain, dysmenorrhoea, sore throat, and for relieving the fever.

4.2 Posology and method of administration

Posology

Adults, the elderly and children over 12 years: 0.5 to1.0 gm every 4 to 6 hours up to a maximum of 4 gm daily.

Children 6 – 12 years: 250 mg to 500 mg every 4 to 6 hours up to a maximum of 4 doses daily.

Children 1-5 years: 120 mg to 250 mg

Do not give to children aged under 1 year.

These doses should not be repeated more frequently than every 4 hours, nor should more than 4 doses be given in any 24 hour period.

4.3 Method of administration:

For oral administration.

4.4 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.5 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or hepatic impairment. The hazard of over dosage is greater in those with non-cirrhotic alcoholic liver disease. Paracetamol warning and precaution seen 4.6 and 4.7.

4.6 Paediatric population

Not recommended for children under 10 years of age.

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Do not exceed the recommended dose.

Do not take paracetamol for more than 3 days without consulting a doctor.

Do not take with any other paracetamol-containing products.

If symptoms persist, consult your doctor.

Keep out of the reach of children.

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage.

4.7 Interaction with other medicinal products and other forms of Interaction

Colestyramine: The rate of absorption of paracetamol is reduced by colestyramine. Therefore, colestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and domperidone: The rate of absorption of paracetamol may be 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 daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.8 Additional information on special populations

Not applicable.

4.9 Paediatric population

Not applicable.

4.10 Pregnancy and lactation

Paracetamol is generally considered to be the analgesic of choice in pregnant patients. However, the frequent use of paracetamol in late pregnancy may be associated with an increased risk of persistent wheezing in the infants. No adverse effects have been observed in breast feeding infants whose mothers were receiving paracetamol.

4.11 Effects on ability to drive and use machines

Paracetamol has no influence on the ability to drive and use machines.

4.12 Undesirable effects

The information below lists reported adverse reactions, ranked using the following frequency classification:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system disorders

Hypersensitivity including skin rash may occur.

Not known: anaphylactic shock, angioedema.

Blood and lymphatic system disorders

Not known: blood dyscrasias including thrombocytopenia and agranulocytosis.

Skin and subcutaneous disorders

Very rare cases of serious skin reactions such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis, fixed drug eruption 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.

4.13 Overdose

Symptoms:

Symptoms of paracetamol over dosage 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.

Treatment:

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patient should be referred to hospital urgently for immediate medical attention.

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 24hours after ingestion of paracetamol. 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 suitable alternative for remote areas, outside hospital.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides

ATC code: N02BE01

Paracetamol is an effective analgesic and antipyretic agent, but has only weak anti-inflammatory properties. Its mechanism of action is not fully understood. It has been suggested that it may act predominantly by inhibiting prostaglandin synthesis in the 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. Paracetamol probably produces an antipyretic action by a central effect on the hypothalmic heat-regulating centre to produce peripheral vasodilatation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus. The drug has no effect on the cardiovascular and respiratory systems, and unlike salicylates it does not cause gastric irritation or bleeding.

5.2 Pharmacokinetic properties

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Distribution

Peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. 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 tissue damage.

Elimination

It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of Excipients

Maize starch

Pregelatinized Starch

Povidone K-30

Purified water

Purified talc

Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry and dark place, between 15ºC-30ºC.

6.5 Nature and contents of container

10 x 10's Alu/PVC Blister

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorization Holder

Astra lifecare (India) Pvt. Ltd

Plot No. 57/P, Sarkhej – Bavla Highway,

Post. Rajoda –382220, Taluka: Bavla,

Dist. Ahmedabad, India.

8. Marketing Authorization Number(s)

ASL/IND/011

04490/06912/REN/2018

9. Date of First Registration/Renewal of the Registration

Date of first authorisation: 04/06/2009

Date of latest renewal: May 23, 2019

10. Date of Revision of the Text

Not Applicable